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I

(Legislative acts)

REGULATIONS

**REGULATION (EU) 2022/2495 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 14 December 2022
amending Regulation (EU) No 1380/2013 as regards restrictions to the access to Union waters**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Union fishing vessels have equal access to Union waters and resources subject to the rules of the Common Fisheries Policy (CFP).
- (2) Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁽³⁾ provides for derogations from the equal access rule.
- (3) In accordance with that Regulation, Member States are authorised to restrict fishing to fishing vessels that traditionally fish in those waters from ports on the adjacent coast in waters up to 12 nautical miles from their baselines.
- (4) Member States are also authorised to restrict access to waters up to 100 nautical miles from the baselines of the Union outermost regions referred to in Article 349, first paragraph, of the Treaty on the Functioning of the European Union (TFEU) to vessels registered in the ports of those regions.
- (5) Existing rules restricting access to resources within the 12 nautical mile zones of Member States have benefitted conservation by restricting fishing effort in the most sensitive part of Union waters. Those rules have also preserved traditional fishing activities on which the social and economic development of certain coastal communities is highly dependent.

⁽¹⁾ OJ C 517, 22.12.2021, p. 123.

⁽²⁾ Position of the European Parliament of 22 November 2022 (not yet published in the Official Journal) and decision of the Council of 8 December 2022.

⁽³⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

- (6) Existing rules restricting access to marine biological resources around the Union outermost regions referred to in Article 349, first paragraph, TFEU have contributed to the preservation of the local economy of those regions, having regard to their structural, social and economic situation.
- (7) The existing derogations concerning restrictions to access to Union waters will expire on 31 December 2022. Those derogations should, however, be extended for a period of 10 years beyond that date, in order to ensure continuity of the current protection measures and to avoid disrupting the balance that has been achieved since the introduction of this special regime. Those derogations are an integral part of the CFP and the duration and scope of that extension may be revised in the framework of any review of the CFP.
- (8) In accordance with Article 510 of the Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part ⁽⁴⁾, a review of the implementation of Heading Five of that Agreement, including of the provisions in relation to access to waters, is to be carried out four years after the end of the adjustment period, which ends on 30 June 2026.
- (9) The Commission should report to the European Parliament and to the Council on the application of the general rules on access to waters referred to in Article 5 of Regulation (EU) No 1380/2013 before the expiry of the derogations. That report should be submitted by 30 June 2031.
- (10) Annex I to Regulation (EU) No 1380/2013 should be amended following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union. That Annex should also be amended following a joint request by Italy and Greece regarding the access of Italian fishing vessels to the 6-12 n.m. area of Greek territorial waters in the Ionian Sea and a proposal by Greece for access of Italian fishing vessels to the 6-12 n.m. area of the Greek exclusive economic zone (EEZ), in line with the Annex to this Regulation.
- (11) Regulation (EU) No 1380/2013 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1380/2013 is amended as follows:

(1) Article 5 is amended as follows:

- (a) in paragraphs (2), (3) and (4), the date ‘31 December 2022’ is replaced by the date ‘31 December 2032’;
- (b) the following paragraph is added:

‘5. The Commission shall report to the European Parliament and to the Council on the application of this Article by 30 June 2031.’;

(2) Annex I is replaced by the text set out in the Annex to this Regulation.

⁽⁴⁾ OJ L 149, 30.4.2021, p. 10.

Article 2

This Regulation shall enter into force on the seventh day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States from 1 January 2023.

Done at Strasbourg, 14 December 2022.

For the European Parliament

The President

R. METSOLA

For the Council

The President

M. BEK

ANNEX

‘ANNEX I

ACCESS TO COASTAL WATERS WITHIN THE MEANING OF ARTICLE 5(2)

1. Coastal waters of Ireland

(a) ACCESS FOR FRANCE

Geographical area	Species	Importance or particular characteristics
Irish coast (6 to 12 nautical miles)		
1. Erris Head north-west Sybil Point west	Demersal	Unlimited
	Nephrops	Unlimited
2. Mizen Head south Stags south	Demersal	Unlimited
	Nephrops	Unlimited
	Mackerel	Unlimited
3. Stags south Cork south	Demersal	Unlimited
	Nephrops	Unlimited
	Mackerel	Unlimited
	Herring	Unlimited
4. Cork south, Carnsore Point south	All species	Unlimited
5. Carnsore Point south, Haulbowline south-east	All species, except shellfish	Unlimited

(b) ACCESS FOR THE NETHERLANDS

Geographical area	Species	Importance or particular characteristics
Irish coast (6 to 12 miles)		
1. Stags south Carnsore Point south	Herring	Unlimited
	Mackerel	Unlimited

(c) ACCESS FOR GERMANY

Geographical area	Species	Importance or particular characteristics
Irish coast (6 to 12 nautical miles)		
1. Old Head of Kinsale south Carnsore Point south	Herring	Unlimited
2. Cork south Carnsore Point south	Mackerel	Unlimited

(d) ACCESS FOR BELGIUM

Geographical area	Species	Importance or particular characteristics
Irish coast (6 to 12 nautical miles)		
1. Cork south Carnsore Point south	Demersal	Unlimited
2. Wicklow Head east Carlingford Lough south-east	Demersal	Unlimited

2. Coastal waters of Belgium

Geographical area	Member State	Species	Importance or particular characteristics
3 to 12 nautical miles	Netherlands	All species	Unlimited
	France	Herring	Unlimited

3. Coastal waters of Denmark

Geographical area	Member State	Species	Importance or particular characteristics
North Sea coast (Danish/German frontier to Hanstholm) (6 to 12 nautical miles)			
Danish/German frontier to Blåvands Huk	Germany	Flatfish	Unlimited
		Shrimps and prawns	Unlimited
	Netherlands	Flatfish	Unlimited
		Roundfish	Unlimited
Blåvands Huk to Bovbjerg	Belgium	Cod	Unlimited only from 1 June to 31 July
		Haddock	Unlimited only from 1 June to 31 July
	Germany	Flatfish	Unlimited
	Netherlands	Plaice	Unlimited
		Sole	Unlimited
Thyborøn to Hanstholm	Belgium	Whiting	Unlimited only from 1 June to 31 July
		Plaice	Unlimited only from 1 June to 31 July

Geographical area	Member State	Species	Importance or particular characteristics
	Germany	Flatfish	Unlimited
		Sprat	Unlimited
		Cod	Unlimited
		Saithe	Unlimited
		Haddock	Unlimited
		Mackerel	Unlimited
		Herring	Unlimited
		Whiting	Unlimited
	Netherlands	Cod	Unlimited
		Plaice	Unlimited
		Sole	Unlimited
Skagerrak (Hanstholm to Skagen) (4 to 12 nautical miles)	Belgium	Plaice	Unlimited only from 1 June to 31 July
	Germany	Flatfish	Unlimited
		Sprat	Unlimited
		Cod	Unlimited
		Saithe	Unlimited
		Haddock	Unlimited
		Mackerel	Unlimited
		Herring	Unlimited
		Whiting	Unlimited
	Netherlands	Cod	Unlimited
		Plaice	Unlimited
		Sole	Unlimited
Kattegat (3 to 12 miles)	Germany	Cod	Unlimited
		Flatfish	Unlimited
		Nephrops	Unlimited
		Herring	Unlimited
North of Zealand to the parallel of the latitude passing through Forsnæs lighthouse	Germany	Sprat	Unlimited
Baltic Sea (including Belts, Sound, Bornholm) (3 to 12 nautical miles)	Germany	Flatfish	Unlimited
		Cod	Unlimited
		Herring	Unlimited
		Sprat	Unlimited
		Eel	Unlimited
		Salmon	Unlimited
		Whiting	Unlimited
		Mackerel	Unlimited

Geographical area	Member State	Species	Importance or particular characteristics
Skagerrak (4 to 12 miles)	Sweden	All species	Unlimited
Kattegat (3 to 12 miles) ⁽¹⁾	Sweden	All species	Unlimited
Baltic Sea (3 to 12 miles)	Sweden	All species	Unlimited

⁽¹⁾ Measured from the coastline.

4. Coastal waters of Germany

Geographical area	Member State	Species	Importance or particular characteristics
North Sea coast (3 to 12 nautical miles) all coasts	Denmark	Demersal	Unlimited
		Sprat	Unlimited
		Sandeel	Unlimited
	Netherlands	Demersal	Unlimited
		Shrimps and prawns	Unlimited
Danish/German frontier to the northern tip of Amrum at 54° 43' N	Denmark	Shrimps and prawns	Unlimited
Baltic coast (3 to 12 miles)	Denmark	Cod	Unlimited
		Plaice	Unlimited
		Herring	Unlimited
		Sprat	Unlimited
		Eel	Unlimited
		Whiting	Unlimited
		Mackerel	Unlimited

5. Coastal waters of France and the overseas departments

Geographical area	Member State	Species	Importance or particular characteristics
North east Atlantic coast (6 to 12 nautical miles)			
Belgian/French frontier to east of Departement Manche (Vire-Grandcamp les Bains estuary 49° 23' 30" N-1° 02' WNNE)	Belgium	Demersal	Unlimited
		Scallops	Unlimited
	Netherlands	All species	Unlimited
Dunkerque (2° 20' E) to Cap d'Antifer (0° 10' E)	Germany	Herring	Unlimited only from 1 October to 31 December
Atlantic coast (6 to 12 nautical miles)			

Geographical area	Member State	Species	Importance or particular characteristics
Spanish/French frontier to 46° 08' N	Spain	Anchovies	Directed fishing, unlimited only from 1 March to 30 June
			Fishing for live bait from 1 July to 31 October only
		Sardines	Unlimited only from 1 January to 28 February and from 1 July to 31 December
			In addition, activities relating to the abovementioned species must be pursued in accordance with, and within the limits of, the activities pursued during 1984
Mediterranean coast (6 to 12 nautical miles)			
Spanish frontier Cap Leucate	Spain	All species	Unlimited

6. Coastal waters of Spain

Geographical area	Member State	Species	Importance or particular characteristics
Atlantic coast (6 to 12 nautical miles)			
French/Spanish frontier to Cap Mayor lighthouse (3° 47' W)	France	Pelagic	Unlimited in accordance with, and within the limits of, the activities pursued during 1984
Mediterranean coast (6 to 12 nautical miles)			
French frontier/Cap Creus	France	All species	Unlimited

7. Coastal waters of Croatia ⁽¹⁾

Geographical area	Member State	Species	Importance or particular characteristics
12 miles limited to the sea area under the sovereignty of Croatia situated to the north of the 45 degrees and 10 minutes parallel north latitude along the west Istrian coast, from the outer limit of the territorial sea of Croatia, where this parallel touches the land of the west Istrian coast (the cape Grgatov rt Funtana)	Slovenia	Demersal and small pelagic species including sardine and anchovy	100 tonnes for a maximum number of 25 fishing vessels which includes 5 fishing vessels equipped with trawl nets

⁽¹⁾ The abovementioned regime shall apply from the full implementation of the arbitration award resulting from the Arbitration Agreement between the Government of the Republic of Slovenia and the Government of the Republic of Croatia, signed in Stockholm on 4 November 2009.

8. Coastal waters of the Netherlands

Geographical area	Member State	Species	Importance or particular characteristics
(3 to 12 nautical miles) whole coast	Belgium	All species	Unlimited
	Denmark	Demersal	Unlimited
		Sprat	Unlimited
		Sandeel	Unlimited
		Horse-mackerel	Unlimited
	Germany	Cod	Unlimited
		Shrimps and prawns	Unlimited
(6 to 12 nautical miles) whole coast	France	All species	Unlimited

9. Coastal waters of Slovenia ⁽¹⁾

Geographical area	Member State	Species	Importance or particular characteristics
12 miles limited to the sea area under the sovereignty of Slovenia situated to the north of the 45 degrees and 10 minutes parallel north latitude along the west Istrian coast, from the outer limit of the territorial sea of Croatia, where this parallel touches the land of the west Istrian coast (the cape Grgatov rt Funtana)	Croatia	Demersal and small pelagic species including sardine and anchovy	100 tonnes for a maximum number of 25 fishing vessels which includes 5 fishing vessels equipped with trawl nets

⁽¹⁾ The abovementioned regime shall apply from the full implementation of the arbitration award resulting from the Arbitration Agreement between the Government of the Republic of Slovenia and the Government of the Republic of Croatia, signed in Stockholm on 4 November 2009.

10. Coastal waters of Finland

Geographical area	Member State	Species	Importance or particular characteristics
Baltic Sea (4 to 12 miles) ⁽¹⁾	Sweden	All species	Unlimited
⁽¹⁾ 3 to 12 miles around Bogskär Isles.			

11. Coastal waters of Sweden

Geographical area	Member State	Species	Importance or particular characteristics
Skagerrak (4 to 12 nautical miles)	Denmark	All species	Unlimited
Kattegat (3 to 12 miles) ⁽¹⁾	Denmark	All species	Unlimited
Baltic Sea (4 to 12 miles)	Denmark	All species	Unlimited
	Finland	All species	Unlimited
⁽¹⁾ Measured from the coastline.			

12. Coastal waters of Greece

Geographical area	Member State	Species	Importance or particular characteristics
Ionian Sea 6 to 12 nautical miles in Greek territorial waters	Italy	Cephalopods Crustaceans Demersal Large pelagic species	A maximum number of 68 vessels'
South-Southeast of the island of Crete (East of 26°00'00" E) 6 to 12 nautical miles in Greek EEZ			
South-Southeast of the island of Koufonisi 6 to 12 nautical miles in Greek EEZ			
South-Southwest of the island of Kasos 6 to 12 nautical miles in Greek EEZ			
South-Southeast of the island of Karpathos 6 to 12 nautical miles in Greek EEZ			
South-Southwest (West of 27°59'02.00" E) of the island of Rhodes 6 to 12 nautical miles in Greek EEZ.			

COUNCIL REGULATION (EU, Euratom) 2022/2496
of 15 December 2022
amending Regulation (EU, Euratom) 2020/2093 laying down the multiannual financial framework for
the years 2021 to 2027

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 312 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽¹⁾,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with a special legislative procedure,

Whereas:

- (1) Following Russia's unprovoked and unjustified war of aggression against Ukraine, the Union has been supporting Ukraine with a series of financial measures. The support has been provided on an ad hoc basis for a limited period of time and has required significant provisioning from the Union budget and Member States' guarantees.
- (2) Ukraine will require continued assistance to sustain the functioning of the State. Together with other international partners, the Union is expected to contribute to covering Ukraine's urgent funding needs. To that end, the Union has established a new instrument under Regulation (EU) 2022/2463 of the European Parliament and of the Council ⁽²⁾. Under that instrument, a significant part of the envisaged financial assistance is to be provided in the form of loans.
- (3) In the context of increased external instability, it is appropriate to provide for a structured financing solution for the years 2023 and 2024 to ensure continued financial support for Ukraine.
- (4) It is therefore appropriate to enable the Union to provide the necessary budgetary resources in a sustainable and sound manner. This should be done by extending the existing mechanism in the form of a Union budget guarantee to cover the financial assistance which is made available to Ukraine in the years 2023 and 2024. That mechanism should enable a mobilisation of up to 100 % of the financial liability amounts needed to honour repayment obligations of the Union under the borrowing and lending operations in the event that the Union does not receive from Ukraine the due payment on time.
- (5) It should be possible to mobilise the necessary appropriations in the Union budget over and above the ceilings of the multiannual financial framework for Member States, as well as for financial assistance to Ukraine available for the years 2023 and 2024. That possibility should be without prejudice to the obligation to respect the own resources ceiling laid down in Article 3(1) of Council Decision (EU, Euratom) 2020/2053 ⁽³⁾.
- (6) In principle, and unless further exceptional developments arise, that Union budget guarantee should cover short-term financial relief to Ukraine for an amount of up to EUR 18 000 000 000 as specified in Regulation (EU) 2022/2463 and the use of the macro-financial assistance during 2024 should be limited to disbursements in the first quarter of that year as specified in that Regulation.

⁽¹⁾ Consent of 24 November 2022 (not yet published in the Official Journal).

⁽²⁾ Regulation (EU) 2022/2463 of the European Parliament and of the Council of 14 December 2022 establishing an instrument for providing support to Ukraine for 2023 (macro-financial assistance +) (OJ L 322, 16.12.2022, p. 1).

⁽³⁾ Council Decision (EU, Euratom) 2020/2053 of 14 December 2020 on the system of own resources of the European Union and repealing Decision 2014/335/EU, Euratom (OJ L 424, 15.12.2020, p. 1).

- (7) This Regulation should only apply to programmes of financial assistance to Ukraine available for the years 2023 and 2024.
- (8) Council Regulation (EU, Euratom) 2020/2093 ^(*) should therefore be amended accordingly.
- (9) In view of the urgency entailed by the exceptional circumstances caused by Russia's unprovoked and unjustified war of aggression against Ukraine, it is considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.
- (10) In light of the situation in Ukraine, this Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 2(3) of Regulation (EU, Euratom) 2020/2093, the following subparagraph is added:

'Where it is necessary to mobilise a guarantee for financial assistance to Ukraine which is available for the years 2023 and 2024 and authorised in accordance with Article 220(1) of the Financial Regulation, the necessary amount shall be mobilised over and above the MFF ceilings.'

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 December 2022.

For the Council
The President
M. BEK

^(*) Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433 I, 22.12.2020, p. 11).

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/2497

of 12 October 2022

amending Annex I to Council Regulation (EC) No 1217/2009 as regards the divisions of France and the United Kingdom in the Union Farm Accountancy Data Network

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1217/2009 of 30 November 2009 setting up a network for the collection of accountancy data on the incomes and business operation of agricultural holdings in the European Union ⁽¹⁾, and in particular Article 3 thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1217/2009 contains a list of Farm Accountancy Data Network divisions ('FADN divisions') for each Member State.
- (2) In accordance with that Annex, France is divided into 25 divisions. For the purposes of Regulation (EC) No 1217/2009, France has requested to merge the FADN divisions Guadeloupe and Martinique into one FADN division: Antilles françaises. That request is justified: farms in both current FADN divisions have very similar types of farming (highly specialized in fruit growing, particularly bananas, as well as in sugar cane production and horticulture) and the merge of the Guadeloupe and Martinique divisions into one FADN division will provide a larger sample size with more robust results on more types of farming. That merge should therefore be reflected in the list of FADN divisions set out in Annex I to Regulation (EC) No 1217/2009.
- (3) Following the withdrawal of the United Kingdom from the Union, FADN data will no longer be collected in that country. Therefore, the United Kingdom should be removed from the list of FADN divisions set out in Annex I to Regulation (EC) No 1217/2009.
- (4) Annex I to Regulation (EC) No 1217/2009 should therefore be amended accordingly.
- (5) In order to give sufficient time to adapt the data collection for the French new division, the updated list of FADN divisions provided for in this Regulation should apply as from the accounting year 2023,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1217/2009 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 328, 15.12.2009, p. 27.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from the accounting year 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 October 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I to Regulation (EC) No 1217/2009 is amended as follows:

(1) the list of FADN divisions concerning France is replaced by the following:

'France

1. Île de France
2. Champagne-Ardenne
3. Picardie
4. Haute-Normandie
5. Centre
6. Basse-Normandie
7. Bourgogne
8. Nord-Pas de Calais
9. Lorraine
10. Alsace
11. Franche-Comté
12. Pays de la Loire
13. Bretagne
14. Poitou-Charentes
15. Aquitaine
16. Midi-Pyrénées
17. Limousin
18. Rhône-Alpes
19. Auvergne
20. Languedoc-Roussillon
21. Provence-Alpes-Côte d'Azur
22. Corse
23. Antilles françaises
24. La Réunion';

(2) the entry for the United Kingdom is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2498**of 9 December 2022****specifying technical items of data sets of the sample survey in the income and living conditions domain on access to services pursuant to Regulation (EU) 2019/1700 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/1700 of the European Parliament and the Council of 10 October 2019 establishing a common framework for European statistics relating to persons and households, based on data at individual level collected from samples, amending Regulations (EC) No 808/2004, (EC) No 452/2008 and (EC) No 1338/2008 of the European Parliament and of the Council, and repealing Regulation (EC) No 1177/2003 of the European Parliament and of the Council and Council Regulation (EC) No 577/98 ⁽¹⁾, and in particular Article 7(1) thereof,

Whereas:

- (1) To ensure that implementation of the income and living conditions domain is conducted accurately, the Commission should specify the technical items of the data sets on access to services.
- (2) The income and living conditions domain provides the information required by the European Semester and the European Pillar of Social Rights, in particular on income distribution, poverty and social exclusion. It also provides information for various other Union policies related to living conditions and poverty. In this context, detailed information on access to services, in particular on use of services, affordability, unmet needs and reasons should be provided to the Commission (Eurostat).
- (3) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee established by Article 7 of Regulation (EC) No 223/2009 of the European Parliament and of the Council ⁽²⁾.

HAS ADOPTED THIS REGULATION:

Article 1

The technical characteristics of the data sets in the income and living conditions domain as regards the detailed topics 'Use of services, including care services and services for independent living', 'Affordability of services', 'Unmet needs and reasons' are set out in the Annex and refer to:

- (a) the variable's identifier;
- (b) the variable's name;
- (c) the modality label and code;
- (d) the collection unit;
- (e) the reference period.

⁽¹⁾ OJ L 261 I, 14.10.2019, p. 1.

⁽²⁾ Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Technical characteristics of variables

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
Use of services, including care services and services for independent living					
HC190	Presence in the household of people who need help due to long-term physical or mental ill-health, infirmity, or because of old age	1	Yes	Household	Current
		2	No		
HC190_F	Presence in the household of people who need help due to long-term physical or mental ill-health, infirmity, or because of old age (flag)	1	Filled		
		-1	Missing		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
HC200	Professional home care services received	1	Yes	Household	Current
		2	No		
HC200_F	Professional home care services received (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-2	Not applicable (no one in the household needs professional homecare HC190 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC280	Frequency of use of public transport	1	Daily	All current household members aged 16 and over or selected respondent (where applies)	Last 12 months
		2	Every week (not every day)		
		3	Every month (not every week)		
		4	Less than once a month		
		5	Never		
PC280_F	Frequency of use of public transport (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
PC310	Entitlement to unemployment benefits	1	Yes	All current household members aged 16 and over or selected respondent (where applies)	Current
		2	No		
		3	Don't know		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC310_F	Entitlement to unemployment benefits (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-2	Not applicable (Not employee or self- employed PL032 = 2,3,4,5,6,7,8)		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
PC320	Entitlement to sickness benefits	1	Yes	All current household members aged 16 and over or selected respondent (where applies)	Current
		2	No		
		3	Don't know		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC320_F	Entitlement to sickness benefits (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-2	Not applicable (Not employee or self- employed PL032 = 2,3,4,5,6,7,8)		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
PC330	Feeling discriminated when in contact with administrative offices or public services (including job centre, health and social services)	1	I was not in contact with any administrative offices or public services	All current household members aged 16 and over or selected respondent (where applies)	Last 12 months
		2	Mainly due to age (too young/old)		
		3	Mainly due to sex (male/ female/non-binary)		
		4	Mainly due to disability or long-term health problem		
		5	Mainly due to immigrant or ethnic origin		
		6	Mainly due to religion/belief (OPTIONAL)		
		7	Mainly due to sexual orientation (OPTIONAL)		
		8	Mainly due to other reason		
		9	No, I have not felt discriminated against		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC330_F	Feeling discriminated when in contact with administrative offices or public services (including job centre, health and social services) (flag)	1 -1 -3 -7	Filled Missing Not selected respondent Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
PC340	Feeling discriminated when looking for housing	1 2 3 4 5 6 7 8 9	I was not looking for housing Mainly due to age (too young/old) Mainly due to sex (male/female/non-binary) Mainly due to disability or long-term health problem Mainly due to immigrant or ethnic origin Mainly due to religion/belief (OPTIONAL) Mainly due to sexual orientation (OPTIONAL) Mainly due to other reason No, I have not felt discriminated against	All current household members aged 16 and over or selected respondent (where applies)	Last 5 years
PC340_F	Feeling discriminated when looking for housing (flag)	1 -1 -3 -7	Filled Missing Not selected respondent Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC350	Feeling discriminated in education	1	I was not a student or a parent of a student (in the last 12 months)	All current household members aged 16 and over or selected respondent (where applies)	Last 12 months
		2	Mainly due to age (too young/old)		
		3	Mainly due to sex (male/female/non-binary)		
		4	Mainly due to disability or long-term health problem		
		5	Mainly due to immigrant or ethnic origin		
		6	Mainly due to religion/belief (OPTIONAL)		
		7	Mainly due to sexual orientation (OPTIONAL)		
		8	Mainly due to other reason		
		9	No, I have not felt discriminated against		
PC350_F	Feeling discriminated in education (flag)	1	Filled		
		-1	Missing		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC360	Feeling discriminated in public spaces (shop, café, restaurant, leisure facilities etc.)	1	Mainly due to age (too young/old)	All current household members aged 16 and over or selected respondent (where applies)	Last 12 months
		2	Mainly due to sex (male/female/non-binary)		
		3	Mainly due to disability or long-term health problem		
		4	Mainly due to immigrant or ethnic origin		
		5	Mainly due to religion/belief (OPTIONAL)		
		6	Mainly due to sexual orientation (OPTIONAL)		
		7	Mainly due to other reason		
		8	No, I have not felt discriminated against		
PC360_F	Feeling discriminated in public spaces (shop, café, restaurant, leisure facilities etc.) (flag)	1	Filled		
		-1	Missing		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
Affordability of services					
HC221	Payment for professional home care services	1	Fully paid by private, public health insurance, or other social protection branches	Household	Last 12 months
		2	Partially paid by the user/household		
		3	Fully paid by the user/household		
		4	Don't know		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
HC221_F	Payment for professional home care services (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-2	Not applicable (Home care services not used HC200 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
HC230	Affordability of professional home care services	1	With great difficulty	Household	Last 12 months
		2	With difficulty		
		3	With some difficulty		
		4	Fairly easily		
		5	Easily		
		6	Very easily		
HC230_F	Affordability of professional home care services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (Home care services not used HC200 = 2 or HC221 = 1)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
HC300	Financial burden of public transport	1	Heavy burden	Household	Last 12 months
		2	Somewhat burden		
		3	Not a burden at all		
		4	No one in the household used public transport		
HC300_F	Financial burden of public transport (flag)	1	Filled		
		-1	Missing		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
RC370	Payment for formal childcare services	1	Yes	All household members not over 12 years old	Last 12 months
		2	No		
RC370_F	Payment for formal childcare services (flag)	1	Collected via survey/ interview		
		2	Collected from administrative data		
		3	Imputed		
		4	Not possible to establish a source		
		-1	Missing		
		-2	Not applicable (not 0–12 years old)		
		-4	Not applicable (no formal childcare services used RL030 = 0 and RL040 = 0)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
HC040	Affordability of formal childcare services	1	With great difficulty	Household	Last 12 months
		2	With difficulty		
		3	With some difficulty		
		4	Fairly easily		
		5	Easily		
		6	Very easily		
HC040_F	Affordability of formal childcare services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (no children aged 0–12 in the household)		
		-4	Not applicable (no formal childcare services used RL030 = 0 and RL040 = 0 or RC370 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Unmet needs and reasons

HC240	Unmet needs for professional home care services	1 2	Yes No	Household	Current
HC240_F	Unmet needs for professional home care services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (no one in the household needed home care HC190 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
HC250	Main reason for not receiving (more) professional home care services	1	Cannot afford it	Household	Current
		2	Refused by person needing such services		
		3	No such care services available		
		4	Quality of the services available not satisfactory		
		5	Other reasons		
HC250_F	Main reason for not receiving (more) professional home care services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (HC240 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
RC380	Unmet needs for formal childcare services	1	Yes	All household members not over 12 years old	Current
		2	No		
RC380_F	Unmet needs for formal childcare services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (not 0–12 years old)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
RC390	Main reason for not making (more) use of formal childcare services	1	Cannot afford it	All household members not over 12 years old	Current
		2	No places available		
		3	Places available, but not nearby		
		4	Places available, but opening hours not suitable		
		5	Places available, but quality of services available not satisfactory		
		6	Other reasons		
RC390_F	Main reason for not making (more) use of formal childcare services (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (not 0–12 years old)		
		-4	Not applicable (no unmet needs RC380 = 2)		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		
PC290	Main reason for not using regularly public transport	1	Too expensive	All current household members aged 16 and over or selected respondent (where applies)	Last 12 months
		2	No public transport available in the area		
		3	Physical access too difficult		
		4	Frequency too low or inconvenient schedules		
		5	Too long travel time		
		6	Safety or security concerns		
		7	Other reason		

Variable's identifier	Variable's name	Modality code	Modality label	Collection unit	Reference period
PC290_F	Main reason for not using regularly public transport (flag)	1	Filled		
		-1	Missing		
		-2	Not applicable (PC280 = 1,2,3)		
		-3	Not selected respondent		
		-7	Not applicable (Not collected according to the implementation of the 'multiannual rolling planning')		

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2499**of 12 December 2022****amending and correcting Implementing Regulation (EU) 2015/220 laying down rules for the application of Council Regulation (EC) No 1217/2009 setting up a network for the collection of accountancy data on the incomes and business operation of agricultural holdings in the European Union**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1217/2009 of 30 November 2009 setting up a network for the collection of accountancy data on the incomes and business operation of agricultural holdings in the European Union ⁽¹⁾, and in particular Article 5(1), third subparagraph, Article 5a(2), Article 8(3), third and fourth subparagraphs, and Article 19(3) thereof,

Whereas:

- (1) Article 10(3), third subparagraph, of Commission Implementing Regulation (EU) 2015/220 ⁽²⁾ provides for the possibility to extend the deadline for farm return data transmission until 31 December after the end of the accounting year in question by 3 months. This possibility was granted as from the 2019 accounting year due to the COVID-19 pandemic. The pressure due to the pandemic is fading away and most of the Member States transmitted the data without making use of the extension. The possibility to extend the deadline for data transmission is therefore not necessary anymore. To give enough time to Member States to adapt to this change, the possibility to extend the deadline should cease to be applicable from the 2022 accounting year.
- (2) To allow the Commission services to support adequately the Member States' authorities in charge of transmitting the accountancy data before the data transmission deadline, and to avoid that the Commission and Member States staff are mobilised during the end of the year period, the deadline for the data transmission should be anticipated to 15 December after the end of the accounting year in question. This change should be applicable from the 2022 accounting year. However, due to the specificity of the accountancy rules in Germany and taking into account Germany's past record in delivering such data, Germany should be allowed to submit the farm returns to the Commission up to 15 weeks after that deadline of 15 December.
- (3) Article 14 of Implementing Regulation (EU) 2015/220 provides for the Union financial contribution to the data collection costs of the Member States. The current standard fee per farm return has fixed and variable parts. In order to significantly simplify the standard fee structure and the processing of data by the Member States and the Commission, a standard fee with only a fixed part, amounting to the sum of the current fixed and variable parts should be set. Such simplification is easy to put in place and it should be applicable from the 2022 accounting year.
- (4) Following the request of France to merge its two FADN divisions 'Guadeloupe' and 'Martinique' into one FADN division called 'Antilles françaises' as farms in both current FADN divisions have very similar types of farming (highly specialized in fruit growing, particularly bananas, as well as in sugar cane production and horticulture). This merge will provide a larger sample size with more robust results on more types of farming. It is appropriate to allow that Member State to revise its selection plan for the accounting year 2023. Annexes I and II to Implementing Regulation (EU) 2015/220 should therefore be amended accordingly.

⁽¹⁾ OJ L 328, 15.12.2009, p. 27.

⁽²⁾ Commission Implementing Regulation (EU) 2015/220 of 3 February 2015 laying down rules for the application of Council Regulation (EC) No 1217/2009 setting up a network for the collection of accountancy data on the incomes and business operation of agricultural holdings in the European Union (OJ L 46, 19.2.2015, p. 1).

- (5) Following the request of Hungary to change the number of returning holdings and the threshold of economic size due to structural changes in agriculture, it is appropriate to allow that Member State to revise its selection plan and the threshold of economic size for the accounting year 2023 and to redistribute or adjust the number of returning holdings accordingly. Annexes I and II to Implementing Regulation (EU) 2015/220 should therefore be amended accordingly.
- (6) Following the withdrawal of the United Kingdom from the Union, the FADN data collection will not be pursued in that country. Annexes I and II to Implementing Regulation (EU) 2015/220 should therefore be amended accordingly.
- (7) As the Union aims to diversify its energy sources, the category of heating fuels in Table H of Annex VIII to Implementing Regulation (EU) 2015/220 should be sub-divided into natural and manufactured gases, oil and petroleum products, solid fossil fuels as well as renewable fuels to inform more about their specific costs at the farm level, the proposed sub-division of category of heating fuels should apply as from the accounting year 2023 on a voluntary basis and compulsorily from the accounting year 2025 onwards.
- (8) Table J of Annex VIII to Implementing Regulation (EU) 2015/220 requires Member States to provide the average number of animals of the agricultural holding. This is then used to calculate the standard output of the farm and its economic size. In order to allow reflecting an exceptional situation (e.g. disease on the holding or culling for sanitary reason) that leads to a temporary decrease of the average number of animals without affecting the capacity of the holding to produce after the end of the exceptional situation, it is proposed to introduce a reference number for animals to characterise the production capacity of the given holding. The proposed new variable should apply as from the accounting year 2022 on a voluntary basis.
- (9) As from 2023, Regulation (EU) 2021/2115 of the European Parliament and of the Council ⁽³⁾ reforming the common agricultural policy will apply, therefore, it is necessary to update a list of payments and grants in Table M of Annex VIII to Implementing Regulation (EU) 2015/220.
- (10) Annex VIII to Implementing Regulation (EU) 2015/220 sets out the form and layout of the accountancy data contained in the farm returns. In order to simplify and clarify the farm return questionnaire, that Annex should be adapted to reflect the first wave of outcomes provided by the Working Group on the FADN simplification and modernisation. In the explanatory notes to Table B, the note to code UO (B.UO. UAA for owner farming) erroneously contains a reference to crop code 11 300 that is no longer valid. That error should be corrected.
- (11) Part B of Annex IV to Implementing Regulation (EU) 2015/220 provides for the table of correspondence and regrouping codes linking Commission Implementing Regulation (EU) 2018/1874 ⁽⁴⁾ and the FADN farm returns. In the list of codes regrouping several variables included in IFS 2020 set out in section II of Part B, the entry related to the P16 code contains a misprint that requires correction.
- (12) Implementing Regulation (EU) 2015/220 should therefore be amended and corrected accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Farm Accountancy Data Network,

⁽³⁾ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/1874 of 29 November 2018 on the data to be provided for 2020 under Regulation (EU) 2018/1091 of the European Parliament and of the Council on integrated farm statistics and repealing Regulations (EC) No 1166/2008 and (EU) No 1337/2011, as regards the list of variables and their description (OJ L 306, 30.11.2018, p. 14).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2015/220

Implementing Regulation (EU) 2015/220 is amended as follows:

(1) in Article 10, paragraph 3 is replaced by the following:

‘3. The farm returns shall be transmitted to the Commission by 15 December after the end of the accounting year in question.

However, Germany may submit the farm returns to the Commission within 15 weeks after the deadline referred to in the first subparagraph.’;

(2) Article 14 is replaced by the following:

‘Article 14

Amount of the standard fee

1. The standard fee referred to in Article 19(1), point (a), of Regulation (EC) No 1217/2009 shall be fixed at EUR 180 per farm return.

2. If the 80 % threshold referred to in Article 19(1), point (a), of Regulation (EC) No 1217/2009 is neither met at the level of a FADN division, nor at the level of the Member State concerned, the reduction referred to in that provision shall be applied only at national level.’;

(3) Annexes I, II and VIII are amended in accordance with Annex I to this Regulation;

(4) Table J of Annex VIII is amended in accordance with Annex II to this Regulation.

Article 2

Corrections to Implementing Regulation (EU) 2015/220

Implementing Regulation (EU) 2015/220 is corrected as follows:

(1) in Annex IV to Implementing Regulation (EU) 2015/220, the entry for code P16 is replaced by the following:

‘P16.Oilseeds= SO_CLND022 (Rape and turnip rape seeds) + SO_CLND023 (Sunflower seed) + SO_CLND024 (Soya) + SO_CLND025 (Oil flax (Linseed)) + SO_CLND026 (Other oilseed crops n.e.c.)’;

(2) in Annex VIII to Implementing Regulation (EU) 2015/220, the explanatory note for code B.UO. ‘UAA for owner farming’ is replaced by the following:

‘B.UO.10.A UAA (arable land, permanent grassland, permanent crops and kitchen gardens) of which the farmer is the owner, tenant for life or leaseholder and/or UAA held on similar terms.’.

Article 3

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 1, points (1), (2) and (4), shall apply to the transmission of farm returns from the accounting year 2022.

Article 1, point (3) shall apply from the accounting year 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes I, II and VIII to Implementing Regulation (EU) 2015/220 are amended as follows:

(1) Annex I is amended as follows:

(a) the entry for France is replaced by the following:

'France (with the exception of La Réunion and Antilles françaises)	25 000
France (only La Réunion and Antilles françaises)	15 000'

(b) the entry for Hungary is replaced by the following:

'Hungary	8 000'
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(c) the entry for the United Kingdom is deleted;

(2) Annex II is amended as follows:

(a) the entry for France is replaced by the following:

'France		
121	Île-de-France	190
131	Champagne-Ardenne	370
132	Picardie	270
133	Haute-Normandie	170
134	Centre	410
135	Basse-Normandie	240
136	Bourgogne	340
141	Nord-Pas de Calais	280
151	Lorraine	230
152	Alsace	200
153	Franche-Comté	210
162	Pays de la Loire	460
163	Bretagne	480
164	Poitou-Charentes	360
182	Aquitaine	550
183	Midi-Pyrénées	480
184	Limousin	220
192	Rhône-Alpes	480
193	Auvergne	360
201	Languedoc-Roussillon	430
203	Provence-Alpes-Côte d'Azur	420
204	Corse	170
207	La Réunion	160
208	Antilles françaises	120
Total France		7 600'

- (b) the entry for Hungary is replaced by the following:

Hungary		
764	Észak-Magyarország	180
767	Alföld	1 200
768	Dunántúl	570
	Total Hungary	1 950'

- (c) the entry for the United Kingdom is deleted;

- (3) Annex VIII is amended as follows:

- (a) the paragraphs below the title are replaced by the following:

'The data to be collected is classified by table and broken down into groups, categories and columns. The convention used to refer to a specific data field is:

<table letter>.<group>.<category code>(<other specific category codes>).column

Specific data values are captured at column level. In the tables set out below, clear cells are where data values can be accepted; greyed cells marked with a "—" have no meaning in the group context, so no data is accepted in those.

Examples:

- B.UT.20.A (column A of the group UT, category 20, from table B) represents the "Area" of "Rented UAA" to be recorded under the "UAA for tenant farming" in table B.
- I.A.10110.1.0.TA (column TA of the group A, category 10110, from table I) represents the total area of "Common wheat and spelt" for type of crop 1 "Field scale crops – main crop, combined crop" and missing data code 0 "No data missing".
- M.S.1150.1.2.V (column V of the group S, category 1150 with other specific category codes 1 and 2 from table M) represents the subsidy value of "Basic Income Support for Sustainability – based on payments entitlements" that is financed solely from the Union budget and is granted per ha.

When a value is not relevant or missing for any particular holding, do not enter value "0".

Tables are represented by one letter, groups by one or more letters, categories by numeric codes and columns by one or more letters.

For tables A to M, the first table shows the high level matrix for groups and columns. The second table shows how this breaks down for categories where each category is represented by one or more codes and sub-codes.

The data in a farm return should be given with the following degrees of accuracy:

financial values: values in EUR or in national monetary units without decimal. However, for national currencies where the unit represents a low relative value compared to the EUR, it may be agreed between the liaison agency of the Member State in question and the staff of the Commission which manages the FADN, to express the values in hundreds or thousands of national currency units,

physical quantities: in quintals (1 q = 100 kg) except in the case of eggs, which will be expressed in thousands and wine and related products which will be expressed in hectolitres,

areas: in ares (1 a = 100 m²), except in the case of mushrooms which will be expressed in square metres of total cropped area and except in Table M "Subsidies", where basic units are to be registered in ha,

average livestock numbers: to two decimal places, except for poultry and rabbits, which are to be given in whole numbers, and bees which are to be given in number of occupied hives,

labour units: to two decimal places.

For each table category and column value, further definitions and instructions are set out after the table concerned.;

(b) Table A (General information on the holding) is amended as follows:

(i) in the first and the second part of the table, the column 'Number of the accounting office' (AO) is deleted;

(ii) the second part of the table is amended as follows:

(1) the row for code 50 is deleted;

(2) the rows for codes 230, 231 and 232 are replaced by the following:

'Code (*)	Description	Group	R	S	H	DG	MI	N	DT	W	TF	ES	C
230	Member of Producer Organisations (POs)	OT	-	-	-	-	-	-	-	-	-	-	AO-T230C
231	Economic relevance of Producer Organisations (POs) to the farm	OT	-	-	-	-	-	-	-	-	-	-	AO-T231C
232	Number of members of Producer Organisations (POs)	OT	-	-	-	-	-	-	-	-	-	-	AO-T232C'

(c) the explanatory notes to Table A are amended as follows:

(i) the notes for codes 60 and 70 under A.AI. (Accounting information) of Table A are replaced by the following:

'A.AI. Accounting information

A.AI.60.C. *Type of accounting*: an indication is to be given on the type of accounting that the farm keeps. The following code numbers are to be used:

1. Double-entry accounting.
2. Single-entry accounting.
3. None.

A.AI.70.DT. *Date of closure of accounts*: to be recorded in format "YYYY-MM-DD", for example 2009-06-30 or 2009-12-31.;

(ii) the note for code 230 under A.OT. (Other particulars concerning the holding) of Table A, is replaced by the following:

'A.OT.230.C *Member of Producer Organisations (POs)*: Indication if the farm (farm holder(s) or manager(s)) is a member of a producer organisation which shares costs and/or promotes the marketing of agricultural products, and if yes, which of the farm's products are marketed by the producer organisation (choose all sectors covered by POs the farm is a member of). For the purpose of this survey, "producer organisations" refer to any type of entity that has been formed on the initiative of producers to pursue joint activities in a specific sector (horizontal cooperation). Producer organisations must be controlled by producers, they can take different legal forms e.g. agricultural cooperatives, farmers' associations, or private companies with producers as shareholders.

0. not a member of a producer organisation

A member of a producer organisation to share production, administrative and investments costs and/or, a member of a producer organisation to market the farm's products such as:

31. cereals

32. oilseeds and protein crops

33. fruits and vegetables (including citrus fruits, but excluding olives)

34. olives

35. vineyards

36. beef

37. cow's milk

38. pigmeat

39. sheep and goats (milk and meat)

40. poultry meat

41. eggs

42. other sector.;

(d) Table C (Labour) is replaced by the following:

Category of labour		Code(*)						
Group of information		Columns						
		General				Total work on the holding (agricultural work and work for OGA directly related to the holding)		Share of work for OGA directly related to the holding
		Number of persons	Gender	Year of birth	Agricultural training of the manager	Annual time worked	Number of Annual Work Units (AWU)	% of annual time worked
		P	G	B	T	Y1	W1	Y2
		Integer	Enter code	Four digits	Enter code	(hours)	(AWU)	%
UR	Unpaid regular							
UC	Unpaid casual	-	-	-	-		-	
PR	Paid regular							
PC	Paid casual	-	-	-	-		-	

Code (*)	Description	Group	P	G	B	T	Y1	W1	Y2
10	Holder(s)/manager(s)	UR	-						-
20	Holder(s)/not manager(s)	UR	-			-			-
30	Manager(s)/not holder(s)	UR	-						-
40	Spouse(s)/partner(s) of holder(s)	UR		-	-	-			
50	Other	UR, PR		-	-	-			
60	Casual work	UC, PC	-	-	-	-		-	
70	Paid manager	PR	-						-

(e) the explanatory notes to Table C are amended as follows:

(i) the notes to items under C.PR (Paid regular labour) are replaced by the following:

‘C.PR. Paid regular labour

Labour paid (in cash and/or in kind) on the normal scale for services rendered and which during the accounting year (excluding normal holidays) worked for at least one whole day per week for the holding.

The following categories are to be shown:

C.PR.70. Paid manager

Salaried person responsible for the day-to-day management of the holding.

C.PR.50. Other

All regular paid labour (except for the holding's salaried manager) is aggregated under this group. Includes also foreman and sub-managers not responsible for management of the whole farm.’;

(ii) in the notes to the columns in Table C, the note to ‘Share of work for OGA in % of annual work units (column W2)’ is deleted;

(f) in Table D (Assets), the second part is replaced by the following:

Code (*)	Description of categories	OV	AD	DY	IP	S	SA	CV
1005	Cash, receivables, other current assets and equivalents		-	-	-	-	-	
1040	Inventories		-	-				
2010	Biological assets – plants							
3010	Agricultural land		-	-				
3020	Land improvements							
3030	Farm buildings							
4010	Machinery and equipment							

5010	Forest land including standing timber		-	-				
7005	Intangible assets							
8010	Other non-current assets							

(g) the explanatory notes to Table D are amended as follows:

(i) the notes to codes 1010, 1020 and 1030 are deleted and the following note is inserted before the note to code 1040:

‘1005. Cash, receivables, other current assets and equivalents

Cash and other assets that can be easily converted to cash. Short-term assets, amounts owed to the holding, normally arising from business activities. Any other assets that are easily sold or expected to be paid within a year.’;

(ii) the notes to codes 7010 and 7020 are deleted and the following note is inserted after the note to code 5010:

‘7005. Intangible assets

All intangible assets both that can be easily bought or sold (e.g. quotas and rights when they are tradable without land and an active market exists) as well as that cannot easily be bought or sold (e.g. software, licences, etc.). The heading must be completed and the amounts entered are subject to depreciation in column DY.’;

(h) in Table H (Inputs), the second part is replaced by the following:

‘Code (*)	Group	Description of categories	V	Q
1010	LM	Wages and social security costs for paid labour		-
1020	LM	Contract work and machinery hire		-
1030	LM	Current upkeep of machinery and equipment		-
1040	LM	Motor fuels and lubricants		-
1050	LM	Car expenses		-
2010	SL	Purchased concentrated feedstuffs for grazing stock (equines, ruminants)		-
2020	SL	Purchased coarse fodder for grazing stock (equines, ruminants)		-
2030	SL	Purchased feedstuffs for pigs		-
2040	SL	Purchased feedstuffs for poultry and other small animals		-
2050	SL	Farm-produced feedstuffs for grazing stock (equines, ruminants)		-
2060	SL	Farm-produced feedstuffs for pigs		-
2070	SL	Farm-produced feedstuffs for poultry and other small animals		-
2080	SL	Veterinary expenses		-
2090	SL	Other specific livestock costs		-
3010	SC	Seeds and seedlings purchased		-
3020	SC	Seeds and seedlings produced and used on the farm		-
3030	SC	Fertilisers and soil improvers		-
3031	SC	Quantity of N used in mineral fertilisers	-	

3032	SC	Quantity of P2O5 used in mineral fertilisers	-	
3033	SC	Quantity of K2O used in mineral fertilisers	-	
3034	SC	Purchased manure		-
3040	SC	Crop protection products		-
3090	SC	Other specific crop costs		-
4010	OS	Specific costs for forestry and wood processing		-
4020	OS	Specific costs for crop processing		-
4030	OS	Specific costs for cow's milk processing		-
4045	OS	Specific costs for other animals' milk processing		-
4070	OS	Specific costs for meat processing and other animal products processing		-
4090	OS	Other specific costs for other gainful activities		-
5010	FO	Current upkeep of land improvements and buildings		-
5020	FO	Electricity		-
5030	FO	Heating fuels, total		-
5031	FO	of which natural gas and manufactured gases		-
5032	FO	of which oil and petroleum products		-
5033	FO	of which solid fossil fuels		-
5034	FO	of which renewable fuels (wood, straw, biogas, ...)		-
5040	FO	Water		-
5051	FO	Agricultural insurance		-
5055	FO	Other farm insurance		-
5061	FO	Taxes and other dues		-
5062	FO	Taxes and other charges on land and buildings		-
5070	FO	Rent paid, total		-
5071	FO	of which rent paid for land		-
5080	FO	Interest and financial charges paid		-
5090	FO	Other farming overheads		-

(i) the explanatory notes to Table H are amended as follows:

(1) the notes to codes 4040, 4050 and 4060 are deleted and the following note is inserted after the note to code 4030:

'4045. Specific costs for other animals' milk processing

Ingredients, raw materials or semi-processed products, own or purchased and other specific costs of other animals' (e.g.: buffalo, sheep, goat) milk processing (e.g. the specific packaging or marketing costs). Labour costs, contract work and mechanisation are not included; these are shown under the appropriate cost codes.;

(2) the note to code 5030 is replaced by the following:

'5030. Heating fuels (total)

Total consumption value of purchased heating fuels for farm business use, including the heating of glasshouses. This category includes heating consumption of purchased fossil fuels: natural and manufactured gases, oil, petroleum products and solid fossil fuels as well as consumption of purchased renewable energy sources (e.g. wood, straw, pellets, biogas).

5031. Of which natural gas and manufactured gases

Total consumption of natural gas and other manufactured, fossil-based gases for farm business use, including the heating of glasshouses.

5032. Of which oil and petroleum products

Total consumption of oil and petroleum products for farm business use, including the heating of glasshouses.

5033. Of which solid fossil fuels

Total consumption of solid fossil fuels (e.g. coal) for farm business use, including the heating of glasshouses.

5034. Of which renewable fuels

Total consumption of renewable fuels (e.g. wood, straw, pellets, biogas) for farm business use, including the heating of glasshouses.

The submission of data relating to variables 5031, 5032, 5033 and 5034 is voluntary as from the accounting year 2023 and mandatory as from the accounting year 2025.’

(j) Table I (Crops) is amended as follows:

(i) in the second part of the table, the entries under the title ‘Roots and Tubers’ are replaced by the following:

‘Roots and Tubers’	
10300	Potatoes (including early potatoes and seed potatoes)
10310	- of which potatoes for starch
10390	- of which other potatoes
10400	Sugar beet (excluding seed)
10500	Other root crops, fodder beet and fodder plants of the <i>Brassicae</i> family, grown for the root or the stem, and other fodder root and tuber crops n.e.c.’

(ii) the fourth part of the table on the missing data codes is replaced by the following:

‘The missing data codes are to be selected from the list below:

Code (***)	Description
0	Code 0 is entered when no data are missing.
1	Code 1 should be entered when the area covered by a crop cannot be reported, for example in the case of sales of marketable crop products purchased as standing crops or coming from land rented for a period of less than 1 year on an occasional basis.
2	Code 2 should be entered when the actual production cannot be determined in quintals (or hectolitres for wine and wine-related products) because of the conditions of sale or when there is no actual production.
4	Code 4 should be entered when the area covered by a crop cannot be reported and there is no actual production or actual production cannot be determined in quintals (or hectolitres for wine and wine-related products).’

- (k) in the explanatory notes to the groups of information in Table I, the note to items under I.PR (Production) is replaced by the following:

I.PR Production

For the group of information production (PR) the quantities of crops produced (Q) during the accounting year (excluding any losses in the field and at the farm) are to be recorded. These quantities are indicated for the principal products of the holding (except by-products).

These quantities should be indicated in quintals (100 kg) with the exemption of wine and wine-related products, which are expressed in hectolitres. When, because of the conditions of sale, actual production in quintals cannot be determined, the missing data code 2 should be entered.

For the 10790 "Other vegetables" and 90900 "Other", the quantity should not be provided.;

- (l) in Table K (Animal products and services) the second part on the description of products and services and the third part on the missing data codes are replaced by the following:

'Code (*)	Description
261	Cows' milk
262	Buffalo's cows' milk
311	Sheep's milk
321	Goat's milk
330	Wool
531	Eggs for human consumption (all poultry)
532	Eggs for hatching (all poultry)
700	Honey and products of beekeeping
800	Manure
900	Other animal products
1100	Contract rearing
1200	Other animal services

Code (**)	Description
0	Code 0 is entered when no data are missing.
2	Code 2 should be entered for when the actual production cannot be determined in quintals (or thousands of eggs) because of the conditions of sale.
4	Code 4 should be entered when there are only stocks and no actual production.'

- (m) the explanatory notes to Table K are amended as follows:

- (i) the note to code 1100 is replaced by the following:

'1100. Contract rearing

Amount of receipts for contract rearing corresponding mainly to payment for services rendered and where the holder does not assume the economic risk normally involved in rearing or fattening these animals, e.g.: cattle, sheep, goats, pigs, poultry.;

- (ii) the notes to the missing data codes are deleted;

(iii) the third paragraph under the title 'Groups of information in Table K' is replaced by the following:

'For animal services such as contract rearing (codes 1100) and others (code 1200) the only information to provide concern the receipts that should be recorded under the information on sales (SA) in column value (V).';

(n) in Table L (OGA directly related to the farm), the second part on the description of the OGA codes and the third part on the missing data codes are replaced by the following:

'Code (*)	Description
261	Processing of cow's milk
263	Processing of other animals' milk
900	Processing of meat or other animal products
1010	Processing of crop
1020	Forestry and wood processing
2010	Contractual work
2020	Tourism, accommodation, catering and other leisure activities
2030	Production of renewable energy
9000	Other "other gainful activities" directly related to the farm

Code (**)	Description
0	Code 0 is entered when no data are missing.
1	Code 1 should be entered in the case of production obtained by processing purchased livestock or animal or crops products.
2	Code 2 should be entered when the actual production cannot be determined in quintals because of the conditions of sale.
4	Code 4 should be entered when there are only stocks and no actual production.'

(o) the explanatory notes to Table L are amended as follows:

(i) the note to code 262 is replaced by the following:

'263. Processing of other animals' milk, e.g. buffalo's milk, sheep's milk, goat's milk';

(ii) the notes to the missing data codes are deleted;

(iii) the second paragraph under the title 'Groups of information in Table L' (Quantity (column Q)) is replaced by the following:

'In the case of milk processed products (codes 261, 263), the quantity of liquid milk is indicated regardless of the form in which it is sold, consumed on the farm or used for benefits in kind or for farm purposes (cream, butter, cheese, etc.).';

(p) Table M (Subsidies) and the pertaining explanatory notes are replaced by the following:

'Structure of the table

	Category of subsidy/administrative information	Code (*)		
	Financing	Code (**)		
	Basic unit	Code (***)		
Group of information		Columns		
		Number of basic units	Value	Type
		N	V	T
S	Subsidy			-
AI	Administrative information		-	

The categories are to be selected from the list below:

Code (*)	Group	Description of categories	Columns		
			N	V	T
		Decoupled payments			
1250	S	Basic Income Support for Sustainability			-
1300	S	Complementary redistributive income support for sustainability			-
1400	S	Schemes for the climate, the environment and animal welfare (eco-schemes)			-
1600	S	Complementary income support for young farmers			-
1700	S	Payments for small farmers			-
		Coupled Income Support			
		Arable crops			
		COP (cereals, oilseeds and protein crops)			
23111	S	Cereals			-
23112	S	Oilseeds			-
23114	S	Protein crops & grain legumes			-
2312	S	Potatoes			-
23121	S	Of which potatoes for starch			-
2313	S	Sugar beet			-
		Industrial crops			
23141	S	Flax			-
23142	S	Hemp			-
23143	S	Hops			-
23144	S	Sugar cane			-
23145	S	Chicory			-

Code (*)	Group	Description of categories	Columns		
			N	V	T
23149	S	Other industrial crops			-
2315	S	Vegetables			-
2316	S	Fallow land			-
2317	S	Rice			-
2319	S	Arable crops not defined			-
2320	S	Permanent grassland			-
2321	S	Dried fodder			-
2322	S	Crop specific payment for cotton			-
2323	S	National restructuring programme for the cotton sector			-
2324	S	Seed production			-
		Permanent crops			
23311	S	Berries			-
23312	S	Nuts			-
2332	S	Pome and stone fruit			-
2333	S	Citrus plantations			-
2334	S	Olive plantations – olive oil and table olives			-
2335	S	Vineyards			-
2339	S	Permanent crops not mentioned elsewhere			-
		Animals			
2341	S	Dairy			-
2342	S	Beef and veal			-
2343	S	Cattle (type not specified)			-
2344	S	Sheep and goat			-
2345	S	Pigs and poultry			-
2346	S	Silkworms			-
2347	S	Apiculture products			-
2349	S	Animals not mentioned elsewhere			-
2410	S	Short rotation coppices			-
2490	S	Other coupled payments not mentioned elsewhere			-
		Grants and subsidies of exceptional character			
2810	S	Disaster payments			-
2890	S	Other grants and subsidies of exceptional character			-
2900	S	Other direct payments not mentioned elsewhere			-

Code (*)	Group	Description of categories	Columns		
			N	V	T
		Rural development			
3100	S	Investments, including in irrigation			-
3200	S	Setting-up of young farmers and new farmers and rural business start-up			-
3310	S	Management commitments (environmental, climate-related and other) (excluding animal welfare and organic farming)			-
3320	S	Animal welfare payments			-
3350	S	Organic farming			-
3400	S	Area-specific disadvantages resulting from certain mandatory requirements (e.g. Natura 2000, Water Framework Directive)			-
3500	S	Natural or other area-specific constraints			-
	S	Forestry/non-productive investments			
3610	S	Investments in forest area development and improvement of the viability of forests			-
3620	S	Natura 2000 payments for forestry and forest-environmental and climate services and forest conservation support			-
3750	S	Support to restoring agricultural production potential damaged by natural disasters and catastrophic events and introduction of appropriate prevention actions			-
3760	S	Risk management tools			-
3900	S	Other payments for rural development			-
		Grants and subsidies on costs			
4100	S	Wages and social security			-
4200	S	Motor fuels			-
		Livestock			
4310	S	Feed for grazing livestock			-
4320	S	Feed for pig and poultry			-
4330	S	Other livestock costs			-
		Crop			
4410	S	Seeds			-
4420	S	Fertilisers			-
4430	S	Crop protection			-
4440	S	Other specific crop costs			-
		Farming overheads			
4510	S	Electricity			-
4520	S	Heating fuels, total			-
4521	S	of which natural gas and manufactured gases			-

Code (*)	Group	Description of categories	Columns		
			N	V	T
4522	S	of which oil and petroleum products			-
4523	S	of which solid fossil fuels			-
4524	S	of which renewable fuels			-
4530	S	Water			-
4540	S	Insurance			-
4550	S	Interest			-
4600	S	Costs for OGA			-
4900	S	Other costs			-
		Grants and subsidies on livestock purchases			
5100	S	Dairy purchases			-
5200	S	Beef purchases			-
5300	S	Sheep and goat purchases			-
5400	S	Pigs and poultry purchases			-
5900	S	Other animals purchases			-
9000	S	Differences from the previous accounting years			-
		Obligations of Member States relating to good agricultural and environmental conditions of land (GAEC standards 2, 8 and 9)			
10010	AI	GAEC 2 on wetland and peatlands	-	-	
10011	AI	GAEC 2: number of hectares of wetland and peatlands – permanent grassland		-	-
10012	AI	GAEC 2: number of hectares of wetland and peatlands – arable land		-	-
10013	AI	GAEC 2: number of hectares of wetland and peatlands – permanent crops		-	-
10300	AI	GAEC 8: the minimum share of arable land devoted to non-productive areas and features	-	-	
10310	AI	GAEC 8: number of hectares of land laying fallow		-	-
10311	AI	GAEC 8: number of hectares of terraces		-	-
10312	AI	GAEC 8: number of hectares of hedgerows, individual or group of trees, trees rows		-	-
10313	AI	GAEC 8: number of hectares of field margins, patches or buffer strips		-	-
10318	AI	GAEC 8: number of hectares of catch crops		-	-
10319	AI	GAEC 8: number of hectares of nitrogen-fixing crops		-	-
10324	AI	GAEC 8: number of hectares of ditches		-	-

Code (*)	Group	Description of categories	Columns		
			N	V	T
10325	AI	GAEC 8: number of hectares of streams		-	-
10326	AI	GAEC 8: number of hectares of small ponds;		-	-
10327	AI	GAEC 8: number of hectares of small wetlands		-	-
10328	AI	GAEC 8: number of hectares of stonewalls		-	-
10329	AI	GAEC 8: number of hectares of cairns		-	-
10330	AI	GAEC 8: number of hectares of cultural features		-	-
10400	AI	GAEC 9: ban on conversion or ploughing	-	-	
10401	AI	GAEC 9: number of hectares of permanent grassland in Natura 2000 sites		-	-
10402	AI	GAEC 9: number of hectares of designated environmentally sensitive permanent grassland in Natura 2000 sites protected under GAEC 9 and declared by farmers;		-	-
10403	AI	GAEC 9: number of hectares of designated environmentally sensitive permanent grassland outside Natura 2000 sites, protected under GAEC 9 and declared by farmers, where applicable.		-	-

The codes describing how the subsidy is financed are to be selected from the list below:

Code (**)	Description
0	Not applicable: this code is to be used in the case of administrative information
1	The subsidy is financed solely from the EU budget.
2	The measure is co-financed by the EU and the Member State.
3	The measure is not financed from the EU budget but by other public sources.

The codes defining the basic units are to be selected from the list below:

Code (***)	Description
0	Not applicable: this code is to be used in the case of administrative information
1	The subsidy is granted per head of livestock.
2	The subsidy is granted per ha.
3	The subsidy is granted per tonne.
4	Farm/other: the subsidy is granted for the whole farm or in a way which does not fit in the other categories.

Table M "SUBSIDIES" covers grants and subsidies received by agricultural holdings from public bodies, both national and EU. It also covers administrative information on greening payments.

GROUPS OF INFORMATION IN TABLE M

S Subsidies

Grants and subsidies are defined by category of subsidy (S), financing and basic units. For each entry, the number of basic units (N) and the amount received (V) are to be recorded. There might be several records per category of subsidy as the basic units and/or financing origins might differ.

As a general rule, grants and subsidies registered in Table M correspond to the current accounting year regardless of when the payment is received (accounting year is equal to claim year). Investment subsidies and rural development payments other than payments to areas facing natural or other specific constraints constitute an exception to this general rule as registered amounts should refer to payments actually received during the accounting year (accounting year is equal to payment year).

AI Administrative information

Certain obligations of Member States relating to good agricultural and environmental conditions of land (GAEC standards 2, 8 and 9) are defined by category of administrative information (AI). The number of basic units (N) and/or the type (T) are to be recorded for each entry, as specified in the table.

The number of basic units (N) corresponds to area concerned by GAEC standards are expressed in hectares.

The type (T) refers to the application of the GAEC at farm level and is to be selected from the list below:

Code	Description
1	Agricultural holding has an obligation to comply with the administrative requirement.
2	Agricultural holding benefits from an exemption specified in GAEC.'

ANNEX II

Annex VIII to Implementing Regulation (EU) 2015/220 is amended as follows:

- (1) in Table J (Livestock production), the first part is replaced by the following:

‘Structure of the table

Category of livestock	Code (*)
-----------------------	----------

Group of Information		Columns		
		Average number	Number	Value
		A	N	V
AN	Average number		-	-
RN	Reference number	-		-
OV	Opening valuation	-		
CV	Closing valuation	-		
PU	Purchases	-		
SA	Total Sales	-		
SS	Sales for slaughtering	-		
SR	Sales for further rearing/breeding	-		
SU	Sales with unknown destination	-		
FC	Farmhouse consumption	-		
FU	Farm use	-		

- (2) in the explanatory notes to Table J, the following note is inserted after the note on ‘J.AN. Average number (to be recorded for column A only)’:

J.RN. Reference number (to be recorded for column N only)

The reference number is the number of animals typically present on the farm at a given moment. It is used to calculate the standard output of the holding and its economic size. Contrary to the average number (AN), it enables to account for a period during which there is a lower number or no livestock on the holding for an exceptional period of time due to an exceptional break in the production cycle (e.g. disease outbreaks).

Number (column N)

Number of livestock should be indicated in heads or in number for beehives, expressed to two decimal places.

This information should not be provided for the other animals (category 900).

The data relating to the variable “J.RN.Reference number” may be provided in exceptional cases (e.g. disease on the holding, or culling for sanitary reason) as from the accounting year 2022. The submission is voluntary.’

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2500**of 13 December 2022****entering a name in the register of protected designations of origin and protected geographical indications ('Keleméri bányánhús' (PGI))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Hungary's application to register the name 'Keleméri bányánhús' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Keleméri bányánhús' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Keleméri bányánhús' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.1. Fresh meat (and offal), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 December 2022.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 315, 19.8.2022, p. 21.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION REGULATION (EU) 2022/2501**of 14 December 2022****establishing a fisheries closure for giant red shrimp in GFCM geographical subareas 8, 9, 10 and 11 for vessels flying the flag of Italy and having an overall length equal or superior to 18 meters and inferior to 24 meters**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, and in particular Article 36(2) thereof,

Whereas:

- (1) Council Regulation (EU) 2022/110 ⁽²⁾ lays down fishing opportunities for 2022.
- (2) According to the information received by the Commission, the maximum allowable fishing effort related to giant red shrimp in the General Fisheries Commission for the Mediterranean (GFCM) geographical subareas 8, 9, 10 and 11 and applicable to vessels flying the flag of or registered in Italy having an overall length equal or superior to 18 meters and inferior to 24 meters, is deemed to have been reached for 2022.
- (3) It is therefore necessary to prohibit certain fishing activities for that stock group.

HAS ADOPTED THIS REGULATION:

*Article 1***Effort exhaustion**

The maximum allowable fishing effort allocated to Italy for the stock group of giant red shrimp in GFCM geographical subareas 8, 9, 10 and 11 for 2022 referred to in the Annex shall be deemed to be reached from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing activities for the stock group referred to in Article 1 by vessels flying the flag of or registered in Italy and having an overall length equal or superior to 18 meters and inferior to 24 meters shall be prohibited from the date set out in the Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ Council Regulation (EU) 2022/110 of 27 January 2022 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Mediterranean and Black Seas (OJ L 21, 31.1.2022, p. 165).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2022.

*For the Commission,
On behalf of the President,
Virginijus SINKEVIČIUS
Member of the Commission*

ANNEX

No	13/TQ110
Member State	Italy
Fishing effort group code	EFF2/MED2_TR3
Stock group	Giant red shrimp in GSAs 8, 9, 10 and 11
Overall length of vessels concerned	≥ 18 m and < 24 m
Closing date	1.10.2022

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2502**of 19 December 2022****correcting the French language version of Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular Article 31 thereof,

Whereas:

- (1) The French language version of Commission Regulation (EU) No 965/2012 ⁽²⁾ contains errors in subpart D, section 2, point CAT.IDE.H.320, point b), the introductory phrase, of annex IV (part CAT); subpart K, point SPA.HOFO.110, point b), point 9), of annex V (part SPA); subpart D, section 2, point NCC.IDE.H.235, of annex VI (part NCC); subpart D, point NCO.IDE.H.185, point c), of annex VII (part NCO); subpart D, section 2, point SPO.IDE.H.203, point c), of annex VIII (part SPO) that alter the meaning of the provisions.
- (2) The French language version of Regulation (EU) No 965/2012 should therefore be corrected accordingly. The other language versions are not affected.
- (3) The measures provided for in this Implementing Regulation are in accordance with the opinion of the Committee for the application of common safety rules in the field of civil aviation,

HAS ADOPTED THIS REGULATION:

Article 1

(Does not concern the English language.)

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2503**of 19 December 2022****amending and correcting Implementing Regulation (EU) 2019/627 as regards practical arrangements for the performance of official controls in live bivalve molluscs, fishery products, or related to UV-radiation****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 18(8) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption.
- (2) Commission Implementing Regulation (EU) 2019/627 ⁽²⁾ lays down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625.
- (3) Article 10 of Implementing Regulation (EU) 2019/627 lays down obligations for the official veterinarian as regards checks of documents, in particular to take into account official certificates provided for in Commission Implementing Regulation (EU) 2019/628 ⁽³⁾. However, reference is made to the wrong certificate, and that reference should therefore be corrected. Since Implementing Regulation (EU) 2019/628 has been repealed and the certificates replaced by those in Commission Implementing Regulation (EU) 2020/2235 ⁽⁴⁾, it is also appropriate to replace all references to Implementing Regulation (EU) 2019/628 by the correct references in Implementing Regulation (EU) 2020/2235.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

⁽³⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

- (4) Article 45, point (l), of Implementing Regulation (EU) 2019/627 lays down that fresh meat is to be declared unfit for human consumption if it has been treated illegally with ionising radiation, including UV-radiation. Most UV-radiation is not to be considered as ionising radiation as defined in Article 4, point (46), of Council Directive 2013/59/Euratom ⁽⁵⁾, Article 45, point (l), of Implementing Regulation (EU) 2019/627 should therefore be amended.
- (5) The specific requirements for official controls concerning live bivalve molluscs from classified production areas and relaying areas do not apply to live *Holothuroidea* that are not filter feeders, in accordance with Article 51 of Implementing Regulation (EU) 2019/627.
- (6) Regulation (EU) 2021/1756 of the European Parliament and of the Council ⁽⁶⁾ amended Article 18 of Regulation (EU) 2017/625, extending to all echinoderms which are not filter feeders, and not only to *Holothuroidea*, the possibility to derogate from the requirement to classify the production and relaying areas, laid down in Article 18(7), point (g), of Regulation (EU) 2017/625. In addition, based on Article 18(7)(g) of Regulation (EU) 2017/625, Commission Delegated Regulation (EU) 2022/2258 ⁽⁷⁾ amended Article 11 of Delegated Regulation (EU) 2019/624 ⁽⁸⁾, whereby the classification of production and relaying areas is not required in relation to the harvesting of echinoderms which are not filter feeders. Consequently, Article 51 of Implementing Regulation (EU) 2019/627 should be amended accordingly.
- (7) Article 71 of Implementing Regulation (EU) 2019/627 lays down rules concerning the decisions that the competent authorities can take after controls on fishery products. Point (a) of that Article mistakenly refers to Section VII instead of Section VIII on fishery products of Annex III to Regulation (EC) No 853/2004. For reasons of consistency, that reference in Article 71 of Implementing Regulation (EU) 2019/627 should be corrected.
- (8) Annex VI to Implementing Regulation (EU) 2019/627 establishes practical arrangements for official controls on fishery products in accordance with Article 70 of that Implementing Regulation. In particular, it defines the analytical methods to be applied when the organoleptic examination gives rise to any doubt as to the freshness of the fishery products. In its scientific opinion ⁽⁹⁾, EFSA identified methods capable of distinguishing between 'superchilled' fish and previously frozen fish commercially presented as 'superchilled'. As those analytical methods should be added to Annex VI to Implementing Regulation (EU) 2019/627, that Annex should be amended.
- (9) Implementing Regulation (EU) 2019/627 should therefore be amended and corrected accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁵⁾ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

⁽⁶⁾ Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs (OJ L 357, 8.10.2021, p. 27).

⁽⁷⁾ Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022 amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs (OJ L 299, 18.11.2022, p. 5).

⁽⁸⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

⁽⁹⁾ EFSA Journal 2021;19(1):6378.

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2019/627 is amended as follows:

(1) in Article 10:

‘(a) in paragraph 2, ‘in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628 (*)’ is replaced by ‘in accordance with Article 31 of Commission Implementing Regulation (EU) 2020/2235 (*)’

(*) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1);

(b) in paragraph 3, ‘in accordance with Article 29 of Commission Implementing Regulation (EU) 2019/628’ is replaced by ‘in accordance with Article 32 of Implementing Regulation (EU) 2020/2235’;

(2) in Article 45, point (l) is replaced by the following:

‘(l) has been treated illegally with ionising radiation or UV-radiation;’

(3) Article 51 is replaced by the following:

‘Article 51

Exclusion

This Title applies to live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods. This Title does not apply to non-filter feeder live marine gastropods and to non-filter feeder live echinoderms.’;

(4) in Article 71, point (a) is replaced by the following:

‘(a) official controls carried out in accordance with Article 70 reveal they are not in compliance with organoleptic, chemical, physical or microbiological requirements or requirements for parasites as established in Section VIII of Annex III to Regulation (EC) No 853/2004 or Regulation (EC) No 2073/2005;’;

(5) in Article 72, point 1, ‘the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628.’ is replaced by ‘the model health certificate set out in Chapter 29 to Annex III to Implementing Regulation (EU) 2020/2235.’;

(6) in Annex VI, in Chapter I, in point B, ‘Freshness indicators’, the following paragraph is inserted between the first and the second paragraphs:

‘When the organoleptic examination gives rise to any doubt that previously frozen fish is commercially presented as fresh, samples may be taken for verification purposes and subjected to laboratory tests such as the Hydroxyacyl-coenzyme A dehydrogenase (HADH) test, histology, ultraviolet–visible–near–infrared (UV-VIS/NIR) spectroscopy and hyperspectral imaging.’.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2504**of 19 December 2022****amending Annexes III and V to Implementing Regulation (EU) 2020/2235 as regards model animal health/official certificates and official certificates for the entry into the Union of consignments of certain fishery products and highly refined products of animal origin, and model private attestation for entering certain composite products into the Union****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on laying specific hygiene rules for food of animal origin ⁽¹⁾, and in particular Article 7(2), point (a), thereof,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽²⁾, and in particular Articles 238(3) and 239(3) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽³⁾, and in particular Article 90, first paragraph, points (a) and (b), and Article 126(3) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/2235 ⁽⁴⁾ lays down rules regarding, inter alia, official certificates provided for in Regulation (EU) 2017/625 required for the entry into the Union of certain consignments of products of animals origin. In particular, Annex III to Implementing Regulation (EU) 2020/2235 lays down, inter alia, model animal health/official certificates and official certificates for the entry into the Union of consignments of certain fishery products and highly refined products of animal origin.
- (2) Chapters 30 and 31 of Annex III to Implementing Regulation (EU) 2020/2235 set out, respectively, the model official certificate for the entry into the Union of fishery products or fishery products derived from bivalve molluscs intended for human consumption entering the Union directly from a reefer, freezer or factory vessel flying the flag of a third country as provided for in Article 11(3) of Commission Delegated Regulation (EU) 2019/625 ⁽⁵⁾ (model FISH/MOL-CAP) and the model animal health/official certificate for the entry into the Union of live bivalve molluscs, echinoderms, tunicates, marine gastropods and products of animal origin from those animals intended

⁽¹⁾ OJ L 139, 30.4.2004, p. 55.

⁽²⁾ OJ L 84, 31.3.2016, p. 1.

⁽³⁾ OJ L 95, 7.4.2017, p. 1.

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

⁽⁵⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

for human consumption (model MOL-HC). Commission Delegated Regulation (EU) 2022/2258 ⁽⁶⁾ amended Article 11 of Delegated Regulation (EU) 2019/624 ⁽⁷⁾, whereby the classification of production and relaying areas is not required in relation to the harvesting of echinoderms which are not filter feeders. The model official certificate and the model animal health/official certificate for the entry into the Union of such fishery products should therefore be amended accordingly.

- (3) Chapter 46 of Annex III to Implementing Regulation (EU) 2020/2235 sets out the model official certificate for the entry into the Union of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption (model HRP). Delegated Regulation (EU) 2022/2258 amended Regulation (EC) No 853/2004, adding fat derivatives and food flavourings that are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽⁸⁾, subject to treatments excluding any public or animal health risk, as highly refined products. The model official certificate for the entry into the Union of such highly refined products should be amended accordingly.
- (4) Annex III to Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.
- (5) The model private attestation set out in Annex V to Implementing Regulation (EU) 2020/2235 for operators entering shelf-stable composite products into the Union should also be updated to facilitate filling out of the document, reflecting the experience gained, adding explanations and notes in order to facilitate provision of the information by importing food business operators. Gelatine, collagen and certain highly refined products can be imported without submitting a residue monitoring plan and, consequently, it should not be necessary that countries are listed in the Annex to Commission Decision 2011/163/EU ⁽⁹⁾ to be allowed to export these products to the Union or to use these products as ingredients in composite products for export to the Union, although listing in accordance with Articles 18, 19 or 22 of Commission Implementing Regulation (EU) 2021/405 ⁽¹⁰⁾ remains mandatory. Therefore, the private attestation set out in Annex V to Implementing Regulation (EU) 2020/2235 should be replaced by an updated version.
- (6) Annex V to Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.
- (7) Implementing Regulation (EU) 2020/2235 should therefore be amended accordingly.
- (8) In order to avoid any disruption to trade as regards the entry into the Union of consignments of certain fishery products, highly refined products of animal origin, and shelf-stable composite products, certificate/attestation issued in accordance with Implementing Regulation (EU) 2020/2235, issued prior to the amendments made by this Regulation, should continue to be authorised during a transitional period provided that such certificate/attestation was issued no later than 15 April 2023.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022 amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs (OJ L 299, 18.11.2022, p. 5).

⁽⁷⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

⁽⁸⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

⁽⁹⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes III and V to Implementing Regulation (EU) 2020/2235 are amended in accordance with the Annex to this Regulation.

Article 2

1. For a transitional period until 15 July 2023, consignments of certain fishery products and highly refined products of animal origin accompanied by the relevant model animal health/official certificates or official certificates issued in accordance with the models set out in Chapters 30, 31 and 46 of Annex III to Implementing Regulation (EU) 2020/2235 as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for the entry into the Union, provided that such certificate was issued no later than 15 April 2023.

2. For a transitional period until 15 July 2023, consignments of shelf-stable composite products accompanied by the private attestation issued in accordance with the model set out in Annex V to Implementing Regulation (EU) 2020/2235 as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for the entry into the Union, provided that such attestation was issued no later than 15 April 2023.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes III and V to Implementing Regulation (EU) 2020/2235 are amended as follows:

(1) Annex III is amended as follows:

- (a) in the introductory table setting out the list of the model animal health/official certificates and model official certificates for the entry into the Union contained in that Annex, the Section concerning the model official certificate for highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption, is replaced by the following:

‘highly refined products as described in Annex III, Section XVI of Regulation (EC) No 853/2004, intended for human consumption

HRP	Chapter 46: Model official certificate for the entry into the Union of highly refined products as described in Annex III, Section XVI of Regulation (EC) N° 853/2004, intended for human consumption’
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(b) Chapters 30 and 31 are replaced by the following:

'CHAPTER 30

MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF FISHERY PRODUCTS OR FISHERY PRODUCTS DERIVED FROM BIVALVE MOLLUSCS INTENDED FOR HUMAN CONSUMPTION ENTERING THE UNION DIRECTLY FROM A REEFER, FREEZER OR FACTORY VESSEL FLYING THE FLAG OF A THIRD COUNTRY AS PROVIDED FOR IN ARTICLE 11(3) OF DELEGATED REGULATION (EU) 2019/625 (MODEL FISH/MOL-CAP)

COUNTRY		Official certificate to the EU	
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference
		I.3 Central Competent Authority	QR CODE
		I.4 Local Competent Authority	
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code	
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code	
	I.8 Region of origin Code	I.10 Region of destination Code	
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code	
		I.13	
		I.14 Date and time of departure	
	I.15	I.16 Entry Border Control Post	
I.17 Accompanying documents Type Code Country ISO country code Commercial document reference			
I.18			
I.19			
I.20	Certified as or for		
☐ Products for human consumption ☐ Canning industry ☐ Further processing			
I.21	I.22 ☐ For internal market		
	I.23		
I.24	Total number of packages	I.25	Total quantity
		I.26	Total net weight/gross weight (kg)
I.27 Description of consignment			
CN code	Species	☐ Final consumer	Number of packages
	Date of collection/production		Net weight
			Batch No
			Type of packaging
			Treatment type
			Identification mark

COUNTRY		Certificate model FISH/MOL-CAP	
Part II: Certification	II. Health information	II.a Certificate reference	II.b IMSOC reference
	II.1 Public health attestation		
	I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council ^(A), Regulation (EC) No 852/2004 of the European Parliament and of the Council ^(B), Regulation (EC) No 853/2004 of the European Parliament and of the Council ^(C) and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ^(D) and hereby certify that the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods described in Part I: (a) were produced in accordance with these requirements, in particular that the vessel appears on the list of vessels from which imports to the Union are permitted (being 'EU-listed'); (b) the vessel applies general hygiene requirements, implements a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and is listed as a Union approved establishment; (c) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been caught and handled on board vessels, landed, handled and, where appropriate, prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV, of Annex III, to Regulation (EC) No 853/2004. Viscera and parts that may pose a danger to public health have been removed as quickly as possible and kept apart from products intended for human consumption; (d) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods satisfy the health standards laid down in Section VIII, Chapter V, of Annex III, to Regulation (EC) No 853/2004 [satisfy the health standards laid down in Section VII, Chapter V, of Annex III to Regulation (EC) No 853/2004] (delete as appropriate) and, where appropriate, the criteria laid down in Commission Regulation (EC) No 2073/2005 ^(E); (e) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII, of Annex III to Regulation (EC) No 853/2004; (f) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004; (g) in the case of Pectinidae, marine gastropods and echinoderms that are not filter feeders harvested outside classified production areas, these comply with the specific requirements laid down in Section VII, Chapter IX, of Annex III to Regulation (EC) No 853/2004;		

^(A) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

^(B) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

^(C) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

^(D) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

^(E) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

COUNTRY		Certificate model FISH/MOL-CAP	
II. Health information	II.a	Certificate reference	II.b IMSOC reference
(h) the fishery products fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Article 29 of Council Directive 96/23/EC ^(f), and the concerned animals and products are listed in Commission Decision 2011/163/EU ^(g) for the concerned country of origin; (i) the fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been produced under conditions guaranteeing compliance with the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ^(h); and (j) frozen fishery products or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods have been kept at a temperature of not more than -18°C in all parts of the product. Whole fish initially frozen in brine intended for the production of canned food may be kept at a temperature of not more than -9°C. Notes In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this official certificate include the United Kingdom in respect of Northern Ireland. This official certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235. Part I: Box reference I.2: A unique document number according to your own classification. Box reference I.5: The name and address (street, town and post code) of the physical or legal person to whom the consignment is imported directly to in the Member State of destination. Box reference I.7: The country whose flag is being flown by the vessel issuing this document. Box reference I.11: The name of the vessel and approval number as listed in accordance with Article 10 of Commission Delegated Regulation (EU) 2019/625 ⁽ⁱ⁾ from which the fishery products are directly imported. Box reference I.20: Tick "<i>Canning industry</i>" for whole fish initially frozen in brine at -9°C or at a temperature higher than -18°C and intended for canning in accordance with the requirements of Section VIII, Chapter I, point II(7), of Annex III to Regulation (EC) No 853/2004. Tick "<i>Products for human consumption</i>" or "<i>Further processing</i>" for the other cases. Box reference I.27: Insert the appropriate Harmonised System (HS) code(s) using one or more of the following headings: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0511, 1504, 1516, 1518, 1603, 1604, 1605 or 2106. Box reference I.27: Description of consignment: "<i>Treatment type</i>": specify whether chilled, frozen or processed.			

^(f) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

^(g) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

^(h) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽ⁱ⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

Captain of the vessel

Name (in capital letters):

Date:

Stamp:

Signature:

CHAPTER 31

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY IN THE UNION OF LIVE BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES, MARINE GASTROPODS AND PRODUCTS OF ANIMAL ORIGIN FROM THESE ANIMALS INTENDED FOR HUMAN CONSUMPTION (MODEL MOL-HC)

COUNTRY		Animal health/Official certificate to the EU	
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference
		I.3 Central Competent Authority	QR CODE
		I.4 Local Competent Authority	
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code	
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code	
	I.8 Region of origin Code	I.10 Region of destination Code	
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code	
	I.13 Place of loading	I.14 Date and time of departure	
	I.15 Means of transport ☐ Aircraft ☐ Vessel ☐ Railway ☐ Road vehicle Identification	I.16 Entry Border Control Post	
		I.17 Accompanying documents Type Code Country ISO country code Commercial document reference	
I.18 Transport conditions	☐ Ambient	☐ Chilled	☐ Frozen
I.19 Container number/Seal number Container No Seal No			

I.20 Certified as or for					
☐ Products for human consumption		☐ Live aquatic animals for human consumption		☐ Dispatch centre	
				☐ Further processing	
I.21 ☐ For transit			I.22 ☐ For internal market		
Third country			ISO country code		
I.23					
I.24 Total number of packages		I.25 Total quantity		I.26 Total net weight/gross weight (kg)	
I.27 Description of consignment					
CN code	Species	Cold store	Identification mark	Type of packaging	Net weight
		Treatment type	Nature of commodity	Number of packages	Batch No
☐ Final consumer		Date of collection/production	Manufacturing plant		

COUNTRY		Certificate model MOL-HC	
	II. Health information	II.a Certificate reference	II.b IMSOC reference
	II.1. ⁽⁴⁾Public health attestation [To be deleted when the Union is not the final destination of the live bivalve molluscs, echinoderms, tunicates, marine gastropods and products of animal origin from these animals] I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽¹⁾, Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽²⁾, Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾ and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ⁽⁴⁾ and hereby certify that the ⁽⁴⁾[live bivalve molluscs] ⁽⁴⁾[live echinoderms] ⁽⁴⁾[live tunicates] ⁽⁴⁾[live marine gastropods] ⁽⁴⁾[products of animal origin derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods] described in Part I were produced in accordance with these requirements, and in particular that they: (a) have been obtained in a region/regions or a country/countries which, at the date of issue of this animal health/official certificate is/are authorised for the entry into the Union of ⁽⁴⁾[live bivalve molluscs] ⁽⁴⁾[live echinoderms] ⁽⁴⁾[live tunicates] ⁽⁴⁾[live marine gastropods] ⁽⁴⁾[products of animal origin derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods], and listed in Annex VIII to Commission Implementing Regulation (EU) 2021/405 ⁽⁵⁾; (b) come from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and being listed as a Union approved establishment; (c) have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II, of Annex III to Regulation (EC) No 853/2004; (d) ⁽⁴⁾[were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV, of Annex III to Regulation (EC) No 853/2004]; (e) ⁽⁴⁾[were prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters III and IV, of Annex III to Regulation (EC) No 853/2004]; (f) satisfy the health standards laid down in Section VII, Chapter V, of Annex III to Regulation (EC) No 853/2004, ⁽⁴⁾[Section VIII, Chapter V, of Annex III to Regulation (EC) No 853/2004] and the criteria laid down in Commission Regulation (EC) No 2073/2005 ⁽⁶⁾; (g) have been packaged, stored and transported in compliance with ⁽⁴⁾[Section VII, Chapters VI and VIII, of Annex III to Regulation (EC) No 853/2004] ⁽⁴⁾[Section VIII, Chapters VI, VII and VIII, of Annex III to Regulation (EC) No 853/2004]; (h) have been marked and labelled in accordance with ⁽⁴⁾[Section I of Annex II and Section VII, Chapter VII, of Annex III to Regulation (EC) No 853/2004] ⁽⁴⁾[Section I of Annex II to Regulation (EC) No 853/2004];		

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽²⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽³⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

⁽⁴⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

⁽⁶⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

- (i) in the case of Pectinidae, marine gastropods and echinoderms that are not filter feeders harvested outside classified production areas, these comply with the specific requirements laid down in Section VII, Chapter IX, of Annex III to Regulation (EC) No 853/2004;
- (j) come from a production area classified in accordance with Article 52 of Commission Implementing Regulation (EU) 2019/627 ⁽⁶⁾ as [A] [B] or [C] at the moment of their harvesting (*please indicate the classification of the production area at the moment of harvesting*) (except for Pectinidae, marine gastropods and echinoderms that are not filter feeders, which are harvested outside classified production areas);
- (k) have satisfactorily undergone the official controls laid down in ⁽⁴⁾[Articles 51 to 66 of Implementing Regulation (EU) 2019/627 or in Article 11 of Commission Delegated Regulation (EU) 2019/624 ⁽⁹⁾] ⁽⁴⁾ [Articles 69, 70 and 71 of Implementing Regulation (EU) 2019/627];
- (l) fulfil the guarantees covering live animals and products thereof, if of aquaculture origin, provided by the residue plans submitted in accordance with Article 29 of Council Directive 96/23/EC ⁽⁸⁾, and the concerned animals and products are listed in Commission Decision 2011/163/EU ⁽⁵⁾ for the concerned country of origin;
- (m) have been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁷⁾, and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ⁽¹⁰⁾.

⁽²⁾II.2. Animal health attestation for live bivalve molluscs of ⁽³⁾listed species intended for human consumption and products of animal origin from those molluscs which are intended for further processing in the Union before human consumption, excluding wild molluscs and their products landed from fishing vessels

I, the undersigned official veterinarian, hereby certify that:

II.2.1. According to official information, the ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾ [products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] meet the following animal health requirements:

II.2.1.1. they originate from ⁽⁴⁾[an establishment] ⁽⁴⁾[a habitat] which is not subject to national restriction measures for animal health reasons or because of the occurrence of abnormal mortalities with an undetermined cause, including the relevant listed diseases referred to in Annex I to Commission Delegated Regulation (EU) 2020/692 ⁽⁴⁾ and emerging diseases;

⁽⁶⁾ Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

⁽⁹⁾ Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

⁽⁸⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽⁵⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

⁽⁷⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽¹⁰⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

II.2.1.2. the ⁽⁴⁾[aquatic animals are not intended to be killed] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals, have been obtained from animals which were not intended to be killed] under a national programme for the eradication of diseases, including the relevant listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 and emerging diseases.

⁽⁴⁾[II.2.2. The ⁽⁴⁾[aquaculture animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquaculture animals other than live aquaculture animals referred to in Box I.27 of Part I, have been obtained from animals which] meet the following requirements:

II.2.2.1. they come from an aquaculture establishment which is ⁽⁴⁾[registered] ⁽⁴⁾[approved] by, and under the control of, the competent authority of the third country or territory of origin and which has a system in place to maintain and to keep for a period of at least 3 years, up-to-date records containing information regarding:

- (i) the species, categories and number of aquaculture animals on the establishment;
- (ii) the movements of aquatic animals into, and aquaculture animals out of, the establishment;
- (iii) the mortality in the establishment;

II.2.2.2. they come from an aquaculture establishment which receives regular animal health visits from a veterinarian for the purpose of the detection of, and information on, signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 and of emerging diseases, at a frequency that is proportionate to the risk posed by the establishment.]

II.2.3. General animal health requirements

The ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I have been obtained from animals which] meet the following animal health requirements:

⁽⁴⁾[II.2.3.1. they are subject to the requirements referred to in Part II.2.4, and originate from a ⁽⁴⁾[country] ⁽⁴⁾[territory] ⁽⁴⁾[zone] ⁽⁴⁾[compartment] with ⁽⁵⁾code: __ __ - __ which, at the date of issue of this animal health/official certificate, is listed in Part 1 of Annex XXI to Commission Implementing Regulation (EU) 2021/404 ^(w) for the entry into the Union of those ⁽⁴⁾[aquatic animals] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals];]

⁽⁴⁾[II.2.3.2. they are aquatic animals that have undergone clinical inspection by an official veterinarian within a period of 72 hours prior to the time of loading for dispatch to the Union. During the inspection, the animals showed no clinical symptoms of transmissible disease and, according to the relevant records of the establishment, there was no indication of disease problems;]

II.2.3.3. they are aquatic animals which are dispatched directly from the place of origin to the Union;

II.2.3.4. they have not been in contact with aquatic animals of a lower health status.

^(w) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

either⁽⁴⁾⁽⁶⁾ [II.2.4.

Specific health requirements

⁽⁴⁾ [II.2.4.1.

Requirements for ⁽³⁾listed species for infection with *Mikrocytos mackini* or infection with *Perkinsus marinus*

The ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a ⁽⁴⁾[country] ⁽⁴⁾[territory] ⁽⁴⁾[zone] ⁽⁴⁾[compartment] declared free from ⁽⁴⁾[Infection with *Mikrocytos mackini*] ⁽⁴⁾[Infection with *Perkinsus marinus*] in accordance with conditions which are at least as stringent as those laid down in Article 66 or in Article 73(1) and Article 73(2), point (a), of Commission Delegated Regulation (EU) 2020/689 ^(N) and in the case of aquatic animals, all ⁽³⁾listed species for the relevant disease(s) are:

- (i) introduced from another country, territory, zone or compartment which has been declared free from the same disease(s);
- (ii) not vaccinated against ⁽⁴⁾[that] ⁽⁴⁾[those] disease(s).]

⁽⁴⁾⁽⁷⁾ [II.2.4.2.

Requirements for ⁽³⁾listed species for infection with *Marteilia refringens*, infection with *Bonamia exitiosa* or infection with *Bonamia ostreae*

The ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a ⁽⁴⁾[country] ⁽⁴⁾[territory] ⁽⁴⁾[zone,] ⁽⁴⁾[compartment] declared free from ⁽⁴⁾[infection with *Marteilia refringens*] ⁽⁴⁾[infection with *Bonamia exitiosa*] ⁽⁴⁾[infection with *Bonamia ostreae*] in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689 and in the case of aquatic animals, all ⁽³⁾listed species for the relevant disease(s) are:

- introduced from another country, territory, zone or compartment which has been declared free from the same disease(s);
- not vaccinated against ⁽⁴⁾[that] ⁽⁴⁾[those] disease(s).]

⁽⁴⁾⁽⁸⁾ [II.2.4.3.

Requirements for ⁽⁹⁾species susceptible to infection with *Ostreid herpes virus 1 μvar* (*OsHV-1 μvar*)

The ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from a ⁽⁴⁾[country] ⁽⁴⁾[territory] ⁽⁴⁾[zone] ⁽⁴⁾[compartment] which fulfils the health guarantees as regards *OsHV-1 μvar* which are necessary to comply with the national measures which apply in the Member State of destination in accordance with Article 175 of Delegated Regulation (EU) 2020/692, and for which the Member State or part thereof, is listed in ⁽⁴⁾[Annex I] ⁽⁴⁾[Annex II] to Commission Implementing Decision (EU) 2021/260 ^(Y).]

or ⁽⁴⁾⁽⁶⁾ [II.2.4.

Specific health requirements

The ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] are destined for a disease control aquatic food establishment within the Union which is approved in accordance with Article 11 of Commission Delegated Regulation (EU) 2020/691 ^(Z), where they are to be processed for human consumption.]

^(N) Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

^(Y) Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission decision 2010/221/EU (OJ L 59, 19.2. 2021, p. 1).

^(Z) Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals (OJ L 174, 3.6.2020, p. 345).

- II.2.5. To the best of my knowledge, and as declared by the operator, the ⁽⁴⁾[aquatic animals referred to in Box I.27 of Part I] ⁽⁴⁾[products of animal origin from aquatic animals other than live aquatic animals referred to in Box I.27 of Part I, have been obtained from animals which] originate from ⁽⁴⁾[an establishment] ⁽⁴⁾[a habitat] where:
- (i) there were no abnormal mortalities with an undetermined cause; and
 - (ii) the animals have not been in contact with aquatic animals of ⁽³⁾listed species which did not comply with the requirements referred to in point II.2.1.

II.2.6. Transport requirements

Arrangements have been made to transport the aquatic animals referred to in Box I.27 of Part I in accordance with the requirements laid down in Articles 167 and 168 of Delegated Regulation (EU) 2020/692 and specifically that:

- II.2.6.1. when the animals are transported in water, the water is not changed in a third country or territory, zone or compartment which is not listed for entry of the particular species and category of aquatic animals into the Union;
- II.2.6.2. the animals are not transported under conditions that jeopardise their health status, in particular:
 - (i) when the animals are transported in water, it does not alter their health status;
 - (ii) the means of transport and the containers are constructed in such a way that the health status of the aquatic animals is not jeopardised during transportation;
 - (iii) the ⁽⁴⁾[container] ⁽⁴⁾[well-boat] is ⁽⁴⁾[previously unused] ⁽⁴⁾[cleaned and disinfected in accordance with a protocol and with products approved by the competent authority of the ⁽⁴⁾[third country] ⁽⁴⁾[territory] of origin, prior to loading for dispatch to the Union];
- II.2.6.3. from the time of loading at the place of origin until the time of arrival in the Union, the animals in the consignment are not transported in the same water or ⁽⁴⁾[container] ⁽⁴⁾[well-boat] together with aquatic animals which are of a lower health status or which are not intended for entry into the Union;
- II.2.6.4. where a water exchange is necessary in a ⁽⁴⁾[country] ⁽⁴⁾[territory] ⁽⁴⁾[zone] ⁽⁴⁾[compartment] which is listed for entry of the particular species and category of aquatic animals into the Union, it only occurs ⁽⁴⁾[in the case of transport on land, at water exchange points approved by the competent authority of the ⁽⁴⁾[third country] ⁽⁴⁾[territory] where the water exchange takes place] ⁽⁴⁾[in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located en-route from the place of origin to the place of destination in the Union].

II.2.7. Labelling requirements

Arrangements have been made to identify and label the ⁽⁴⁾[means of transport] ⁽⁴⁾[containers] in accordance with Article 169 of Delegated Regulation (EU) 2020/692 and specifically that:

- II.2.7.1. the consignment is identified by ⁽⁴⁾[a legible and visible label on the exterior of the container] ⁽⁴⁾[an entry in the ships manifest when transported by well-boat], which clearly links the consignment to this animal health/official certificate;
- ⁽⁴⁾[II.2.7.2. in the case of live aquatic animals, the legible and visible label referred to in point II.2.7.1 contains:
 - (a) details of the number of containers in the consignment;
 - (b) the name of the species present in each container;

- (c) details of the number of animals in each container for each of the species present;
- (d) the following statement: 'live molluscs intended for human consumption in the European Union';]

⁽⁴⁾[II.2.7.3. in the case of products of animal origin from aquatic animals other than live aquatic animals, the legible and visible label referred to in point II.2.7.1 contains at least the following statement: 'molluscs intended for human consumption after further processing in the European Union'.]

⁽⁴⁾ ⁽¹⁰⁾ **II.2.8. Validity of animal health/official certificate**

This animal health/official certificate shall be valid for the period of 10 days from the date of issue. In the case of transport by waterway/sea of aquatic animals, this period of 10 days may be extended by the duration of the journey by waterway/sea.

Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this animal health/official certificate include the United Kingdom in respect of Northern Ireland.

This animal health/official certificate is intended for entry into the Union of live bi-valve molluscs and products of animal origin from those animals intended for human consumption, including when the Union is not the final destination of such bivalve molluscs and their products.

'Aquatic animals' are animals as defined in Article 4, point (3), of Regulation (EU) 2016/429 of the European Parliament and of the Council ^(AA) 'Aquaculture animals' are aquatic animals which are subject to aquaculture as defined in Article 4, point (7), of Regulation (EU) 2016/429.

'Further processing' means any type of measures and techniques, carried out before the placing on the market for human consumption, affecting anatomical wholeness, such as bleeding, evisceration, heading, slicing and filleting which produce waste or by-products which could cause a risk of disease spread.

All aquatic animals and products of animal origin from aquatic animals other than live aquatic animals, to which Part II.2.4. of this animal health/official certificate applies, must originate from a country/territory/zone/compartment which appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.

Part II.2.4. of the animal health/official certificate **shall not apply to** the following aquatic animals, and they may therefore originate from a country or region thereof which is listed in Annex VIII to Implementing Regulation (EU) 2021/405:

- (a) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are no longer able to survive as living animals if returned to the aquatic environment;
- (b) molluscs which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packages laid down in Regulation (EC) No 853/2004;
- (c) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.

This animal health/official certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.

^(AA) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')(OJ L 84, 31.3.2016, p. 1).

Part I:

Box reference I.8: Region of origin: indicate the production area and its classification at the time of harvest, except for Pectinidae, marine gastropods and echinoderms harvested outside classified production areas.

Part II:

- (1) Part II.1 shall not apply to countries with special public health certification requirements laid down in equivalence agreements or other Union legislation.
- (2) Part II.2. of this animal health/official certificate shall not apply and must be deleted when the consignment consists of: (a) species other than those listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 ^(AB); or (b) wild aquatic animals and products of animal origin from those aquatic animals which are landed from fishing vessels for direct human consumption; or (c) products of animal origin from aquatic animals other than live aquatic animals which are ready for direct human consumption, without undergoing further processing in the Union.
- (3) Species listed in columns 3 and 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882. Species listed in column 4 shall only be regarded as vectors under the conditions set out in Article 171 of Delegated Regulation (EU) 2020/692.
- (4) Keep if appropriate/delete if not applicable. In the case of Part II.2.4.1, deletion is not permitted if the consignment contains listed species for infection with *Mikrocytos mackini* or infection with *Perkinsus marinus*, other than in the circumstances referred to in footnote (6).
- (5) Code of the third country/territory/zone/compartiment as it appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404.
- (6) Parts II.2.3.1, II.2.3.2. and II.2.4 shall not apply and must be deleted if the consignment contains only the following aquatic animals:
- (a) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are no longer able to survive as living animals if returned to the aquatic environment,
 - (b) molluscs which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packages laid down in Regulation (EC) No 853/2004,
 - (c) molluscs which are packaged and labelled for human consumption in accordance with the specific requirements for those animals laid down in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.
- (7) Applicable only when the Member State/zone/compartiment of destination in the Union either has disease-free status for a category C disease as defined in Article 1, point (3), of Implementing Regulation (EU) 2018/1882, or is subject to an optional eradication programme established in accordance with Article 31(2) of Regulation (EU) 2016/429, otherwise delete.

^(AB) Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

(8)	Applicable when the Member State of destination in the Union or part thereof, has approved national measures for a specific disease as listed in Annex I or Annex II to Implementing Decision (EU) 2021/260, otherwise delete.	
(9)	Susceptible species as referred to in the second column of the table in Annex III to Implementing Decision (EU) 2021/260.	
(10)	Shall apply only to the consignments of live aquatic animals.	
(11)	to be signed by: — an official veterinarian when Part II.2 Animal health attestation is not deleted, — a certifying officer or an official veterinarian when Part II.2 Animal health attestation is deleted.	
[Official veterinarian]⁽⁴⁾⁽¹¹⁾ / [Certifying officer]⁽⁴⁾⁽¹¹⁾		
Name (in capital letters)		
Date	Qualification and title	
Stamp	Signature	

;

(c) Chapter 46 is replaced by the following:

‘CHAPTER 46

MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF HIGHLY REFINED PRODUCTS AS DESCRIBED IN ANNEX III, SECTION XVI OF REGULATION (EC) NO 853/2004, INTENDED FOR HUMAN CONSUMPTION (MODEL HRP)

COUNTRY		Official certificate to the EU	
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference
		I.3 Central Competent Authority	QR CODE
		I.4 Local Competent Authority	
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code	
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code	
	I.8 Region of origin Code	I.10 Region of destination Code	
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code	
	I.13 Place of loading	I.14 Date and time of departure	
	I.15 Means of transport ☐ Aircraft ☐ Vessel ☐ Railway ☐ Road vehicle Identification	I.16 Entry Border Control Post	
		I.17 Accompanying documents Type Code Country ISO country code Commercial document reference	
I.18 Transport conditions	☐ Ambient	☐ Chilled	☐ Frozen
I.19 Container number/Seal number Container No Seal No			

I.20 Certified as or for	☐ Products for human consumption		
I.21	I.22 ☐ For internal market		
	I.23		
I.24 Total number of packages	I.25 Total quantity	I.26 Total net weight/gross weight (kg)	
I.27 Description of consignment			
CN code	Species	Cold store	Identification mark
			Type of packaging
			Net weight
			Number of packages
			Batch No
☐ Final consumer	Date of collection/production	Manufacturing plant	

COUNTRY		Model certificate HRP	
II. Health information		II.a Certificate reference	II.b IMSOC reference
Part II: Certification	II.1. Public health attestation I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council ^(AC) , Regulation (EC) No 852/2004 of the European Parliament and of the Council ^(AD) , Regulation (EC) No 853/2004 of the European Parliament and of the Council ^(AE) and Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ^(AF) , and hereby certify that the highly refined products described in Part I were produced in accordance with these requirements, in particular that they:		
	(a) come from (an) establishment(s) that has(ve) been registered and implement(s) a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004 and regularly audited by the competent authority;		
	(b) have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004;		
	(c) comply with the requirements of Annex III, Section XVI, to Regulation (EC) No 853/2004; and		
	(d) ⁽¹⁾ if amino acids, that		
	(i) human hair was not used as a source for their production; and		
	(ii) they comply with Regulation (EC) No 1333/2008 of the European Parliament and of the Council ^(AG) ;		
	(e) ⁽¹⁾ if fat derivatives, that they were submitted to one of the following processes:		
	⁽¹⁾ (i) transesterification or hydrolysis at a temperature of at least 200°C, under corresponding appropriate pressure, for at least 20 minutes; or		
	⁽¹⁾ (ii) saponification with NaOH 12M, in a batch process at 95°C for three hours or in a continuous process at 140°C 2 bars (2 000 hPa) for eight minutes; or		
	⁽¹⁾ (iii) hydrogenation at 160°C at 12 bars (12 000 hPa) for 20 minutes;		
	(f) if food flavourings, that they are authorised in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ^(AH)		
	Notes In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this official certificate include the United Kingdom in respect of Northern Ireland. This official certificate is intended for the entry into the Union of highly refined product as described in Section XVI of Annex III to Regulation (EC) No 853/2004.		

^(AC) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

^(AD) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

^(AE) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

^(AF) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

^(AG) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16)

^(AH) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).

COUNTRY		Model certificate HRP	
II. Health information	II.a	Certificate reference	II.b IMSOC reference
This official certificate shall be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.			
Part I:			
Box reference I.27: Insert the appropriate Harmonised System (HS) code(s) using headings such as 2106, 2906, 2907, 2922, 2930, 2932, 2936, 3503, 3507, or 3913.			
Part II:			
(1) Delete as appropriate.			
Certifying officer			
Date		Qualification and title	
Stamp		Signature	

;

(2) Annex V is replaced by the following:

‘ANNEX V

MODEL PRIVATE ATTESTATION BY THE OPERATOR ENTERING SHELF-STABLE COMPOSITE PRODUCTS INTO THE UNION IN ACCORDANCE WITH ARTICLE 14 OF REGULATION (EU) 2019/625

COUNTRY				
Part I: Description of consignment	I.1 Consignor/Exporter		I.2 Attestation	
	Name		I.2a IMSOC reference	
	Address			
	Country	ISO country code		
	I.5 Consignee/Importer⁽⁷⁾		I.6 Operator responsible for the consignment	
	Name		Name	
	Address		Address	
	Country		Country	
	ISO country code		ISO country code	
	I.7 Country of origin		I.9 Country of destination	
ISO country code		ISO country code		
I.8 Region of origin		I.10 Region of destination		
Code		Code		
I.11 Place of dispatch		I.12 Place of destination		
Name		Name		
Address		Address		
Registration/Approval No		Country		
Country		ISO country code		
I.13 Place of loading		I.14 Date and time of departure		
I.15 Means of transport		I.16 Entry Border Control Post		
☐ Aircraft ☐ Vessel		I.17 Accompanying documents		
☐ Railway ☐ Road vehicle		Type		
Identification		Code		
		Country		
		ISO country code		
		Commercial document reference		
I.18	Transport conditions	☐ Ambient ☐ Chilled.		
I.19 Container number/Seal number				
Container No		Seal No		
I.20	Certified as or for ☐ Products for human consumption			
		I.22 ☐ For internal market		
I.24 Total number of packages		I.26 Total net weight/gross weight (kg)		
I.27 Description of consignment				
CN code		Type of packaging	Net weight	
	Nature of commodity	Number of packages	Batch No	
☐ Final consumer	Manufacturing plant	Date of production		

	II. Health information	II.a Attestation	II.b IMSOC reference
	Part II: Attestation	I, the undersigned, <i>(name, address, and full details of the importer)</i> as representative of the importing food business operators of the consignment of composite products described in Part I declare that the composite products accompanied by this attestation: 1. comply with the applicable requirements referred to in Article 126(2) of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) ^(A); 2. do not need to be stored or transported under controlled temperature, unless the shelf-stable composite product needs to be transported chilled for organoleptic quality reasons; 3. contain no colostrum-based products and no processed meat other than gelatine⁽³⁾, collagen⁽³⁾ or highly refined products⁽³⁾ referred to in Annex III, Section XVI, to Regulation (EC) No 853/2004 of the European Parliament and of the Council ^(A); 4. contain the following list of ingredients of plant origin and of processed products of animal origin⁽¹⁾:; 5. contain processed products of animal origin, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 originating from the following approved establishment(s)⁽²⁾:; 6. contain processed products of animal origin which originate, with the exception of gelatine, collagen, and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, from third countries or regions thereof authorised to export each processed product of animal origin to the Union as listed in Commission Decision 2011/163/EC ^(AK) or from an EU Member State; 7. originate from third countries or regions thereof authorised to export meat products, dairy products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Implementing Regulation (EU) 2021/405 ^(AL) or Commission Implementing Regulation (EU) 2021/404 ^(AM) and included in the list laid down in the Annex to Decision 2011/163/EU for the species/commodity from which the processed products of animal origin contained in the composite products, with the exception of collagen, gelatine and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, are derived; 8. have been produced in an establishment which fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004 of the European Parliament and of the Council ^(AN);	

^(A) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

^(A) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

^(AK) Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

^(AL) Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

^(AM) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

^(AN) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

9. have been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council ^(AO), and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006 ^(AP);
10. contain dairy products⁽³⁾, which:
 - ⁽³⁾⁽⁴⁾ *either* have not undergone a specific risk-mitigating treatment provided for in Annex XXVII to Commission Delegated Regulation (EU) 2020/692 ^(AQ);
 - ⁽³⁾⁽⁵⁾ *or* have undergone a specific risk-mitigating treatment provided for in column A or B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
 - ⁽³⁾⁽⁶⁾ *or* have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in column B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
11. contain egg products, which have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in the table set out in Annex XXVIII to Delegated Regulation (EU) 2020/692⁽³⁾.

Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this attestation include the United Kingdom in respect of Northern Ireland.

Part I:

Box reference I.6: Optional in the case of products exempted from official controls at border control posts.

Box reference I.13: Optional in the case of products exempted from official controls at border control posts.

Box reference I.15: Optional in the case of products exempted from official controls at border control posts.

Box reference I.16: Optional in the case of products exempted from official controls at border control posts.

Box reference I.18: Indicate chilled when the shelf-stable composite product is being transported under controlled temperature for organoleptic quality reasons.

Box reference I.19: Optional in the case of products exempted from official controls at border control posts.

Box reference I.27: If the private attestation covers several composite products, the description of goods in Box I.27 must be presented clearly and separately for each composite product (one line by product).

Description of consignment:

"Type of packaging": Indicate the type of packaging according to the definition given in Recommendation No 21 (9) of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).

"Net weight": Indicate the mass of each composite product covered by the private attestation. Those data are needed to calculate the total net weight in box I.26.

^(AO) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

^(AP) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

^(AQ) Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

	<i>"Manufacturing plant"</i> : Indicate registration number or address of the plant where the final composite product is produced.	
Date		Qualification and title of the importer
Stamp		Signature

⁽¹⁾ Please list the ingredients in descending order of weight. Grouping certain ingredients by dairy products, fishery products, egg products, products of non-animal origin as relevant is allowed.

⁽²⁾ Please introduce the approval number of the establishment(s) having produced the processed products of animal origin contained in the composite product and the third country or territory, or zone thereof, or the EU Member State, where the approved establishment is located, as provided for in Article 4(2) of Regulation (EC) No 853/2004, and indicated by the importing food business operator.

⁽³⁾ Keep as appropriate.

⁽⁴⁾ Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of raw milk and dairy products not subject to a risk-mitigating treatment in accordance with Annex XVII to Implementing Regulation (EU) 2021/404 ^(AR);

and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and dairy products not subject to a risk-mitigating treatment in accordance with Annex XVII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

⁽⁵⁾ Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of dairy products subject to a risk-mitigating treatment in accordance with Annex XVIII to Implementing Regulation (EU) 2021/404;

and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and/or dairy products in accordance with Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

⁽⁶⁾ If:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is not listed for the entry into the Union of raw milk and/or dairy products in Annexes XVII or XVIII to Implementing Regulation (EU) 2021/404;

^(AR) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).

and

- (b) the approved establishment of origin of the dairy product (indicated in point 5 of Part II of the attestation) is located:
 - (i) in a third country or territory, or zone thereof listed for the entry into the Union of raw milk and/or dairy products in accordance with Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or
 - (ii) in the Union.
- ⁽⁷⁾ Importer: Representative of the importing food business operators as laid down in Article 14(1) of Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).'
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DECISIONS

COUNCIL DECISION (EU) 2022/2505

of 8 December 2022

on the position to be taken on behalf of the European Union within the Joint Committee established by the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part, as regards the adoption of the Rules of Procedure of the Joint Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the Article 207(4), first subparagraph, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part ('the Agreement') was concluded by means of Council Decision 97/126/EC ⁽¹⁾, and entered into force on 1 January 1997.
- (2) Article 31(1) of the Agreement establishes a Joint Committee, which is to, inter alia, ensure the proper implementation of the Agreement.
- (3) Article 31(3) of the Agreement provides that the Joint Committee is to adopt its own rules of procedure.
- (4) It is appropriate to establish the position to be taken on the Union's behalf within the Joint Committee with regard to the adoption of its rules of procedure, as those rules of procedure will be binding on the Union.
- (5) The position of the Union within the Joint Committee should therefore be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf within the Joint Committee established by the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part, as regards the adoption of its rules of procedure, shall be to support the adoption of the draft Decision of the Joint Committee attached to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

⁽¹⁾ Council Decision 97/126/EC of 6 December 1996 concerning the conclusion of an agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part (OJ L 53, 22.2.1997, p. 1).

Done at Brussels, 8 December 2022.

For the Council
The President
V. RAKUŠAN

DRAFT

DECISION No .../2023 OF THE EC/FAROE ISLANDS JOINT COMMITTEE
of ...
adopting its Rules of Procedure

THE EC/FAROE ISLANDS JOINT COMMITTEE,

Having regard to the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part ⁽¹⁾, and in particular Article 31(3) thereof,

Whereas:

- (1) Article 31(1) of the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part ('the Agreement') establishes a Joint Committee which is to, inter alia, ensure the proper implementation of the Agreement.
- (2) Article 31(3) of the Agreement provides that the Joint Committee is to adopt its own rules of procedure.
- (3) The rules of procedure as set out in the Annex to this Decision should therefore be adopted in order to regulate the functioning of the Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The Rules of Procedure of the Joint Committee, as set out in the Annex to this Decision, are hereby adopted.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at ...,

For the Joint Committee
The President

⁽¹⁾ OJ L 53, 22. 2.1997, p. 2.

*ANNEX***Rules of procedure of the EC/Faroe Islands Joint Committee established pursuant to Article 31(1) of the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part***Article 1***Role and Name of the Joint Committee**

1. The Committee established pursuant to Article 31(1) of the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part, (hereafter referred to as the 'Agreement') is responsible for all matters referred to in Article 31 of the Agreement.
2. The Committee referred to in paragraph 1 shall be referred to in documents of the Committee, including decisions and recommendations, as EC/Faroe Islands Joint Committee (hereafter referred to as the 'Joint Committee').

*Article 2***Composition and Chairperson**

1. Pursuant to Article 32 of the Agreement, the Joint Committee is composed of representatives of the European Union and the Government of the Faroe Islands at senior official level, or their designees.
2. Each Party shall in turn hold the chairpersonship of the Joint Committee. The Party holding the chairpersonship shall be represented by a senior official who shall be the chairperson of the Joint Committee. The chairperson is deemed to have the authorisation of representing the Party which holds the chairpersonship until the date on which that Party has notified a new chairperson to the other Party.
3. In the application of paragraph 2, the chairpersonship shall transfer from one Party to the other at the beginning of each calendar year and have a duration of one year. The first chairpersonship shall begin on the date of adoption of these Rules of Procedure and end on 31 December of the same year.
4. The Parties shall ensure that the Party which holds the chairpersonship of the Joint Committee is also the Party which organises the annual Joint Committee pursuant to Article 4(1) and (2) of these Rules of Procedure in the year of the chairpersonship.

*Article 3***Secretariat**

1. An official of the European Commission and of the Faroe Islands shall act together as Secretary of the Joint Committee.
2. Each Party shall notify to the other Party the name, position and contact details of the official who is the member of the Secretariat of the Joint Committee for that Party. This official is deemed to continue acting as member of the Secretariat for the Party until the date the Party has notified to the other Party a new member.

*Article 4***Meetings**

1. The Joint Committee shall meet once a year in order to review the general functioning of the Agreement, unless the chairperson and the representative of the other party to the Joint Committee provide otherwise. The Joint Committee shall, in addition, meet whenever special circumstances so require or in urgent cases at the request of either Party.

2. The meetings shall be held at an agreed date and time alternately in Brussels and in Tórshavn, unless the chairperson and the representative of the other party to the Joint Committee decide otherwise.
3. The meetings shall be convened by the chairperson.
4. A meeting may be held in person, by videoconference or by any other means.

Article 5

Delegations

Within a reasonable period of time in advance of a meeting, the official acting as Secretary of the Joint Committee for a Party shall inform the official acting as Secretary of the other Party of the intended composition of the delegations of the European Union and of the Faroe Islands respectively. The lists shall specify the name and function of each member of the delegation.

Article 6

Agenda for the meetings

1. At least 14 days in advance of a meeting, a provisional agenda for each meeting shall be drawn up by the Secretary of the Joint Committee on the basis of a proposal made by the Party hosting the meeting with a deadline for the other Party to provide comments.
2. The agenda shall be adopted by the Joint Committee at the beginning of each meeting. Items not appearing on the provisional agenda may be placed on the agenda by consensus.

Article 7

Invitation of experts

The Parties of the Joint Committee may, by mutual agreement, invite experts (i.e. non-government officials) to attend the meetings of the Joint Committee in order to provide information on specific subjects and only for the parts of the meeting where such specific subjects are discussed.

Article 8

Minutes

1. Draft minutes of each meeting shall be drawn up by the official acting as member of the Secretariat of the Party hosting the meeting, within 15 days from the end of the meeting, unless the chairperson and the representative of the other party to the Joint Committee decide otherwise. The draft minutes shall be transmitted for comments to the member of the Secretariat of the other Party.
2. Where these Rules of Procedure apply to the meetings of sub-committees, the minutes of the sub-committee's meeting shall be made available for any subsequent meetings of the Joint Committee.
3. The minutes shall, as a general rule, summarise each item on the agenda, specifying where applicable:
 - (a) all documents submitted to the Joint Committee;
 - (b) any statement that the representative of the Parties to the Joint Committee requested to be entered in the minutes; and
 - (c) the decisions taken, recommendations made, statements agreed upon and conclusions adopted on specific items.

4. The minutes shall include a list of all decisions of the Joint Committee taken by written procedure, pursuant to Article 9(2), since the last meeting of the Joint Committee.
5. An annex to the minutes shall also include a list of the names, titles and capacity of all individuals who attended the meeting of the Joint Committee.
6. The Secretary shall adjust the draft minutes on the basis of comments received and the draft minutes, as revised, shall be approved by the Parties within 30 days of the date of the meeting, or by any other date agreed by the Parties. Once approved, two originals of the minutes shall be established by the Secretariat, and the Parties shall each receive one original of the minutes.

Article 9

Decisions and recommendations

1. The Joint Committee may adopt decisions and recommendations in respect of all matters where the Agreement so provides. The Joint Committee shall adopt decisions and recommendations by consensus, as provided for in Articles 31(1) and 32(2) of the Agreement.
2. In the period between meetings, the Joint Committee may adopt decisions or recommendations by written procedure.
3. The text of a draft decision or recommendation shall be presented in writing by the member of the Secretariat of the proposing Party to the member of the Secretariat of the other Party in the working language of the Joint Committee. The other Party shall have one month, or any longer period of time specified by the proposing Party, to express its agreement with the draft decision or recommendation. If the other Party does not express its agreement, the proposed decision or recommendation shall be discussed and may be adopted at the next meeting of the Joint Committee. The draft decisions or recommendations shall be deemed to be adopted once the other Party expresses its agreement and shall be recorded in the minutes of the meeting of the Joint Committee pursuant to Article 8(3).
4. Where the Joint Committee is empowered under the Agreement to adopt decisions or recommendations, such acts shall be entitled 'Decision' or 'Recommendation' respectively. The Secretariat of the Joint Committee shall give any decision or recommendation a progressive serial number, the date of adoption and a description of their subject-matter. Each decision and recommendation shall provide for the date of its entry into force.
5. The decisions and recommendations adopted by the Joint Committee shall be established in duplicate, authenticated by the Parties and a version of them transmitted to each Party.

Article 10

Transparency

1. The Parties may agree to meet in public.
2. Each Party may decide on the publication of the decisions and recommendations of the Joint Committee in its respective official publication or online.
3. All documents submitted by a Party should be considered as confidential, unless the chairperson and the representative of the other party to the Joint Committee decide otherwise.
4. Provisional agendas of the meetings shall be made public before the meeting of the Joint Committee takes place. The minutes of the meetings shall be made public following their approval in accordance with Article 8.
5. Publication of the documents referred to in paragraphs 2 to 4 shall be made in compliance with each Party's applicable data protection rules.

*Article 11***Languages**

1. The working language of the Joint Committee shall be English.
2. The Joint Committee shall adopt decisions concerning the amendment or interpretation of the Agreement in the languages of the authentic texts of the Agreement. All other decisions of the Joint Committee, including the one through which these Rules of Procedure are adopted, shall be adopted in the working language referred to in paragraph 1.
3. Each Party shall be responsible for the translation of decisions and other documents into its own official language(s), if required pursuant to this Article, and it shall meet the expenditure associated with such translations.

*Article 12***Expenses**

1. Each Party shall meet any expenses it incurs as a result of participating in the meetings of the Joint Committee, in particular with regard to staff, travel and subsistence expenditure and with regard to video or teleconferences, postal and telecommunications expenditure.
2. Expenditure in connection with the organisation of meetings and reproduction of documents shall be borne by the Party hosting the meeting.
3. Expenditure in connection with the provision of interpretation services to and from the working language of the Joint Committee at meetings shall be borne by the Party hosting the meeting.

*Article 13***Working parties**

1. For the effective performance of its tasks, the Joint Committee may set up under its authority working parties responsible for dealing with specific subjects under the Agreement. To that end, the Joint Committee shall determine the composition and tasks of such working parties.
2. Pursuant to Article 33(3) of the Agreement, the Joint Committee shall supervise the work of all working parties established under the Agreement.
3. The Joint Committee shall be informed in writing of the contact points designated by working parties under the Agreement. All relevant correspondence, documents and communications between the contact points of each working party regarding the implementation of the Agreement shall be forwarded to the Secretariat of the Joint Committee simultaneously.
4. The working parties shall report to the Joint Committee on results and conclusions from each of their meetings.
5. These Rules of Procedure shall apply *mutatis mutandis* to the working parties established under the Agreement.

*Article 14***Amendments to the Rules of Procedure**

These Rules of Procedure may be amended in writing by a decision of the Joint Committee in accordance with Article 9.

COUNCIL IMPLEMENTING DECISION (EU) 2022/2506**of 15 December 2022****on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU, Euratom) 2020/2092 of the European Parliament and of the Council of 16 December 2020 on a general regime of conditionality for the protection of the Union budget ⁽¹⁾, and in particular Article 6(10) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) On 24 November 2021, the Commission sent a request for information to Hungary pursuant to Article 6(4) of Regulation (EU, Euratom) 2020/2092, to which the Hungarian authorities replied on 27 January 2022.
- (2) On 27 April 2022, the Commission sent a written notification to Hungary pursuant to Article 6(1) of Regulation (EU, Euratom) 2020/2092 (the 'notification'). In the notification, the Commission raised its concerns and presented its findings regarding a number of issues related to the public procurement system in Hungary, including:
 - (a) systemic irregularities, deficiencies and weaknesses in public procurement procedures;
 - (b) the high rate of single bidding procedures and the low intensity of competition in procurement procedures;
 - (c) issues related to the use of framework agreements;
 - (d) the detection, prevention and correction of conflicts of interest; and
 - (e) issues related to public interest trusts.
- (3) Those issues and their repetition over time demonstrate a systemic inability, failure or unwillingness, on the part of the Hungarian authorities, to prevent decisions that are in breach of the applicable law, as regards public procurement and conflicts of interest, and thus to adequately tackle risks of corruption. They constitute breaches of the principles of the rule of law, in particular the principles of legal certainty and prohibition of arbitrariness of the executive powers and raise concerns as to the separation of powers.
- (4) In the notification, the Commission set out additional grounds and presented its findings regarding a number of issues related to investigation and prosecution, and the anti-corruption framework, including limitations to the effective investigation and prosecution of alleged criminal activity, the organisation of the prosecution services, and the absence of a functioning and effective anti-corruption framework in practice. Those issues constitute breaches of the principles of the rule of law, in particular regarding legal certainty, the prohibition of arbitrariness of the executive powers and effective judicial protection.
- (5) In the notification, the Commission set out the factual elements and specific grounds on which it based its findings and also requested Hungary to provide certain information and data regarding those factual elements and grounds. In the notification, the Commission gave 2 months to the Hungarian authorities to submit their observations.

⁽¹⁾ OJ L 433 I, 22.12.2020, p. 1.

- (6) On 27 June 2022, Hungary replied to the notification (the 'first reply'). By letters of 30 June and 5 July 2022, Hungary submitted further information to complement the first reply. Moreover, on 19 July 2022, Hungary sent an additional letter proposing a number of remedial measures to address the findings in the notification.
- (7) The Commission assessed the observations submitted in the first reply and concluded that they did not allay its concerns and findings set out in the notification. Furthermore, the Commission considered that neither the first reply nor the additional letters of 30 June and 5 July 2022 contained adequate remedial measures appropriately committed in the context of Regulation (EU, Euratom) 2020/2092. Due to the late submission of the letter of 19 July 2022, it could not be taken into account in the assessment of the first reply. However, the Commission took into consideration all the relevant information in that letter in the course of the next steps of the procedure set out in Article 6 of Regulation (EU, Euratom) 2020/2092, in accordance with the principle of sincere cooperation with Member States.
- (8) In line with Article 6(7) of Regulation (EU, Euratom) 2020/2092, the Commission sent a letter to Hungary on 20 July 2022 (the 'intention letter') to inform the Member State of its assessment pursuant to Article 6(6) of that Regulation, and of the measures that the Commission envisaged to propose for adoption by the Council pursuant to Article 6(9) of that Regulation, in the absence of a commitment from Hungary to take adequate remedial measures. In the intention letter, the Commission gave Hungary the opportunity to submit its observations, in particular on the proportionality of the envisaged measures.
- (9) Hungary replied to the intention letter on 22 August 2022 (the 'second reply'), in which it provided its observations on the Commission's findings, the procedure and the proportionality of the measures referred to in the intention letter. Despite having contested the Commission's findings, Hungary proposed certain remedial measures to address the concerns raised by the Commission. On 13 September 2022, Hungary sent the Commission a letter which included clarifications and further commitments relevant to the remedial measures proposed. In Hungary's view, the remedial measures, including the additional commitments included in the letter of 13 September 2022, fully addressed the Commission's concerns, and the Commission should therefore not have proposed any measures to the Council.
- (10) Considering that the conditions for the application of Regulation (EU, Euratom) 2020/2092 were met, on 18 September 2022 the Commission adopted a proposal for a Council implementing decision on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary (the 'Commission's proposal').
- (11) According to findings set out in the Commission's proposal, there are, firstly, serious systemic irregularities, deficiencies and weaknesses in public procurement procedures in Hungary. Such irregularities have been found following consecutive audits conducted by the Commission services for both the 2007-2013 and the 2014-2020 programming periods. Those audits closed with significant overall amounts of financial corrections, as well as several European Anti-Fraud Office (OLAF) investigations that led to financial recommendations for the recovery of significant amounts from Hungary. In addition, the available data indicate that there were unusually high percentages of contracts awarded following procedures in which just one single bidder participated; the attribution of contracts to specific companies, which have been gradually gaining large market shares; as well as serious deficiencies in the attribution of framework agreements. Moreover, there are concerns regarding the non-application of public procurement and conflict of interest rules to 'public interest trusts' and the entities managed by them, and the lack of transparency with regard to the management of funds by those trusts. Those issues and their recurrence over time demonstrate a systemic inability, failure or unwillingness, on the part of the Hungarian authorities, to prevent decisions that are in breach of the applicable law, as regards public procurement and conflicts of interest, and thus to adequately tackle risks of corruption. They constitute breaches of the principles of the rule of law, in particular the principles of legal certainty and prohibition of arbitrariness of the executive powers and raise concerns as regards the separation of powers.

- (12) Secondly, there are additional issues as regard limitations to the effective investigation and prosecution of alleged criminal activity, the organisation of the prosecution services, and the absence of a functioning and effective anti-corruption framework. In particular, there is a lack of effective judicial remedies by an independent court against decisions of the prosecution service not to investigate or prosecute alleged corruption, fraud and other criminal offences affecting the Union's financial interests, a lack of a requirement to give reasons when such cases are attributed or reassigned, and an absence of rules to prevent arbitrary decisions in their regard. In addition, there is a lack of a comprehensive anti-corruption strategy which covers the most relevant corruption prevention areas; an under-utilisation of the full range of preventive tools to assist the investigation of corruption, in particular high-level corruption cases; as well as an overall lack of effective prevention and repression of criminal fraud and corruption offences. Those issues constitute breaches of the principles of the rule of law, in particular regarding legal certainty, the prohibition of arbitrariness of the executive powers and effective judicial protection.
- (13) According to the Commission, the observations put forward in the replies from Hungary do not adequately address the findings set out in the notification and the intention letter. In particular, the replies provided no evidence following the recent improvements brought about by Hungary in its procurement system (as regards transparency, intensity of competition, conflicts of interests checks). While some changes took place in the Hungarian public procurement system following the Commission services' audits, there are no indications that those changes have had an impact on the level of competition on the Hungarian market. The data available to the Commission shows not only an increase in the concentration of awards in public procurement, but also an increase in the odds of winning for actors of the Hungarian ruling party. The Commission procured a study which provided a statistical empirical analysis of more than 270 000 public procurement contracts in Hungary between 2005 and 2021. The observations of the study were corroborated with findings of an examination of certain tender data regarding contracts awarded to some of the companies identified as companies with political connections. Moreover, reports by media and stakeholders were collected by the Commission in the tourism, communication and sports sectors. Hungary did not provide any evidence on the applicability (nor the application in practice) of conflict of interest rules relevant for the protection of the Union budget in relation to public interest trusts.
- (14) The identified irregularities, deficiencies and weaknesses are widespread and intertwined, which means that procedures other than those provided for by Regulation (EU, Euratom) 2020/2092 cannot address the risks for the Union budget more effectively. Even if certain means available under sectoral rules may be used, such as audits performed by Commission services, and financial corrections for irregularities not corrected by the Hungarian authorities, those measures generally relate to expenditure already declared to the Commission and the continuation of deficiencies over many years shows that financial corrections are not sufficient to protect the Union's financial interest from either current or future risks.
- (15) Concerning the observance and monitoring of the enabling conditions enshrined in Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽²⁾, it should be noted that the only consequence of failure to fulfil an enabling condition set out in Article 15(5) of that Regulation is that the Commission will not reimburse expenditure related to operations linked to the specific objective to the Member State in question. Regulation (EU, Euratom) 2020/2092 grants a broader range of possible measures to protect the Union's budget, including the suspension of approval of one or more programmes, as well as the suspension of commitments under shared management. The possible measures under Regulation (EU, Euratom) 2020/2092 also concern pre-financing, which is not provided for under Article 15 of Regulation (EU) 2021/1060.

⁽²⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

- (16) As regards the application of public procurement rules and their interpretation, recital 17 of Regulation (EU, Euratom) 2020/2092 clarifies that the Union legislation referred to in Article 6(1) of that Regulation is financial and sector-specific. Infringement procedures are not based on a legislative act but directly on Article 258 of the Treaty on the Functioning of the European Union (TFEU). That provision of primary law cannot be considered as 'Union legislation' within the meaning of Article 6(1) of Regulation (EU, Euratom) 2020/2092.
- (17) Article 22(1) of Regulation (EU) 2021/241 of the European Parliament and of the Council ⁽³⁾ provides that Member States are to take all the appropriate measures to protect the financial interests of the Union when implementing measures under the Recovery and Resilience Facility. In order to ensure compliance with Article 22 of that Regulation, the Commission, on 30 November 2022, presented a proposal for an implementing Decision of the Council on the approval of the assessment of the Recovery and Resilience Plan for Hungary, which contains milestones that incorporate the commitments undertaken by Hungary under the remedial measures agreed with the Commission in the framework of this procedure.

The primary responsibility to comply with Union and national law when implementing measures under the Recovery and Resilience Facility remains with the Member States, in accordance with Article 22(1) of Regulation (EU) 2021/241, whereas the Commission, in accordance with Article 22(5) of that Regulation, can proceed to corrective measures in cases of fraud, corruption, and conflicts of interests affecting the financial interests of the Union that have not been corrected by the Member State, or in the case of a serious breach of an obligation resulting from the loan agreement or the financing agreement. Moreover, the milestones are conditions which require to be fulfilled in order for Hungary to be able to submit requests for future payments under the Recovery and Resilience Plan. As such, they are not able to protect the financial interests of the Union in relation to breaches of the principles of the rule of law that already affect or risk affecting the implementation in Hungary of other spending programmes financed by the Union budget in a sufficiently direct way. Therefore, the application of the provisions of Regulation (EU) 2021/241 would not allow the Commission to protect the Union budget more effectively in this case.

- (18) In light of all the foregoing, no other procedure under Union law would allow the Commission to protect the Union budget more effectively than the procedure set out in Article 6 of Regulation (EU, Euratom) 2020/2092.
- (19) The potential impact of the identified breaches on the sound financial management of the Union budget or the protection of the financial interests of the Union is considered to be particularly significant, given that those breaches are intrinsically linked to the process under which Union funds are used by Hungary in that they consist in improper functioning of the public authorities deciding on the award of contracts financed through the Union budget. In addition, if the identified breaches are coupled with the limits and obstacles in the detection, investigation and correction of fraud, identified as additional grounds related to investigation, prosecution and the anti-corruption framework, the impact can be considered even more significant.
- (20) Considering the nature of the findings in relation to public procurement, the appropriate measures to be adopted under Article 4(1) of Regulation (EU, Euratom) 2020/2092 (the 'appropriate measures') should concern Union funding that is mainly implemented through public procurement. The Commission audits that identified deficient and irregular public procurement processes covered the area of cohesion policy, and despite the fact that the impact of those deficiencies and irregularities on the Union budget has been financially corrected in application of the cohesion policy rules, they demonstrate a systemic inability, failure or unwillingness by the Hungarian authorities to prevent decisions that are in breach of the applicable law as regards public procurement and conflicts of interest, and thus to adequately tackle risks of corruption.

⁽³⁾ Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

- (21) The programmes to be protected by the appropriate measures should in priority be the cohesion policy programmes 2021-2027 that are expected to be implemented mainly through public procurement by analogy to the way Hungary implemented the equivalent programmes under the multiannual financial framework 2014-2020. Those programmes are the Environment and Energy Efficiency Operational Programme Plus, the Integrated Transport Operational Programme Plus and the Territorial and Settlement Development Operational Programme Plus (the 'programmes concerned'). As regards the programmes concerned, the level of implementation through public procurement is estimated at 85 % to 90 %.
- (22) The appropriate measures should also concern actions under Union programmes implemented under direct and indirect management, for which public interest trusts and the entities maintained by them, which are considered as government entities within the meaning of Articles 2(b) and 5(1)(a) of Regulation (EU, Euratom) 2020/2092, may be beneficiaries or implementing entities. As regards the identified breaches relevant to public interest trusts, all Union programmes implemented under direct and indirect management should be targeted by the appropriate measures.
- (23) In line with the proportionality requirements set out in Article 5(3) of Regulation (EU, Euratom) 2020/2092, the appropriate level of the measures to be applied should be determined by a percentage that reflects the ensuing risk for the Union budget.
- (24) In light of the seriousness, frequency and duration of the systemic breaches identified in public procurement, the financial risk for the sound financial management of the Union budget can be considered as very significant and therefore, justifies measures with a very high level of financial impact.
- (25) In accordance with Article 6(6) of Regulation (EU, Euratom) 2020/2092, the information received and any observations made by the Member State concerned, as well as the adequacy of any proposed remedial measures, are to be taken into account when deciding on the appropriate measures. Therefore, the remedial measures proposed by Hungary should be included in the assessment.
- (26) In its second reply, Hungary submitted 17 remedial measures, the commitments of which were complemented with a letter submitted to the Commission on 13 September 2022. According to Hungary's opinion, they would address all issues raised by the Commission in the notification. The proposed remedial measures are as follows:
- (a) reinforcing the prevention, detection and correction of illegalities and irregularities concerning the implementation of Union funds through a newly established Integrity Authority;
 - (b) an Anti-Corruption Task Force;
 - (c) strengthening the anti-corruption framework;
 - (d) ensuring the transparency of the use of Union support by public interest asset management foundations;
 - (e) the introduction of a specific procedure in the case of special crimes related to the exercise of public authority or the management of public property;
 - (f) strengthening audit and control mechanisms to guarantee the sound use of Union support;
 - (g) reducing the share of tender procedures with single bids financed from Union funds;
 - (h) reducing the share of tender procedures with single bids financed from the national budget;
 - (i) the development of a single-bid reporting tool to monitor and report on public procurement procedures closed with single-bids;
 - (j) the development of the Electronic Public Procurement System to increase transparency;
 - (k) the development of a performance measurement framework assessing the efficiency and cost effectiveness of public procurements;

- (l) the adoption of an action plan to increase the level of competition in public procurement;
 - (m) training to be provided for micro, small and medium-sized enterprises on public procurement practices;
 - (n) setting up a support scheme for compensating the costs associated with participating in public procurement of micro, small and medium-sized enterprises;
 - (o) the application of ARACHNE, the Commission's risk scoring tool;
 - (p) strengthening the cooperation with OLAF; and
 - (q) the adoption of a legislative act ensuring enhanced transparency of public spending.
- (27) Thirteen of the remedial measures set Key Implementation Steps to be fulfilled by 19 November 2022. Hungary committed to inform the Commission by 19 November 2022, and every 3 months thereafter, about the implementation of the remedial measures, including the additional commitments contained in the letter of 13 September 2022. For four remedial measures, namely remedial measures (h) and (l) to (n), the Commission indicated that there were no immediate Key Implementation Steps, as they require a longer implementation period, and that it shall monitor their implementation as part of its monitoring of all the remedial measures, on the basis of the quarterly reporting to which Hungary committed by its letter of 19 November 2022, until 31 December 2028.
- (28) In general, Hungary committed to take remedial measures proposed in its second reply to address the issues raised in the notification unconditionally and to maintain them and the related legislation in force without any time limit and to enforce duly the rules set out therein.
- (29) As clarified in the explanatory memorandum accompanying the Commission's proposal, the Commission considered that the proposed remedial measures, taken together, would in principle be capable of addressing the issues regarding systemic irregularities, deficiencies and weaknesses in public procurement, risks of conflicts of interest, and concerns regarding public interest trusts, as well as the additional grounds regarding investigation, prosecution and the anti-corruption framework, provided that all the measures are correctly and effectively implemented.
- (30) However, the Commission also added that the detailed implementing rules for the proposed remedial measures were still to be determined, in particular how key elements of the measures would be transposed in the actual legal texts to be adopted for the implementation of the remedial measures. Given that several of the issues identified in Hungary are not only about changes in the legal framework, but more prominently about the concrete implementation of changes in practice, the latter requiring a more extended timeframe to produce concrete results, pending the implementation of at least the key elements of some of the remedial measures at the time of the Commission's proposal, as indicated in the timelines of the remedial measures submitted by Hungary in its second reply, a risk for the Union budget remained. Pending the entry into force of key legislative texts that would implement many of the proposed remedial measures and taking into account the assessment contained in the explanatory memorandum accompanying the Commission's proposal, as well as the possibility that the measures might not be correctly implemented, or that their effectiveness would be weakened in the details of the measures, the Commission estimated that the level of risk for the Union budget corresponded to 65 % of the programme concerned, i.e. 5 percentage points less than the risk estimated in the absence of remedial measures. It therefore proposed that the Council adopt appropriate measures under Article 6(9) of Regulation (EU, Euratom) 2020/2092.
- (31) Taking into account that Hungary had committed to take remedial measures to address the situation in accordance with a detailed calendar, and that the Commission considered that the proposed remedial measures, taken together, if correctly specified and implemented in accordance with that detailed calendar, could in principle be capable of addressing the issues, on 13 October 2022 the Council, following a request from Hungary, decided that exceptional circumstances existed pursuant to Article 6(10) of Regulation (EU, Euratom) 2020/2092 sufficient to justify extending the deadline for the adoption of the implementing decision by 2 additional months, so as to give the Commission and the Council sufficient time to assess the adoption and effective implementation of the remedial measures, bearing in mind their large number and technical complexity.

- (32) In order to meet the deadlines set in the Key Implementation Steps, Hungary proceeded with the adoption of several legislative acts between the end of September 2022 and the beginning of October. Further intense discussions between the Hungarian authorities and the Commission services were necessary to try to ensure that those acts would be fully aligned with the remedial measures and that they would be effective. As a result of those discussions, the Hungarian Government submitted to the National Assembly a so-called 'service package' on 15 November 2022, with a number of proposed amendments to the legal texts that were adopted at the end of September 2022 and the beginning of October.

The service package is composed of two draft bills, one (T/2033) for adoption according to the ordinary procedure, for which the final vote took place on 22 November 2022, and the other draft bill (T/2032) for adoption according to the procedure applicable for cardinal acts (requiring a two-thirds majority), for which the final vote took place on 7 December 2022. The National Assembly adopted both acts. By letters submitted to the Commission on 19 November, 26 November, 6 December and 7 December 2022 Hungary informed the Commission about the actions taken to implement the commitments previously undertaken.

- (33) On 30 November 2022, the Commission published a Communication on the remedial measures notified by Hungary, providing the Council with an assessment of the adequacy of the remedial measures as adopted by Hungary as of 19 November 2022. Following a request made by the Council on 6 December 2022, the Commission, on 9 December 2022, provided an updated assessment on the further measures taken by Hungary up to 7 December 2022. The Commission communication of 30 November 2022 and the updated assessment of 9 December 2022, taken together with the explanatory memorandum accompanying the Commission's proposal, constitute the basis for the Council's deliberations.

(a) **Reinforcing the prevention, detection and correction of illegalities and irregularities concerning the implementation of Union funds through a newly established Integrity Authority**

- (34) Hungary committed to establishing a new Integrity Authority with the objective of reinforcing the prevention, detection and correction of fraud, conflicts of interest and corruption, as well as other illegalities and irregularities in the implementation of any Union financial support. The creation of the Integrity Authority, a new body in the Hungarian context, is a horizontal measure that aims at remedying the systemic breaches of the principles of the rule of law concerning public procurement affecting the Union's financial interests. It is therefore one of the central remedial measures proposed by Hungary to address the concerns raised by the Commission.
- (35) Hungary included in the proposed remedial measure a number of elements which were positively assessed at the time of the Commission's proposal, in particular regarding : (i) the purpose and objectives of the new Integrity authority, (ii) the scope of its mandate and extensive powers, including powers to instruct contracting authorities to suspend tenders, powers to request administrative investigative bodies to carry out investigations, powers to recommend the exclusion of specific economic operators from Union funding; the right to request a judicial review of all decisions of authorities concerning public procurement procedures that involve any Union support (and that may be subject to judicial review) etc.; (iii) the rules on the appointment of the Integrity Authority's board and on the involvement of an 'eligibility committee' aimed at guaranteeing that the Integrity Authority will be fully independent. In addition, Hungary committed that the Integrity Authority will rely on facts established by judicial decisions, it will be able to seize the courts, and its own decisions will be subject to judicial review.

For this reason, Hungary also committed that all courts in Hungary hearing civil, administrative and criminal cases including those relevant for the protection of the financial interests of the Union will comply with the requirements of independence, impartiality and being established by law, in accordance with Article 19(1) of the Treaty on European Union (TEU) and the relevant Union *acquis*. Hungary also undertook to take Key Implementation Steps for the creation of the Integrity Authority by 19 November 2022. Following the submission of the Commission's proposal, Hungary adopted on 4 October 2022 the Act establishing the Integrity Authority (Act XXVII of 2022 on the control of the use of European Union budget funds, the 'Integrity Authority Act'), which entered into force on 11 October 2022. Further amendments to the Integrity Authority Act were introduced as part of the two draft bills

composing the 'service package' submitted to the National Assembly on 15 November 2022 and voted upon on 22 November 2022 and on 7 December 2022. As required in the remedial measure, Hungary consulted the Council of Europe and the OECD in the process leading to the adoption of the Integrity Authority Act, and took into account certain recommendations. In parallel to the legislative procedures, the Hungarian authorities launched on 23 September 2022 a selection and appointment procedure for members of the Eligibility Committee, and then on 14 October 2022, for members of the board of the Integrity Authority, who were finally appointed by 4 November 2022. The Integrity Authority held its first official meeting on 18 November 2022.

- (36) However, as the Commission found in its communication of 30 November 2022 and confirmed on 9 December 2022 after a thorough assessment, the regulatory framework for the Integrity Authority as set out in the Integrity Authority Act does not fulfil certain commitments taken under the remedial measure, which, therefore, cannot be considered fully effective and adequate pursuant to Regulation (EU, Euratom) 2020/2092. The weaknesses, risks and shortcomings of the remedial measure, which compromise the effectiveness and independence of the Integrity Authority and its capacity to address the Commission's findings, are in particular the following: (i) the lack of a clear rule stating that the Integrity Authority will retain its competence after a project is withdrawn from Union financing; (ii) the weaknesses of the system for the judicial review of the decisions of contracting authorities that do not follow the recommendations of the Integrity Authority; (iii) the weaknesses of the dismissal procedure; (iv) the direct, as opposed to the supervisory, powers of the Integrity Authority in relation to the various groups of declarants, and the lack of a transfer of powers to the Integrity Authority to verify the asset declarations of members of the Government; (v) the limited scope related to the lack of inclusion of all 'high-risk officials' in the scope of the Integrity Authority's verification powers in relation to asset declarations. The Council considers that for these reasons as further exposed in the Commission's communication, the weaknesses identified, and in particular the ones constraining the powers of the Integrity Authority, are of such gravity as to seriously undermine the capacity of the Integrity Authority to remedy the systemic breaches of the principles of the rule of law concerning public procurement affecting the Union's financial interests.

(b) Anti-Corruption Task Force

- (37) Hungary committed to the establishment of an Anti-Corruption Task Force with the task of, inter alia, examining the existing anti-corruption measures and elaborating proposals concerning the improvement of prevention, detection, investigation, prosecution and sanctioning of corrupt practices. A key element of the remedial measure concerned the full, structured and effective participation of non-governmental actors active in the field of anti-corruption along with government representatives. Furthermore, Hungary committed to extensive consultations with national and international stakeholders, including the Commission, during the preparation of the draft legislation. Hungary undertook to take Key Implementation Steps in order to set out the regulatory framework for the new Anti-Corruption Task Force by 30 September 2022. In line with the remedial measure, the relevant provisions of the Integrity Authority Act provide that 50 % of the members of the new Anti-Corruption Task Force are to represent non-governmental actors and be selected based on an open, transparent, non-discriminatory selection process with objective criteria related to expertise and merits. Following the submission of the Commission's proposal, Hungary consulted the OECD and the Council of Europe, and provided for the establishment of the new Anti-Corruption Task Force in the framework of the Integrity Authority Act. The new Anti-Corruption Task Force was finally established on 1 December 2022.
- (38) In light of those developments, based on the Commission's assessment, the Council considers that Hungary took the relevant Key Implementation Steps and that the regulatory framework for the new Anti-Corruption Task Force as set out in the Integrity Authority Act fulfils the commitments set out in the remedial measure.

(c) Strengthening the anti-corruption framework

- (39) Hungary undertook to adopt by 30 September 2022 anti-fraud and anti-corruption strategies defining the tasks of entities involved in the implementation of any Union financial support in relation to the prevention, detection and correction of fraud, conflict of interest and corruption. Hungary further committed to extend the personal and material scope of assets declarations as of 1 November 2022. This remedial measure has a horizontal and systemic nature in order to fight against corruption and ensure transparency in the political sphere. It is therefore one of the central remedial measures proposed by Hungary.
- (40) Following the submission of the Commission's proposal, Hungary undertook a number of steps to address the Key Implementation Steps for that remedial measure. On 30 September 2022, Hungary adopted the strategy against fraud and corruption for the 2021-2027 programming period, and for the implementation of the Recovery and Resilience Plan (Government Decision 1470/2022). The strategy was subsequently amended, and a new version was adopted and published on 15 November 2022 (Government Decision 1540/2022). The National Assembly adopted the 'Act on Asset Declarations' (Act XXXI of 2022) on 25 October 2022, which entered into force on 1 November 2022 with certain exceptions. On 15 November 2022, Hungary submitted to the National Assembly an amending bill concerning the 'Act on Asset Declarations', as part of the service package adopted on 7 December 2022.
- (41) Regarding the anti-fraud and anti-corruption strategies, the Commission found in its Communication of 30 November 2022 that, despite the not meeting the agreed deadline due to the adoption of amendments, Hungary nevertheless fulfilled the commitments set out in the remedial measure. Regarding the asset declarations, the Commission found that in line with the remedial measure, the Act on Asset Declarations extends the personal scope of asset declarations to include persons entrusted with senior political functions and members of the National Assembly, as well as their relatives living in the same household. The Act also extends the material scope of asset declarations to include all relevant assets. However, on the basis of the Commission's assessment, important weaknesses, risks and shortcomings remain in the regulatory framework for asset declaration set up by Hungary, and in particular: (i) the lack of clarity and legal certainty relating to the disclosure obligations for real estate including property outside the jurisdiction of Hungary; (ii) the lack of clarity on the personal, material and temporal scope of the declaration of assets, income and economic interests of certain executives, officials and Members of the National Assembly, and for their spouses or cohabitants and child(ren) living in the same household; (iii) the failure to include in the Act on Asset Declarations an explicit reference to the establishment of a system of asset declarations filed electronically in a digital format, to be stored in a public database searchable without fees or the need to register. The Council considers that for these reasons as further set out in the Commission's communication, the weaknesses identified create possible loopholes in the law and as a consequence undermine the effectiveness of the remedial measure.

(d) Ensuring the transparency of the use of Union support by public interest asset management foundations

- (42) Hungary committed to ensure the transparency of the use of Union support by public interest asset management foundations by amending the relevant regulatory framework by 30 September 2022. Following the submission of the Commission's proposal, the National Assembly adopted a legislative Act amending certain Acts concerning public interest asset management foundations performing public duty, National Tax and Customs Administration and the checks of the European Anti-Fraud Office in relation with the control of the use of European Union budget funds (Act XXIX of 2022) which entered into force on 13 October 2022.
- (43) In line with the remedial measure, Act XXIX of 2022 introduced amendments that enlarged the scope of the rules on public procurement and on conflict of interests to cover also public interest asset management foundations performing public duty. However, the regulatory framework still does not prevent top-level officials, including senior political executives from the National Assembly and Hungary's autonomous bodies, from sitting on boards of public interest asset management foundations, as repeatedly requested by the Commission. Moreover, Hungary

has reintroduced as of 1 November 2022 the possibility (by means of an exception from the general prohibition) for senior political executives to have other remunerated employment, including on boards of public interest asset management foundations. The Council considers that for these reasons as further set out in the Commission's communication, the weaknesses of the regulatory framework combined with the new legislative developments aggravate the possible conflict of interest that the remedial measure was meant to address and therefore renders it inadequate to address the concerns originally raised by the Commission.

(e) Introduction of a specific procedure in the case of special crimes related to the exercise of public authority or the management of public property

- (44) Hungary committed to establish a new judicial review procedure concerning special criminal offences related to the exercise of public authority or the management of public property. Under the remedial measure, the new procedure must provide for the judicial review of the decision of the prosecution service or the investigating authority to dismiss a crime report or terminate the criminal proceedings (i.e. to close a criminal investigation without an indictment) regarding corruption and corruption-related practices. The new procedure must confer on an investigating judge the authority to order the commencement or the continuation of the criminal proceedings. Any natural person and legal person, with the exception of public authorities, could file motions under the procedure, which could also lead to the possibility to file an indictment before a court. This remedial measure is a horizontal measure that aims at remedying structural problems with the effectiveness of prosecutorial action in Hungary and ensuring that effective and deterrent measures are taken to ensure the protection of the Union's financial interests, in line with Article 325 TFEU. It is therefore one of the central remedial measures proposed by Hungary to address the concerns raised by the Commission.
- (45) Hungary included in the proposed remedial measure a number of elements which were positively assessed at the time of the Commission's proposal, such as the possibility for legal entities to file for the judicial review procedure, a guaranteed privileged procedural position for the person reporting a crime, a reference to the fact that exclusive competence to hear the cases under the new procedure will be attributed to a specialised court (i.e. the Buda Central District Court), a reference to the fact that all courts and the investigative judges involved in the new procedure will be compliant with Article 19(1) TEU and the relevant Union *acquis*, and a reasonable timeframe for the procedure in general. Hungary also undertook to take Key Implementation Steps for the adoption and entry into force of the necessary amendments to the Criminal Procedure Code and of relevant implementing regulations by 15 November 2022. Following the submission of the Commission's proposal, the National Assembly adopted an Act amending the Act XC of 2017 on the Code of Criminal Procedure (the 'Act on Judicial Review') on 3 October 2022, which entered into force on 15 November 2022 and was further modified following exchanges with the Commission and adopted in an amended version on 22 November 2022. Hungary initiated an ex-ante review before the Hungarian Constitutional Court, which found the Act on Judicial Review in compliance with the principle of the prosecution monopoly as laid down in the Hungarian Fundamental Law. Hungary finally submitted to the Commission the draft Decrees laying down the implementing regulations necessary for the application of the new review procedure and committed to adopt them without delay so to ensure their entry into force on 1 January 2023.
- (46) The Act on Judicial Review implements a number of the commitments proposed in the remedial measures by introducing relevant amendments to the Code of Criminal Procedure. Additional measures taken by Hungary in the framework of the amendment of the Act on Judicial Review, such as the power for the Integrity Authority to file a motion for revision or repeated revision and the abolition of the power of the Prosecutor General to file an extraordinary remedy against decisions, have also been welcomed by the Commission. However, as shown by the Commission's assessment, specific provisions of the Act on Judicial Review introduce a margin of discretion in the procedure which could be used to affect the outcome following a motion for revision or for prosecution, compromising the effectiveness and overall adequacy of the remedial measure. In particular, (i) the applicable rules do not clearly state the legal consequences for the prosecutor of a judicial decision setting aside its decision following a motion for revision. Since there is no guarantee that judicial review decisions will be duly followed up

through correct prosecutorial action, the discretion granted to the prosecutor seriously undermines the effectiveness and thus the adequacy of the remedial measure. Furthermore (ii) for the cases where a motion for prosecution may be filed, the Act on Judicial Review requires an examination of the ground for the motion for prosecution by the trial court in camera and without hearing evidence, which is additional to the preliminary examination of formal grounds established under the new procedure.

On the basis of the Commission's assessment and of the reasons provided therein, such an examination by the trial court of the ground for the motion for prosecution amounts to a substantive filtering which would risk anticipating or preventing a ruling on the merits, without the possibility to seek and hear evidence in the case. This represents an unnecessary step and undermines the effectiveness of the remedial measure. Finally, the Act on Judicial Review does not clarify the scope of application in time of the new rules and, in particular, fails to clarify that the new procedure will also apply to (non-time-barred) criminal offences committed before 1 January 2023. The Council considers that for these reasons and those further set out in the Commission's communication, the weaknesses identified are of a such gravity as to seriously compromise the adequacy of the remedial measure to address the issues of ineffective investigations, prosecution and sanctioning of criminal offences in the domain of public property.

(f) Strengthening audit and control mechanisms to guarantee the sound use of Union support

- (47) Hungary committed to strengthen audit and control mechanisms to guarantee the sound use of Union support by including in the relevant national legislation provisions to strengthen rules and procedures to more effectively prevent, detect and correct conflicts of interest in the use of Union funds in accordance with Article 61 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ^(*), including an effective control mechanism over the validity of conflict of interest declarations. Following the submission of the Commission's proposal, Hungary undertook a number of steps to address the Key Implementation Steps for this remedial measure. In particular, the National Assembly adopted and further modified Act XXVIII of 2022 which established the Directorate of Internal Audit and Integrity in the Prime Minister's Office and provides it with guarantees of independence and effectiveness. The service package also included a bill changing the regulatory framework governing the Directorate-General for Audit of European Funds ('EUTAF'). Hungary further adopted Government Decree 373/2022, amending decree 374/2022 as well as Government Decree 463/2022, strengthening the rules and procedures to more effectively prevent, detect and correct conflicts of interest. Based on the Commission's communication of 30 November 2022 and the reasons provided therein, the Council considers that Hungary has taken the Key Implementation Steps and that the relevant legislative texts fulfil the commitments set by the remedial measure.

(g) Reducing the share of tender procedures with single bids financed from Union funds

- (48) Hungary undertook to reduce the share of tender procedures financed from Union funds and closed in 2022 with single bids below 15 %, as measured with the Single Market Scoreboard methodology, by 31 December 2022. The Key Implementation Step for this measure was the performance of the first audit by the EUTAF on the compliance with the Single Market Scoreboard methodology by 30 September 2022. Hungary submitted the report on 7 October 2022 and, following comments from the Commission, submitted a revised final version on 3 November 2022. The audit concluded that the methodology used was adequate and in line with the methodology used by the Single Market Scoreboard, with one exception, for which EUTAF has formulated a recommendation. Based on the Commission's communication of 30 November 2022 and the reasons provided therein, the Council considers that Hungary took the Key Implementation Step as required by the remedial measure.

^(*) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

(i) **The development of a single-bid reporting tool to monitor and report on public procurement procedures closed with single-bids**

- (49) Hungary committed to develop a new monitoring and reporting tool for measuring the share of procurement procedures resulting in single bids financed from national resources or from Union support or from both by 30 September 2022. Following the submission of the Commission's proposal, Hungary undertook a number of steps to address the Key Implementation Steps for that remedial measure. In particular, Hungary developed a new monitoring and reporting tool which has been audited as operational, functional and capable of monitoring the ratio of single bid procurement procedures. In line with the remedial measure, the reporting tool will be developed further by 31 December 2022 to include data on geographic indications. Based on the Commission's communication of 30 November 2022 and the reasons provided therein, the Council considers that Hungary has taken the Key Implementation Steps and that the single bid reporting tool has been developed and is operational as required by the remedial measure.

(j) **The development of the Electronic Public Procurement System to increase transparency**

- (50) In order to increase transparency in public procurement, Hungary committed to create and publish on the Electronic Public Procurement System website a database containing information on all contract award notices of public procurement procedures in a structured form, including company identification numbers and the names of each individual member of the consortia and the subcontractors. That database is to be updated regularly and be available to the public free of charge. Following the submission of the Commission's proposal, Hungary informed the Commission that the development of a database with the required functionalities was completed by 30 September 2022. Based on the Commission's assessment of the functionalities of the new database, the Council considers that Hungary has taken the relevant Key Implementation Step for this measure and fulfilled it.

(k) **The development of a performance measurement framework assessing the efficiency and cost-effectiveness of public procurements**

- (51) In order to comply with its commitment to develop a performance measurement framework to assess the efficiency and cost effectiveness of public procurements by 30 September 2022, to be operational by 30 November 2022, Hungary adopted on 5 September 2022 Government Decision 1425/2022. On 30 November 2022, Hungary published on the Electronic Public Procurement System website a document laying down the performance measurement framework. Based on the Commission's assessment of the framework laid down in Government Decision 1425/2022, the Council considers that Hungary has taken the relevant Key Implementation Step and fulfilled its commitments for this measure.

(o) **The application of ARACHNE, the Commission's risk scoring tool**

- (52) As regards the concerns raised about the ability of Hungary to improve conflict of interest checks regarding the use of Union funds, Hungary undertook to apply procedures for the systematic and extended use of all functionalities of the single data-mining and risk-scoring tool (ARACHNE) which the Commission puts at the disposal of Member States for any Union support and for all programming periods, to effectively prevent and detect conflicts of interest, fraud, corruption, double funding and other irregularities. On 30 September 2022, the Hungarian Government adopted Government Decree 373/2022 and amending Decree 374/2022, which entered into force on the same day and set out provisions to ensure the transmission of certain data to ARACHNE on a regular basis. Also on the same day, the first package of data was transmitted to ARACHNE. Based on the Commission's assessment that the Government Decree 373/2022 and amending Decree 374/2022 set out the detailed rules for the systematic and effective use of ARACHNE, the Council considers that Hungary has taken the relevant Key Implementation Step and fulfilled its commitments for this measure.

(p) **Strengthening cooperation with OLAF**

- (53) Hungary committed to strengthen cooperation with OLAF by designating a competent national authority to assist OLAF when carrying out on-the-spot checks in Hungary when an economic operator subject to those checks refuses to cooperate. Hungary also committed to introduce a dissuasive financial-type sanction to be imposed in case an economic operator refuses to cooperate with OLAF for the purposes of OLAF's on-the-spot checks and inspections. Following the submission of the Commission's proposal, the National Assembly adopted on 4 October 2022 Act XXIX of 2022, which amended existing legislation so as to designate the National Tax and Customs Administration as the competent national authority to assist OLAF and to introduce a dissuasive financial sanction to be imposed in case an economic operator refuses to cooperate with OLAF. Based on the Commission's assessment, the Council considers that Hungary has taken the relevant Key Implementation Steps and fulfilled its commitments for this measure.

(q) **The adoption of a legislative act ensuring enhanced transparency of public spending**

- (54) As part of the set of remedial measures, Hungary committed to adopt by 31 October 2022 a legislative act ensuring enhanced transparency of public spending by setting out an obligation for all public bodies to proactively publish a pre-defined set of information on the use of public funds into a central register. Following the submission of the Commission's proposal, the National Assembly adopted on 8 November 2022 Act XL of 2022, which was subsequently amended on 22 November 2022 as part of the service package. An additional amendment of the provisions regarding the establishment of an additional administrative procedure for transparency was adopted on 7 December 2022. The Commission's assessment concluded that Hungary took the Key Implementation Steps required, despite a delay in their implementation. However, on the basis of the Commission's assessment as updated on 9 December 2022, a weakness remains in the regulatory framework which undermine its effectiveness, in particular the lack of an obligation for all contracting authorities to publish information in the absence of data on the 'responsible body' for public expenditure, contracting authority or service providers, suppliers, and capacity providers in the minimum set of data to be uploaded in the central register.
- (55) In summary, Hungary took a number of steps to address the (legislative and non-legislative) Key Implementation Steps listed in the annex to the explanatory memorandum accompanying the Commission's proposal, and many of the commitments undertaken by Hungary in the remedial measures may be considered as fulfilled, as set out above. These positive assessments are without prejudice to further developments in relation to those remedial measures which require to be substantiated in practice, or which require a longer implementation period in line with the engagements taken by Hungary.
- (56) Nevertheless, important weaknesses, risks and shortcomings remain in a number of remedial measures. In particular, significant weaknesses continue to seriously undermine the adequacy of the remedial measures which have horizontal, structural and systemic nature and are of central importance to remedy the systemic breaches of the principles of the rule of law concerning public procurement, the effectiveness of prosecutorial action and the fight against corruption in Hungary. Those weaknesses therefore jeopardise the effectiveness of the remedial measures taken as a whole.
- (57) Bearing in mind the horizontal, structural and systemic character of the measures which remain to be fulfilled, the fact that Hungary has satisfactorily fulfilled a number of commitments in relation to other punctual remedial measures is not sufficient to address the identified breaches of the principles of the rule of law and the impact they have or risk having on the Union budget. As clarified by the Commission in its updated assessment of 9 December 2022, with the sole exception of the remedial measure relating to public interest asset management foundations, the remedial measures have to be assessed in their entirety, as a global package, in light of their overall adequacy to put an end to the situation and on the basis of a qualitative, and not merely quantitative, assessment.

- (58) As a consequence, in light of the assessment carried out above, it should be concluded that the remedial measures notified by Hungary, taken as a whole, as adopted and in view of their details, and the ensuing uncertainty about their application in practice, do not put an end to the identified breaches of the principles of the rule of law. Because the identified cases of noncompliance refer to breaches of a systemic character, they largely affect the sound financial management of the budget of the Union and the protection of the financial interests of the Union in a sufficiently direct way.
- (59) When the Council finds that the conditions laid down in Regulation (EU, Euratom) 2020/2092 are met, it is to adopt measures of an appropriate level so as to ensure that the Union budget is protected from the actual or potential impact which ensues from the identified breaches of the principles of the rule of law.
- (60) In view of the breaches of the principles of the rule of law identified in this Decision, and of their significant impact on the Union budget, and given that the remedial measures so far adopted by Hungary present significant weaknesses that seriously compromise their adequacy to address those breaches, the Council considers that the ensuing risk for the Union budget remains high. According to Recital (18) of Regulation (EU, Euratom) 2020/2092, the degree of cooperation of the Member State concerned should be duly taken into account when determining the measures to be adopted. The Commission initially considered that a reasonable approximation for the risk for the budget correspond to 65 % of the funds of the programmes concerned. However, in light of the number and significance of remedial measures that have been satisfactorily implemented by Hungary to address the identified breaches of the principles of the rule of law, it would be a 'reasonable approximation' to establish the risk for the budget in 55 % of the programmes concerned. Accordingly, 55 % of the commitments in the programmes concerned, once approved, should be suspended. That level can be considered as a reasonable approximation of the impact on, or the serious risks for, the Union budget of the identified breaches of the principles of the rule of law, taking into account the degree of cooperation of Hungary during the procedure, as resulting by the remedial measures implemented, and is therefore proportionate in view of the objective of protecting the Union budget laid down in Regulation (EU, Euratom) 2020/2092.
- (61) As regards the choice among the various types of measures envisaged by Article 5 of Regulation (EU, Euratom) 2020/2092, the Council considers that the suspension of budgetary commitments ensuing from programmes concerned once they will be approved provides for an effective and timely protection of the Union budget by preventing that the breaches of the principles of the rule of law identified in this Decision affect the budget allocated to the programmes concerned. At the same time, the suspension of the budgetary commitments still allows Hungary to start implementing those programmes according to the applicable rules, and therefore preserves the objectives of cohesion policy and the position of final beneficiaries. Moreover, unlike other possible measures, the suspension of budgetary commitments is of a temporary character and does not have definitive effects in accordance with Article 7(3) of Regulation (EU, Euratom) 2020/2092. The measure can therefore be lifted under the procedure foreseen by that Article without loss of Union funding, provided that the situation is fully remedied within 2 years. In line with the proportionality principle, the chosen measure is therefore sufficient to achieve the protection of the Union budget while being the least onerous, taking the circumstances of the case into account.
- (62) Concerning the identified breaches in relation to public interest trusts, the regulatory framework in Hungary has weaknesses, as set out above, which have not remedied the risk of conflict of interest that the remedial measure was meant to address. In light of the inadequacy of the remedial measure, a serious risk for the Union budget remains and can best be addressed by a prohibition on entering into new legal commitments with any public interest trust and any entity maintained by them under any programme under direct or indirect management. Such a measure does not affect the overall allocations of funds from Union programmes under direct and indirect management which may still be used for other entities and is therefore sufficient to achieve the protection of the Union budget while being proportionate to what is strictly necessary to achieve that objective.

- (63) Pursuant to Article 5(2) of Regulation (EU, Euratom) 2020/2092, this Decision does not affect the obligations of Hungary to implement the programmes and funds concerned by this Decision, and in particular its obligations towards final recipients or beneficiaries, including the obligation to make payments under the applicable sector-specific or financial rules. Hungary has to report to the Commission on its compliance with those obligations every 3 months from the adoption of this Decision.
- (64) Hungary should inform the Commission on a regular basis of the implementation of the remedial measures to which it has committed, and in particular of those which require to be substantiated in practice or which require a longer implementation period.
- (65) The Commission should continue monitoring the situation in Hungary and exercise, as appropriate, its prerogatives under Regulation (EU, Euratom) 2020/2092. In particular, the Commission should swiftly assess any development in the implementation of the remedial measures proposed by Hungary so as to submit to the Council without delay the necessary proposals for the lifting of the measures under Article 7 of Regulation (EU, Euratom) 2020/2092 in case the conditions for their adoption are no longer met. The Commission should keep the Council periodically informed,

HAS ADOPTED THIS DECISION:

Article 1

- 1. The conditions set out in Article 4(1) of Regulation (EU, Euratom) 2020/2092 are fulfilled for the adoption of appropriate measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary.
- 2. The remedial measures proposed by Hungary on the basis of Article 6(5) of Regulation (EU, Euratom) 2020/2092, are not fully adequate to address the findings set out in the Commission notification sent to Hungary on 27 April 2022.

Article 2

- 1. 55 % of the budgetary commitments under the following operational programmes in Cohesion Policy, once approved, shall be suspended:
 - (a) Environmental and Energy Efficiency Operational Programme Plus;
 - (b) Integrated Transport Operational Programme Plus;
 - (c) Territorial and Settlement Development Operational Programme Plus.
- 2. Where the Commission implements the Union budget in direct or indirect management pursuant to of Article 62(1) points (a) and (c), of Regulation (EU, Euratom) 2018/1046, no legal commitments shall be entered into with any public interest trust established on the basis of the Hungarian Act IX of 2021 or any entity maintained by such a public interest trust.

Article 3

Hungary shall inform the Commission by 16 March 2023, and every 3 months thereafter, of the implementation of the remedial measures to which Hungary committed with its second reply, including the additional commitments included in Hungary's letter of 13 September 2022.

Article 4

This decision shall take effect on the day of its notification.

Article 5

This Decision is addressed to Hungary.

Done at Brussels, 15 December 2022.

For the Council

The President

M. BEK

COUNCIL DECISION (CFSP) 2022/2507
of 19 December 2022
amending Decision 2010/452/CFSP on the European Union Monitoring Mission in Georgia, EUMM Georgia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 42(4) and 43(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 12 August 2010, the Council adopted Decision 2010/452/CFSP ⁽¹⁾ extending the European Union Monitoring Mission in Georgia (EUMM Georgia) established by Council Joint Action 2008/736/CFSP ⁽²⁾.
- (2) On 17 October 2022, the Council adopted Decision (CFSP) 2022/1970 ⁽³⁾ providing for the deployment in Armenia of EU experts from EUMM Georgia until 19 December 2022.
- (3) On 25 November 2022, the Council adopted Decision (CFSP) 2022/2318 ⁽⁴⁾ extending EUMM Georgia until 14 December 2024.
- (4) A strategic assessment of the task introduced by Decision (CFSP) 2022/1970 led the Political and Security Committee to conclude that, from 20 December 2022, EUMM Georgia should temporarily deploy a team in Armenia to enhance the Union's awareness of the security situation, with a view to contributing to the planning and preparation of a possible civilian mission under the Common Security and Defence Policy (CSDP) in Armenia.
- (5) Decision 2010/452/CFSP should be amended accordingly.
- (6) EUMM Georgia will be conducted in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

In Decision 2010/452/CFSP, Article 3a is replaced by the following:

'Article 3a

EUMM Georgia shall deploy a team in Armenia in order to enhance the Union's awareness of the security situation, with a view to contributing to the planning and preparation of a possible civilian CSDP mission in Armenia.

This task shall end when the Council so decides.'

⁽¹⁾ Council Decision 2010/452/CFSP of 12 August 2010 on the European Union Monitoring Mission in Georgia, EUMM Georgia (OJ L 213, 13.8.2010, p. 43).

⁽²⁾ Council Joint Action 2008/736/CFSP of 15 September 2008 on the European Union Monitoring Mission in Georgia, EUMM Georgia (OJ L 248, 17.9.2008, p. 26).

⁽³⁾ Council Decision (CFSP) 2022/1970 of 17 October 2022 amending Decision 2010/452/CFSP on the European Union Monitoring Mission in Georgia, EUMM Georgia (OJ L 270, 18.10.2022, p. 93).

⁽⁴⁾ Council Decision (CFSP) 2022/2318 of 25 November 2022 amending Decision 2010/452/CFSP on the European Union Monitoring Mission in Georgia, EUMM Georgia (OJ L 307, 28.11.2022, p. 133).

Article 2

This Decision shall enter into force on the date of its adoption.

It shall apply from 20 December 2022.

Done at Brussels, 19 December 2022.

For the Council
The President
J. SÍKELA

COMMISSION IMPLEMENTING DECISION (EU) 2022/2508**of 9 December 2022****establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the textiles industry***(notified under document C(2022) 8984)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) ⁽¹⁾, and in particular Article 13(5) thereof,

Whereas:

- (1) Best available techniques (BAT) conclusions are the reference for setting permit conditions for installations covered by Chapter II of Directive 2010/75/EU and competent authorities should set emission limit values which ensure that, under normal operating conditions, emissions do not exceed the emission levels associated with the best available techniques as laid down in the BAT conclusions.
- (2) In accordance with Article 13(4) of Directive 2010/75/EU, the forum composed of representatives of Member States, the industries concerned and non-governmental organisations promoting environmental protection, established by Commission Decision of 16 May 2011 ⁽²⁾, provided the Commission on 10 May 2022 with its opinion on the proposed content of the BAT reference document for the textiles industry. That opinion is publicly available ⁽³⁾.
- (3) The BAT conclusions set out in the Annex to this Decision take into account the opinion of the forum on the proposed content of the BAT reference document. They contain the key elements of the BAT reference document.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 75(1) of Directive 2010/75/EU,

HAS ADOPTED THIS DECISION:

Article 1

The best available techniques (BAT) conclusions for the textiles industry, as set out in the Annex, are adopted.

Article 2

This Decision is addressed to the Member States.

⁽¹⁾ OJ L 334, 17.12.2010, p. 17.

⁽²⁾ Commission Decision of 16 May 2011 establishing a forum for the exchange of information pursuant to Article 13 of Directive 2010/75/EU on industrial emissions (OJ C 146, 17.5.2011, p. 3).

⁽³⁾ https://circabc.europa.eu/ui/group/06f33a94-9829-4eee-b187-21bb783a0fbf/library/fdb14511-4fc5-4b90-b495-79033a1787af?p=1&n=10&sort=modified_DESC

Done at Brussels, 9 December 2022.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

ANNEX

1. **BEST AVAILABLE TECHNIQUES (BAT) CONCLUSIONS FOR THE TEXTILES INDUSTRY**

SCOPE

These BAT conclusions concern the following activities specified in Annex I to Directive 2010/75/EU:

- 6.2. Pre-treatment (operations such as washing, bleaching, mercerisation) or dyeing of textile fibres or textiles where the treatment capacity exceeds 10 tonnes per day.
- 6.11. Independently operated treatment of waste water not covered by Directive 91/271/EEC, provided that the main pollutant load originates from activities covered by these BAT conclusions.

These BAT conclusions also cover the following:

- The following activities when they are directly associated with activities specified in point 6.2 of Annex I to Directive 2010/75/EU:
 - coating;
 - dry cleaning;
 - fabric production;
 - finishing;
 - lamination;
 - printing;
 - singeing;
 - wool carbonising;
 - wool fulling;
 - spinning of fibres (other than man-made fibres);
 - washing or rinsing associated with dyeing, printing or finishing.
- The combined treatment of waste water from different origins, provided that the main pollutant load originates from activities covered by these BAT conclusions and that the waste water treatment is not covered by Directive 91/271/EEC.
- On-site combustion plants that are directly associated with the activities covered by these BAT conclusions, provided that the gaseous products of combustion are put into direct contact with the textile fibres or textiles (such as direct heating, drying, heat-setting) or when radiant and/or conductive heat is transferred through a solid wall (indirect heating) without using an intermediary heat transfer fluid.

These BAT conclusions do not cover the following:

- Coating and lamination with an organic solvent consumption capacity of more than 150 kg per hour or more than 200 tonnes per year. These are covered by the BAT conclusions on surface treatment using organic solvents including preservation of wood and wood products with chemicals (STS).
- Production of man-made fibres and yarns. This may be covered by the BAT conclusions covering the sector of polymers production.
- Unhairing of hides and skins. This may be covered by the BAT conclusions for the tanning of hides and skins (TAN).

Other BAT conclusions and reference documents which could be relevant for the activities covered by these BAT conclusions include the following:

- Surface Treatment Using Organic Solvents including Preservation of Wood and Wood Products with Chemicals (STS);
- Waste Incineration (WI);
- Waste Treatment (WT);
- Emissions from Storage (EFS);

- Energy Efficiency (ENE);
- Industrial Cooling Systems (ICS);
- Monitoring of Emissions to Air and Water from IED Installations (ROM);
- Economics and Cross-Media Effects (ECM).

These BAT conclusions apply without prejudice to other relevant legislation, e.g. on the registration, evaluation, authorisation and restriction of chemicals (REACH), on the classification, labelling and packaging of substances and mixtures (CLP), on biocidal products (BPR) or on energy efficiency (energy efficiency first principle).

DEFINITIONS

For the purposes of these BAT conclusions, the following definitions apply:

General terms	
Term used	Definition
Air-to-textile ratio	The ratio of the total exhaust gas volume flow (expressed in Nm ³ /h) from the emission point of a textile treatment unit (e.g. stenter) to the corresponding throughput of the textile to be treated (dry textile, expressed in kg/h).
Cellulosic materials	Cellulosic materials include cotton and viscose.
Channelled emissions	Emissions of pollutants to air through any kind of duct, pipe, stack, etc.
Continuous measurement	Measurement using an automated measuring system permanently installed on site.
Desizing	Pre-treatment of textile materials to remove sizing chemicals from woven fabric.
Diffuse emissions	Non-channelled emissions to air.
Direct discharge	Discharge to a receiving water body without further downstream waste water treatment.
Dry cleaning	Cleaning of textile materials with an organic solvent.
Existing plant	A plant that is not a new plant.
Fabric production	Production of fabric, e.g. by weaving or knitting.
Finishing	Physical and/or chemical treatment aiming at giving the textile materials end-use properties such as visual effects, handle characteristics, waterproofness or non-flammability.
Flame lamination	Bonding of fabrics using a thermoplastic foam sheet, exposed to a flame located before the laminating rolls.
Hazardous substance	Hazardous substance as defined in point 18 of Article 3 of Directive 2010/75/EU.
Hazardous waste	Hazardous waste as defined in point 2 of Article 3 of Directive 2008/98/EC of the European Parliament and of the Council ⁽¹⁾
Indirect discharge	Discharge that is not a direct discharge.
Liquor ratio	For a batch process, weight ratio between the dry textile materials and the process liquor used.
n-Octanol/water partition coefficient	The ratio of the equilibrium concentrations of a dissolved substance in a two-phase system consisting of the largely immiscible solvents n-octanol and water.

Major plant upgrade	A major change in the design or technology of a plant with major adjustments or replacements of the process and/or abatement technique(s) and associated equipment.
Mass flow	The mass of a given substance or parameter which is emitted over a defined period of time.
New plant	A plant first permitted at the site of the installation following the publication of these BAT conclusions or a complete replacement of a plant following the publication of these BAT conclusions.
Organic solvent	Organic solvent as defined in Article 3(46) of Directive 2010/75/EU.
Periodic measurement	Measurement at specified time intervals using manual or automated methods.
Pick-up	For a continuous process, weight ratio between the liquid taken up by the textile materials and the dry textile materials.
Process chemicals	Substances and/or mixtures as defined in Article 3 of Regulation (EC) No 1907/2006 ⁽²⁾ that are used in the process(es), including sizing chemicals, bleaching chemicals, dyes, printing pastes and finishing chemicals. Process chemicals may contain hazardous substances and/or substances of very high concern.
Process liquor	Solution and/or suspension containing process chemicals.
Residual pick-up	The remaining capacity of wet textile materials to take up additional liquid (after the initial pick-up).
Scouring	Pre-treatment of textile materials which consists of washing the incoming textile material.
Singeing	Removal of the fibres at the surface of the fabric by passing the fabric through a flame or heated plates.
Sizing	Impregnation of yarn with process chemicals aiming to protect the yarn and provide lubrication during weaving.
Substances of very high concern	Substances meeting the criteria mentioned in Article 57 and included in the Candidate List of Substances of Very High Concern, according to the REACH Regulation ((EC) No 1907/2006).
Synthetic materials	Synthetic materials include polyester, polyamide and acrylic.
Textile materials	Textile fibres and/or textiles.
Thermal treatment	Thermal treatment of textile materials includes thermofixation, heat-setting or a process step (e.g. drying, curing) of the activities covered by these BAT conclusions (e.g. coating, dyeing, pre-treatment, finishing, printing, lamination).

(¹) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

(²) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Pollutants and parameters	
Term used	Definition
Antimony	Antimony, expressed as Sb, includes all inorganic and organic antimony compounds, dissolved or bound to particles.
AOX	Adsorbable organically bound halogens, expressed as Cl, include adsorbable organically bound chlorine, bromine and iodine.
BOD _n	Biochemical oxygen demand. Amount of oxygen needed for the biochemical oxidation of the organic matter to carbon dioxide in <i>n</i> days (<i>n</i> is typically 5 or 7). BOD _n is an indicator for the mass concentration of biodegradable organic compounds.
Chromium	Chromium, expressed as Cr, includes all inorganic and organic chromium compounds, dissolved or bound to particles.
CO	Carbon monoxide.
COD	Chemical oxygen demand. Amount of oxygen needed for the total chemical oxidation of the organic matter to carbon dioxide using dichromate. COD is an indicator for the mass concentration of organic compounds.
Copper	Copper, expressed as Cu, includes all inorganic and organic copper compounds, dissolved or bound to particles.
CMR	Carcinogenic, mutagenic or toxic for reproduction. This includes CMR substances of categories 1A, 1B and 2, as defined in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾ and amended, i.e. with hazard statement codes: H340, H341, H350, H351, H360 and H361.
Dust	Total particulate matter (in air).
HOI	Hydrocarbon oil index. The sum of compounds extractable with a hydrocarbon solvent (including long-chain or branched aliphatic, alicyclic, aromatic or alkyl-substituted aromatic hydrocarbons).
NH ₃	Ammonia.
Nickel	Nickel, expressed as Ni, includes all inorganic and organic nickel compounds, dissolved or bound to particles.
NO _x	The sum of nitrogen monoxide (NO) and nitrogen dioxide (NO ₂), expressed as NO ₂ .
SO _x	The sum of sulphur dioxide (SO ₂), sulphur trioxide (SO ₃), and sulphuric acid aerosols, expressed as SO ₂ .
Sulphide, easily released	The sum of dissolved sulphides and of those undissolved sulphides that are easily released upon acidification, expressed as S ²⁻ .
TOC	Total organic carbon, expressed as C (in water), includes all organic compounds.
TN	Total nitrogen, expressed as N, includes free ammonia and ammonium nitrogen (NH ₄ -N), nitrite nitrogen (NO ₂ -N), nitrate nitrogen (NO ₃ -N) and organically bound nitrogen.

TP	Total phosphorus, expressed as P, includes all inorganic and organic phosphorus compounds, dissolved or bound to particles.
TSS	Total suspended solids. Mass concentration of all suspended solids (in water), measured via filtration through glass fibre filters and gravimetry.
TVOC	Total volatile organic carbon, expressed as C (in air).
VOC	Volatile organic compound as defined in Article 3(45) of Directive 2010/75/EU.
Zinc	Zinc, expressed as Zn, includes all inorganic and organic zinc compounds, dissolved or bound to particles.

(¹) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

ACRONYMS

For the purposes of these BAT conclusions, the following acronyms apply:

Acronym	Definition
CMS	Chemicals management system
DTPA	Diethylenetriaminepentaacetic acid
EDTA	Ethylenediaminetetraacetic acid
EMS	Environmental management system
ESP	Electrostatic precipitator
IED	Industrial Emissions Directive (2010/75/EU)
OTNOC	Other than normal operating conditions
PFAS	Per- and polyfluoroalkyl substances

GENERAL CONSIDERATIONS

Best Available Techniques

The techniques listed and described in these BAT conclusions are neither prescriptive nor exhaustive. Other techniques may be used that ensure at least an equivalent level of environmental protection.

Unless otherwise stated, the BAT conclusions are generally applicable.

Emission levels associated with the best available techniques (BAT-AELs) for emissions to air

The BAT-AELs for emissions to air given in these BAT conclusions refer to concentrations (mass of emitted substances per volume of waste gas) under the following standard conditions: dry gas at a temperature of 273,15 K and a pressure of 101,3 kPa, without correction for oxygen content, and expressed in mg/Nm³.

For averaging periods of BAT-AELs for emissions to air, the following **definition** applies.

Type of measurement	Averaging period	Definition
Periodic	Average over the sampling period	Average value of three consecutive samplings/measurements of at least 30 minutes each. ⁽¹⁾

⁽¹⁾ For any parameter where, due to sampling or analytical limitations and/or due to operational conditions, a 30-minute sampling/measurement and/or an average of three consecutive samplings/measurements is inappropriate, a more representative sampling/measurement procedure may be employed.

For the purpose of calculating the mass flows in relation to BAT 9, BAT 26, BAT 27 and Table 1.5 and Table 1.6, where waste gases from one type of source (e.g. stenter) discharged through two or more separate emission points could, in the judgement of the competent authority, be discharged through a common emission point, these emission points shall be considered as a single emission point (see also BAT 23). Mass flows at the plant/installation level can be used as an alternative.

Emission levels associated with the best available techniques (BAT-AELs) for emissions to water

The BAT-AELs for emissions to water given in these BAT conclusions refer to concentrations (mass of emitted substances per volume of water), expressed in mg/l.

Averaging periods associated with the BAT-AELs refer to either of the following two cases:

- In the case of continuous discharge, daily average values, i.e. 24-hour flow-proportional composite samples.
- In the case of batch discharge, average values over the release duration taken as flow-proportional composite samples, or, provided that the effluent is appropriately mixed and homogeneous, a spot sample taken before discharge.

Time-proportional composite samples can be used provided that sufficient flow stability is demonstrated. Alternatively, spot samples may be taken, provided that the effluent is appropriately mixed and homogeneous.

In the case of total organic carbon (TOC) and chemical oxygen demand (COD), the calculation of the average abatement efficiency referred to in these BAT conclusions (see Table 1.3) is based on the influent and effluent load of the waste water treatment plant.

The BAT-AELs apply at the point where the emission leaves the installation.

Other environmental performance levels

Indicative levels for specific energy consumption

The indicative environmental performance levels related to specific energy consumption refer to yearly averages calculated using the following equation:

$$\text{specific energy consumption} = \frac{\text{energy consumption rate}}{\text{activity rate}}$$

where:

energy consumption rate:	total annual amount of heat and electricity consumed by the thermal treatment, minus the heat recovered from the thermal treatment, expressed in MWh/year;
activity rate:	total annual amount of textile materials treated in the thermal treatment, expressed in t/year.

Indicative levels for specific water consumption

The indicative environmental performance levels related to specific water consumption refer to yearly averages calculated using the following equation:

$$\text{specific water consumption} = \frac{\text{water consumption rate}}{\text{activity rate}}$$

where:

water consumption rate:	total annual amount of water consumed by a given process (e.g. bleaching) including water used for washing and rinsing the textile materials and for cleaning the equipment, minus the water reused and/or recycled to the process, expressed in m ³ /year;
activity rate:	total annual amount of textile materials treated in a given process (e.g. bleaching), expressed in t/year.

Specific wool grease recovery level associated with the best available techniques

The environmental performance level related to specific wool grease recovery refers to a yearly average calculated using the following equation:

$$\text{specific wool grease recovery} = \frac{\text{rate of wool grease recovered}}{\text{activity rate}}$$

where:

rate of wool grease recovered:	total annual amount of wool grease recovered from the pre-treatment of raw wool fibres by scouring, expressed in kg/year;
activity rate:	total annual amount of raw wool fibres pre-treated by scouring, expressed in t/year.

Caustic soda recovery level associated with the best available techniques

The environmental performance level related to caustic soda recovery refers to a yearly average calculated using the following equation:

$$\text{caustic soda recovery} = \frac{\text{rate of caustic soda recovered}}{\text{rate of caustic soda before recovery}}$$

where:

rate of caustic soda recovered:	total annual amount of caustic soda recovered from spent mercerisation rinsing water, expressed in kg/year;
rate of caustic soda before recovery:	total annual amount of caustic soda in the spent mercerisation rinsing water, expressed in kg/year.

1.1. General BAT conclusions

1.1.1. Overall environmental performance

BAT 1. In order to improve the overall environmental performance, BAT is to elaborate and implement an environmental management system (EMS) that incorporates all of the following features:

- i. commitment, leadership, and accountability of the management, including senior management, for the implementation of an effective EMS;

- ii. an analysis that includes the determination of the organisation's context, the identification of the needs and expectations of interested parties, the identification of characteristics of the installation that are associated with possible risks for the environment (or human health) as well as of the applicable legal requirements relating to the environment;
- iii. development of an environmental policy that includes the continuous improvement of the environmental performance of the installation;
- iv. establishing objectives and performance indicators in relation to significant environmental aspects, including safeguarding compliance with applicable legal requirements;
- v. planning and implementing the necessary procedures and actions (including corrective and preventive actions where needed), to achieve the environmental objectives and avoid environmental risks;
- vi. determination of structures, roles and responsibilities in relation to environmental aspects and objectives and provision of the financial and human resources needed;
- vii. ensuring the necessary competence and awareness of staff whose work may affect the environmental performance of the installation (e.g. by providing information and training);
- viii. internal and external communication;
- ix. fostering employee involvement in good environmental management practices;
- x. establishing and maintaining a management manual and written procedures to control activities with significant environmental impact as well as relevant records;
- xi. effective operational planning and process control;
- xii. implementation of appropriate maintenance programmes;
- xiii. emergency preparedness and response protocols, including the prevention and/or mitigation of the adverse (environmental) impacts of emergency situations;
- xiv. when (re)designing a (new) installation or a part thereof, consideration of its environmental impacts throughout its life, which includes construction, maintenance, operation and decommissioning;
- xv. implementation of a monitoring and measurement programme; if necessary, information can be found in the Reference Report on Monitoring of Emissions to Air and Water from IED Installations;
- xvi. application of sectoral benchmarking on a regular basis;
- xvii. periodic independent (as far as practicable) internal auditing and periodic independent external auditing in order to assess the environmental performance and to determine whether or not the EMS conforms to planned arrangements and has been properly implemented and maintained;
- xviii. evaluation of causes of nonconformities, implementation of corrective actions in response to nonconformities, review of the effectiveness of corrective actions, and determination of whether similar nonconformities exist or could potentially occur;
- xix. periodic review, by senior management, of the EMS and its continuing suitability, adequacy and effectiveness;
- xx. following and taking into account the development of cleaner techniques.

Specifically for the textile industry, BAT is also to incorporate the following features in the EMS:

- xxi. an inventory of inputs and outputs (see BAT 2);
- xxii. an OTNOC management plan (see BAT 3);
- xxiii. a water management plan and water audits (see BAT 10);
- xxiv. an energy efficiency plan and energy audits (see BAT 11);
- xxv. a chemicals management system (see BAT 14);
- xxvi. a waste management plan (see BAT 29).

Note

Regulation (EC) No 1221/2009 establishes the European Union eco-management and audit scheme (EMAS), which is an example of an EMS consistent with this BAT.

Applicability

The level of detail and the degree of formalisation of the EMS will generally be related to the nature, scale and complexity of the installation, and the range of environmental impacts it may have.

BAT 2. In order to improve the overall environmental performance, BAT is to establish, maintain and regularly review (including when a significant change occurs) an inventory of inputs and outputs, as part of the environmental management system (see BAT 1), that incorporates all of the following features:

- I. information about the production process(es), including:
 - a. simplified process flow sheets that show the origin of the emissions;
 - b. descriptions of process-integrated techniques and waste water/waste gas treatment techniques to prevent or reduce emissions, including their performance (e.g. abatement efficiency);
- II. information about the quantity and characteristics of materials used, including textile materials (see BAT 5 (a)) and process chemicals (see BAT 15);
- III. information about water consumption and usage (e.g. flow diagrams and water mass balances);
- IV. information about energy consumption and usage;
- V. information about the quantity and characteristics of the waste water streams, such as:
 - a. average values and variability of flow, pH, temperature and conductivity;
 - b. average concentration and mass flow values of relevant substances/parameters (e.g. COD/TOC, nitrogen species, phosphorus, metals, priority substances, microplastics) as well as their variability;
 - c. data on toxicity, bioeliminability and biodegradability (e.g. BOD_m, BOD_n to COD ratio, results of Zahn-Wellens test, biological inhibition potential (e.g. inhibition of activated sludge));
- VI. information about the characteristics of the waste gas streams, such as:
 - a. average values and variability of flow and temperature;
 - b. average concentration and mass flow values of relevant substances/parameters (e.g. dust, organic compounds) as well as their variability; emission factors may be used to assess the variability of emissions to air (see Section 1.9.1);

- c. flammability, lower and higher explosive limits, reactivity, hazardous properties;
- d. presence of other substances that may affect the waste gas treatment system or installation safety (e.g. water vapour, dust);

VII. information about the quantity and characteristics of waste generated.

Applicability

The scope (e.g. level of detail) and nature of the inventory will generally be related to the nature, scale and complexity of the installation, and the range of environmental impacts it may have.

BAT 3. In order to reduce the frequency of the occurrence of OTNOC and to reduce emissions during OTNOC, BAT is to set up and implement a risk-based OTNOC management plan as part of the EMS (see BAT 1) that includes all of the following elements:

- i. identification of potential OTNOC (e.g. failure of equipment critical to the protection of the environment ('critical equipment')), of their root causes and of their potential consequences, and regular review and update of the list of identified OTNOC following the periodic assessment below;
- ii. appropriate design of critical equipment (e.g. waste water treatment, waste gas abatement techniques);
- iii. set-up and implementation of an inspection and preventive maintenance plan for critical equipment (see BAT 1 xii);
- iv. monitoring (i.e. estimating or, where possible, measuring) and recording of emissions during OTNOC and of associated circumstances;
- v. periodic assessment of the emissions occurring during OTNOC (e.g. frequency of events, duration, amount of pollutants emitted) and implementation of corrective actions if necessary;
- vi. regular review and update of the list of identified OTNOC under point i. following the periodic assessment of point v.;
- vii. regular testing of back-up systems.

Applicability

The level of detail and degree of formalisation of the OTNOC management plan will generally be related to the nature, scale and complexity of the installation, and the range of environmental impacts it may have.

BAT 4. In order to improve the overall environmental performance, BAT is to use advanced process monitoring and control systems.

Description

The monitoring and control of processes is carried out with on-line automated systems equipped with sensors and controllers using feedback connections to rapidly analyse and adapt key process parameters to reach optimal process conditions (e.g. optimal uptake of process chemicals).

Key process parameters include:

- volume, pH and temperature of the process liquor;
- amount of textile materials treated;
- dosage of process chemicals;
- drying parameters (see also BAT 13 (d)).

BAT 5. In order to improve the overall environmental performance, BAT is to use both of the techniques given below.

Technique	Description	Applicability
a.	Use of textile materials containing a minimised content of contaminants Criteria for the selection of incoming textile materials (including recycled textile materials) are defined to minimise the content of contaminants including hazardous substances, poorly biodegradable substances and substances of very high concern. These criteria may be based on certification schemes or standards. Regular controls are carried out to verify that incoming textile materials fulfil the predefined criteria. These controls may consist of measurements and/or verification of information provided by suppliers and/or producers of textile materials. These controls may address the content of: — ectoparasiticides (veterinary drugs) and biocides in the incoming raw (or semi-processed) wool fibres; — biocides in the incoming cotton fibres; — manufacturing residues in the incoming synthetic fibres (e.g. monomers, side products of polymer synthesis, catalysts, solvents); — mineral oils (e.g. used for coning, spooling, spinning or knitting) in the incoming textile materials; — sizing chemicals in the incoming textile materials.	Generally applicable.
b.	Use of textile materials with reduced processing needs Use of textile materials with inherent characteristics that reduce the need for processing. These materials include: — spin-dyed man-made fibres; — fibres with inherent flame retardance properties; — elastane fibres or blends of elastane fibres with other polymer fibres that contain reduced amounts of silicone oils and residual solvents; — blends of synthetic fibres with thermoplastic elastomers; — polyester fibres dyeable without carriers.	The applicability may be restricted by product specifications.

1.1.2. Monitoring

BAT 6. BAT is to monitor at least once every year:

- the annual consumption of water, energy and materials used, including textile materials and process chemicals;
- the annual amount of waste water generated;
- the annual amount of materials recovered or reused;
- the annual amount of each type of waste generated and sent for disposal.

Description

Monitoring preferentially includes direct measurements. Calculations or recording, e.g. using suitable meters or invoices, can also be used. The monitoring is broken down, as much as possible, to process level and considers any significant changes in the processes.

BAT 7. For waste water streams identified by the inventory of inputs and outputs (see BAT 2), BAT is to monitor key parameters (e.g. continuous monitoring of waste water flow, pH and temperature) at key locations (e.g. at the inlet and/or outlet of the waste water pre-treatment, at the inlet to the final waste water treatment, at the point where the emission leaves the installation).

Description

When bioeliminability/biodegradability and inhibitory effects are key parameters (e.g. see BAT 19), monitoring is carried out before the biological treatment for:

- bioeliminability/biodegradability using standards EN ISO 9888 or EN ISO 7827, and
 - inhibitory effects on biological treatment using standards EN ISO 9509 or EN ISO 8192,
- with a minimum monitoring frequency to be decided after effluent characterisation.

The effluent characterisation is carried out before starting operation of the plant or before a permit for the plant is updated for the first time after the publication of these BAT conclusions, and after each change (e.g. change of 'recipe') in the plant that may increase the pollutant load.

BAT 8. BAT is to monitor emissions to water with at least the frequency given below and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance(s)/parameter	Standard(s)	Activities/ processes	Minimum monitoring frequency	Monitoring associated with
Adsorbable organically bound halogens (AOX) ⁽¹⁾	EN ISO 9562	All activities/ processes	Once every month ⁽²⁾	BAT 20
Biochemical oxygen demand (BOD _n) ⁽³⁾	Various EN standards available (e.g. EN 1899-1, EN ISO 5815-1)		Once every month	
Brominated flame retardants ⁽¹⁾	EN standard available for some polybrominated diphenyl ethers (i.e. EN 16694)	Finishing with flame retardants	Once every 3 months	
Chemical oxygen demand (COD) ⁽⁴⁾	No EN standard available	All activities/ processes	Once every day ⁽⁵⁾ ⁽⁶⁾	
Colour	EN ISO 7887	Dyeing	Once every month ⁽²⁾	

Hydrocarbon oil index (HOI) ⁽¹⁾		EN ISO 9377-2	All activities/ processes	Once every 3 months ⁽⁷⁾
Metals/ metalloids	Antimony (Sb)	Various EN standards available (e.g. EN ISO 11885, EN ISO 17294-2, EN ISO 15586)	Pre-treatment and/or dyeing of polyester textile materials	Once every month ⁽²⁾
			Finishing with flame retardants using antimony trioxide	
	Chromium (Cr)		Dyeing with chromium mordant or chromium-containing dyes (e.g. metal-complex dyes)	
	Copper (Cu)		Dyeing Printing with dyes	
	Nickel (Ni)			
	Zinc (Zn) ⁽¹⁾		All activities/ processes	
	Hexavalent chromium (Cr(VI))	Various EN standards available (e.g. EN ISO 10304-3, EN ISO 23913)	Dyeing with chromium mordant	Once every month
Pesticides ⁽¹⁾		EN standards available for some pesticides (e.g. EN 12918, EN 16693, EN ISO 27108)	Pre-treatment of raw wool fibres by scouring	To be decided, after effluent characterisation ⁽⁸⁾
Per- and polyfluoroalkyl substances (PFAS) ⁽¹⁾		No EN standard available	All activities/ processes	Once every 3 months
Sulphide, easily released (S ²⁻)		No EN standard available	Dyeing with sulphur dyes	Once every week or once every month ⁽²⁾

Surfactants	Alkylphenols and alkylphenol ethoxylates ⁽¹⁾	EN standards available for some non-ionic surfactants, e.g. alkylphenols and alkylphenol ethoxylates (i.e. EN ISO 18857-1 and EN ISO 18857-2)	All activities/ processes	Once every 3 months
	Other surfactants	EN 903 for anionic surfactants		Once every 3 months ⁽⁷⁾
		No EN standard available for cationic surfactants		
Total nitrogen (TN)		Various EN standards available (e.g. EN 12260, EN ISO 11905-1)		Once every day ⁽⁵⁾ ⁽⁶⁾
Total organic carbon (TOC) ⁽⁴⁾		EN 1484		Once every day ⁽⁵⁾ ⁽⁶⁾
Total phosphorus (TP)		Various EN standards available (e.g. EN ISO 6878, EN ISO 15681-1, EN ISO 15681-2, EN ISO 11885)		Once every day ⁽⁵⁾ ⁽⁶⁾
Total suspended solids (TSS)		EN 872		Once every day ⁽⁵⁾ ⁽⁶⁾
Toxicity ⁽⁹⁾	Fish eggs (<i>Danio rerio</i>)	EN ISO 15088		To be decided based on a risk assessment, after effluent characterisation ⁽⁸⁾
	Daphnia (<i>Daphnia magna</i> Straus)	EN ISO 6341		
	Luminescent bacteria (<i>Vibrio fischeri</i>)	Various EN standards available (e.g. EN ISO 11348-1, EN ISO 11348-2, EN ISO 11348-3)		
	Duckweed (<i>Lemna minor</i>)	Various EN standards available (e.g. EN ISO 20079, EN ISO 20227)		
	Algae	Various EN standards available (e.g. EN ISO 8692, EN ISO 10253, EN ISO 10710)		

- (¹) The monitoring only applies when the substance(s)/parameter(s) (including groups of substances or individual substances in a group of substances) concerned is identified as relevant in the waste water stream based on the inventory of inputs and outputs mentioned in BAT 2.
- (²) In the case of an indirect discharge, the monitoring frequency may be reduced to once every 3 months if the downstream waste water treatment plant is designed and equipped appropriately to abate the pollutants concerned.
- (³) The monitoring only applies in the case of a direct discharge.
- (⁴) TOC monitoring and COD monitoring are alternatives. TOC monitoring is the preferred option because it does not rely on the use of very toxic compounds.
- (⁵) In the case of an indirect discharge, the monitoring frequency may be reduced to once every month if the downstream waste water treatment plant is designed and equipped appropriately to abate the pollutants concerned.
- (⁶) If the emission levels are proven to be sufficiently stable, a lower monitoring frequency of once every month can be adopted.
- (⁷) In the case of an indirect discharge, the monitoring frequency may be reduced to once every 6 months if the downstream waste water treatment plant is designed and equipped appropriately to abate the pollutants concerned.
- (⁸) The effluent characterisation is carried out before starting operation of the plant or before a permit for the plant is updated for the first time after the publication of these BAT conclusions, and after each change (e.g. change of 'recipe') in the plant that may increase the pollutant load.
- (⁹) Either the most sensitive toxicity parameter or an appropriate combination of the toxicity parameters can be used.

BAT 9. BAT is to monitor channelled emissions to air with at least the frequency given below and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance/ parameter	Standard(s)	Activities/processes	Minimum monitoring frequency (¹)	Monitoring associated with
CO	EN 15058	Singeing	Once every 3 years	—
		Combustion		
		Flame lamination		
Dust	EN 13284-1	Singeing	Once every year (²)	BAT 27
		Combustion		
		Thermal treatments associated with pre-treatment, dyeing, printing and finishing		
CMR (other than formaldehyde)(³)	No EN standards available	Coating (⁴)	Once every year	—
		Flame lamination (⁴)		
		Finishing (⁴)		
		Thermal treatments associated with coating, lamination and finishing (⁴)		

Formaldehyde ⁽³⁾	EN standard under development	Coating ⁽⁴⁾	Once every year	BAT 26
		Flame lamination		
		Printing ⁽⁴⁾		
		Singeing		
		Finishing ⁽⁴⁾		
		Thermal treatment ⁽⁴⁾		
NH ₃ ⁽³⁾	EN ISO 21877	Coating ⁽⁴⁾	Once every year	BAT 28
		Printing ⁽⁵⁾		
		Finishing ⁽⁴⁾		
		Thermal treatments associated with coating, printing and finishing ⁽⁴⁾		
NO _x	EN 14792	Singeing	Once every 3 years	—
		Combustion		
SO ₂ ⁽³⁾	EN 14791	Combustion	Once every 3 years	—
TVOC ⁽³⁾	EN 12619	Coating	Once every year ⁽⁶⁾	BAT 26
		Dyeing		
		Finishing		
		Lamination		
		Printing		
		Singeing		
		Thermofixation or heat-setting		
		Thermal treatments associated with coating, dyeing, lamination, printing and finishing		

⁽¹⁾ To the extent possible, the measurements are carried out at the highest expected emission state under normal operating conditions.

⁽²⁾ In the case of a dust mass flow of less than 50 g/h, the minimum monitoring frequency may be reduced to once every 3 years.

⁽³⁾ Monitoring results are reported together with the corresponding air-to-textile ratio.

⁽⁴⁾ The monitoring only applies when the substance concerned is identified as relevant in the waste gas stream based on the inventory of inputs and outputs mentioned in BAT 2.

⁽⁵⁾ The monitoring does not apply if natural gas only, or liquefied petroleum gas only, is used as fuel.

⁽⁶⁾ In the case of a TVOC mass flow of less than 200 g/h, the minimum monitoring frequency may be reduced to once every 3 years.

1.1.3. Water consumption and waste water generation

BAT 10. In order to reduce water consumption and waste water generation, BAT is to use techniques (a), (b) and (c), and an appropriate combination of the techniques (d) to (j) given below.

Technique	Description	Applicability
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Management techniques

a.	Water management plan and water audits	A water management plan and water audits are part of the EMS (see BAT 1) and include: — flow diagrams and water mass balances of the plant and processes as part of the inventory of inputs and outputs mentioned in BAT 2; — establishment of water efficiency objectives; — implementation of water optimisation techniques (e.g. control of water usage, reuse/recycling, detection and repair of leaks). Water audits are carried out at least once every year to ensure that the objectives of the water management plan are met and the water audits recommendations are followed-up and implemented. The water management plan and the water audits may be integrated in the overall water management plan of a larger industrial site.	The level of detail of the water management plan and water audits will generally be related to the nature, scale and complexity of the plant.
b.	Production optimisation	This includes: — optimised combination of processes (e.g. pre-treatment processes are combined, bleaching of textile materials is avoided before dyeing in dark shades); — optimised scheduling of batch processes (e.g. dyeing of the textile materials in dark shades is carried out after dyeing in light shades in the same dyeing equipment).	Generally applicable.

Design and operation techniques

c.	Segregation of polluted and unpolluted water streams	Water streams are collected separately, based on the pollutant content and on the required treatment techniques. Polluted water streams (e.g. spent process liquors) and unpolluted water streams (e.g. cooling waters) that can be reused without treatment are segregated from waste water streams that require treatment.	Applicability to existing plants may be restricted by the layout of the water collection system and the lack of space for temporary storage tanks.
d.	Processes using little or no water	Processes include plasma or laser treatment, and processes using low amounts of water such as ozone treatment.	The applicability may be restricted by the characteristics of the textile materials and/or product specifications.

e.	Optimisation of the amount of process liquor used	Batch processes are carried out with low-liquor-ratio systems (see Section 1.9.4). Continuous processes are carried out with low-volume application systems, such as spraying (see Section 1.9.4).	Generally applicable.
f.	Optimised cleaning of the equipment	This includes: — water-free cleaning (e.g. by wiping or brushing the tanks' inner surfaces, mechanical pre-cleaning of squeegees, rotary screens and drums containing printing pastes (see BAT 44)); — multiple cleaning steps with low amounts of water; the water of the last cleaning step may be reused to clean another part of the equipment.	The applicability of water-free cleaning in existing plants may be restricted by accessibility to the equipment (e.g. closed and semi-closed systems).
g.	Optimised batch processing, washing and rinsing of textile materials	This includes: — use of auxiliary tanks for temporary storage of: — spent washing or rinsing water; — fresh or spent process liquor. — multiple drain and fill steps for rinsing and washing with low amounts of water.	The use of auxiliary tanks in existing plants may be restricted by a lack of space.
h.	Optimised continuous processing, washing and rinsing of textile materials	This includes: — timely process liquor preparation based on online pick-up measurements; — automatic closure of the washing water inflow when the washing machine stops; — countercurrent rinsing and washing; — intermediary mechanical dewatering of textile materials (see BAT 13 (a)) to reduce the carry-over of process chemicals.	Generally applicable.

Reuse and recycling techniques

i.	Water reuse and/or recycling	Water streams may be segregated (see BAT 10 (c)) and/or pre-treated (e.g. membrane filtration, evaporation) before reuse and/or recycling, e.g. for cleaning, rinsing, cooling or in the processing of textile materials. The degree of water reuse/recycling is limited by the content of impurities in the water streams. Reuse and/or recycling of water originating from several plants operating on the same site may be integrated in the overall site water management of a larger industrial site (e.g. using common waste water treatment).	Generally applicable.
j.	Reuse of process liquor	Process liquor, including the process liquor extracted from textile materials by mechanical dewatering (see BAT 13 (a)), is reused after analysis and make-up if needed. The degree of reuse of the process liquor is limited by the modification of its chemical composition, or by its content of impurities and perishability.	Generally applicable.

Table 1.1

Indicative environmental performance levels for specific water consumption

Specific process(es)		Indicative levels (Yearly average) (m ³ /t)
Bleaching	Batch	10–32 ⁽¹⁾
	Continuous	3–8
Scouring of cellulosic materials	Batch	5–15 ⁽¹⁾
	Continuous	5–12 ⁽¹⁾
Desizing of cellulosic materials		5–12 ⁽¹⁾
Combined bleaching, scouring and desizing of cellulosic materials		9–20 ⁽¹⁾
Mercerisation		2–13 ⁽¹⁾
Washing of synthetic material		5–20 ⁽¹⁾
Batch dyeing	Fabric	10–150 ⁽¹⁾
	Yarn	3–140 ⁽¹⁾ ⁽²⁾
	Loose fibre	13–60
Continuous dyeing		2–16 ⁽¹⁾ ⁽³⁾

⁽¹⁾ The lower end of the range may be achieved with a high level of water recycling (e.g. sites with integrated water management for several plants).

⁽²⁾ The range also applies to combined yarn and loose fibre batch dyeing.

⁽³⁾ The higher end of the range may be higher and up to 100 m³/t for plants using a combination of continuous and batch processes.

The associated monitoring is given in BAT 6.

1.1.4. Energy efficiency

BAT 11. In order to use energy efficiently, BAT is to use techniques (a), (b), (c) and (d), and an appropriate combination of the techniques (e) to (k) given below.

Technique	Description	Applicability
<i>Management techniques</i>		
a.	Energy efficiency plan and audits An energy efficiency plan and audits are part of the EMS (see BAT 1) and include: — energy flow diagrams of the plants and processes as part of the inventory of inputs and outputs (see BAT 2); — setting objectives in terms of energy efficiency (e.g. MWh/t of textile materials processed); — implementing actions to achieve these objectives. Audits are carried out at least once every year to ensure that the objectives of the energy efficiency plan are met and the energy audits recommendations are followed-up and implemented.	The level of detail of the energy efficiency plan and audits will generally be related to the nature, scale and complexity of the plant.

b.	Production optimisation	Optimised scheduling of fabric batches to undergo thermal treatment in order to minimise the idling time of the equipment.	Generally applicable.
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Process and equipment selection and optimisation

c.	Use of general energy-saving techniques	This includes: — burner maintenance and control; — energy-efficient motors; — energy-efficient lighting; — optimising steam distribution systems, e.g. by using point-of-use boilers; — regular inspection and maintenance of the steam distribution systems to prevent or reduce steam leaks; — process control systems; — variable speed drives; — optimising air conditioning and building heating.	Generally applicable.
d.	Optimisation of heating demand	This includes: — reducing heat losses by insulating equipment components and by covering tanks or bowls containing warm process liquor; — optimising the temperature of the rinsing water; — avoiding overheating of the process liquors.	Generally applicable.
e.	Wet-on-wet dyeing or finishing of fabric	Dyeing or finishing liquors are applied directly to the wet fabric, thus avoiding an intermediate drying step. Appropriate scheduling of production steps and dosing of chemicals need to be considered.	May not be applicable when chemicals cannot be taken up by the fabric due to insufficient residual pick-up.
f.	Cogeneration	Cogeneration of heat and electricity where the heat (mainly from the steam that leaves the turbine) is used for producing hot water/steam to be used in industrial processes/activities or in a district heating/cooling network.	Applicability in existing plants may be restricted by the plant layout and/or lack of space.

Heat recovery techniques

g.	Recycling of warm cooling water	See BAT 10 (i). This avoids the need for heating cold water.	Generally applicable.
h.	Reuse of warm process liquor	See BAT 10 (j). This avoids the need for heating cold process liquor.	
i.	Heat recovery from waste water	Heat from waste water is recovered by heat exchangers, e.g. to warm up process liquor.	
j.	Heat recovery from waste gases	Heat from waste gases (e.g. from thermal treatment of textile materials, steam boilers) is recovered by heat exchangers and used (e.g. to warm up process water or to preheat combustion air).	
k.	Heat recovery from steam use	Heat, e.g. from hot condensate and boiler blowdown, is recovered.	

BAT 12. In order to increase energy efficiency when using compressed air, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
a.	Optimal design of the compressed air system	Several compressed air units supply air with different pressure levels. This avoids the unnecessary production of high-pressure air.	Generally applicable.
b.	Optimal use of the compressed air system	Compressed air production is stopped during long shutdown or idling times of equipment, and single areas can be isolated (e.g. by valves) from the rest of the system, in particular if they are associated with infrequent use.	
c.	Control of leakages in the compressed air system	The most common sources of air leakages are regularly inspected and maintained (e.g. couplings, hoses, tubes, fittings, pressure regulators).	
d.	Reuse and/or recycling of warm cooling water or warm cooling air from air compressors	Warm cooling air (e.g. from air-cooled air compressors) is reused and/or recycled (e.g. for drying of coils and hanks if needed). For reuse and/or recycling of warm cooling water, see BAT 11 (g).	

BAT 13. In order to increase the energy efficiency of thermal treatment, BAT is to use all of the techniques given below.

Technique		Description	Applicability
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Techniques for reducing the use of heating

a.	Mechanical dewatering of textile materials	The water content of textile materials is reduced by mechanical techniques (e.g. centrifugal extraction, squeezing and/or vacuum extraction).	Generally applicable.
b.	Avoiding overdrying of textile materials	The textile materials are not dried below their natural moisture level.	

Design and operation techniques

c.	Optimising air circulation in stenters	This includes: — adapting the number of air injection nozzles to the width of the fabric; — ensuring the distance between the nozzles and the fabric is as short as possible; — ensuring the pressure drop caused by the stenters' internal components is as small as possible.	Only applicable to new plants or major plant upgrades.
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d.	Advanced process monitoring and control of drying	The drying parameters are monitored and controlled (see BAT 4). These parameters include: — humidity content and temperature of the inlet air; — temperature of textile materials and air within the dryer; — humidity content and temperature of the exhaust air; drying efficiency is optimised by an appropriate humidity content (e.g. above 0,1 kg water/kg dry air); — residual moisture content of the fabric. The exhaust airflow is adjusted to optimise drying efficiency and is reduced during idle periods of drying equipment.	Generally applicable.
e.	Microwave or radio-frequency dryers	Drying of textile materials with high-efficiency microwave or radio frequency dryers.	Not applicable to textile materials containing metallic parts or fibres. Only applicable to new plants or major plant upgrades.
<i>Heat recovery techniques</i>			
f.	Heat recovery from waste gases	See BAT 11 (j).	Only applicable when the waste gas flow is sufficient.

Table 1.2

Indicative environmental performance levels for specific energy consumption

Process	Indicative level (Yearly average) (MWh/t)
Thermal treatment	0,5–4,4

The associated monitoring is given in BAT 6.

1.1.5. Chemicals management, consumption and substitution

BAT 14. In order to improve the overall environmental performance, BAT is to elaborate and implement a chemicals management system (CMS), as part of the EMS (see BAT 1), that incorporates all of the following features:

- I. A policy to reduce the consumption and risks associated with process chemicals, including a procurement policy to select less harmful process chemicals and their suppliers with the aim of minimising the use and risks associated with hazardous substances and substances of very high concern as well as avoiding the procurement of an excess amount of process chemicals. The selection of process chemicals is based on:

- a) the comparative analysis of their bioeliminability/biodegradability, ecotoxicity and potential to be released into the environment (which in the case of emissions to air can be determined by using emission factors for example (see Section 1.9.1));
- b) the characterisation of the risks associated with the process chemicals, based on the chemicals' hazard classification, pathways through the plant, potential release and level of exposure;
- c) the potential for recovery and reuse (see BAT 16 (f) and (g) as well as BAT 39);
- d) the regular (e.g. annual) analysis of the potential for substitution with the aim to identify potentially new available and safer alternatives to the use of (groups of) hazardous substances and substances of very high concern, such as PFAS, phthalates, brominated flame retardants, chromium-(VI)-containing substances; this may be achieved by changing process(es) or using other process chemicals with no or lower environmental impacts;
- e) the anticipatory analysis of regulatory changes related to hazardous substances and substances of very high concern, and safeguarding compliance with applicable legal requirements.

The inventory of process chemicals (see BAT 15) may be used to provide and keep the information needed for the selection of process chemicals.

The criteria for selecting process chemicals and their suppliers may be based on certification schemes or standards. In that case, the compliance of the process chemicals and their suppliers with these schemes or standards is regularly verified.

- II. Goals and action plans to avoid or reduce the use of and risks associated with hazardous substances and substances of very high concern.
- III. Development and implementation of procedures for the procurement, handling, storage and use of process chemicals (see BAT 21), disposal of waste containing process chemicals and return of unused process chemicals (see BAT 29 (d)), to prevent or reduce emissions to the environment.

Applicability

The level of detail of the CMS will generally be related to the nature, scale and complexity of the plant.

BAT 15. In order to improve the overall environmental performance, BAT is to elaborate and implement a chemicals inventory as part of the CMS (see BAT 14).

Description

The chemicals inventory is computer-based and contains information about:

- the identity of the process chemicals;
- the quantities, location and perishability of the process chemicals procured, recovered (see BAT 16 (g)), stored, used and returned to suppliers;
- the composition and physico-chemical properties of process chemicals (e.g. solubility, vapour pressure, n-octanol/water partition coefficient), including properties with adverse effects on the environment and/or human health (e.g. ecotoxicity, bioeliminability/biodegradability).

Such information may be retrieved from Safety Data Sheets, Technical Data Sheets or other sources.

BAT 16. In order to reduce the consumption of chemicals, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Reduction of the need for process chemicals	This includes: — regularly reviewing and optimising the formulation of process chemicals and liquors; — production optimisation (see BAT 10 (b)).	Generally applicable.
b.	Reduction of the use of complexing agents	The use of soft/softened water reduces the amount of complexing agents used in the process liquors, e.g. for dyeing or bleaching (see BAT 38 (b)).	Not applicable to washing and rinsing.
c.	Treatment of textile materials with enzymes	Enzymes are selected (see BAT 14 I. (d)) and used to catalyse the reactions with textile materials to lower the consumption of process chemicals (e.g. in desizing, bleaching and/or washing).	The applicability may be restricted by the availability of suitable enzymes.
d.	Automatic systems for preparation and dosing of process chemicals and process liquors	Automatic systems for weighing, dosing, dissolving, measuring and dispensing which ensure precise delivery of process chemicals and process liquors to the production machines. See BAT 4.	The applicability to existing plants may be restricted by a lack of space, the distance between the preparation and the production machines or by frequent changes of process chemicals and process liquors.
e.	Optimisation of the quantity of process chemicals used	See BAT 10 (e).	Generally applicable.
f.	Reuse of process liquors	See BAT 10 (j).	Generally applicable.
g.	Recovery and use of leftover process chemicals	Residual process chemicals are recovered (e.g. by thoroughly purging pipes or completely emptying packaging) and used in the process. The degree of use may be limited by the content of impurities and the perishability of the process chemicals.	Generally applicable.

BAT 17. In order to prevent or reduce emissions to water of poorly biodegradable substances, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Substitution of alkylphenols and alkylphenol ethoxylates	Alkylphenols and alkylphenol ethoxylates are substituted by biodegradable surfactants, e.g. alcohol ethoxylates.	Generally applicable.

b.	Substitution of poorly biodegradable phosphorus- or nitrogen-containing complexing agents	Complexing agents containing phosphorus (e.g. triphosphates) or nitrogen (e.g. amino polycarboxylic acids such as EDTA or DTPA) are substituted by biodegradable/bioeliminable substances, e.g.: — polycarboxylates (e.g. polyacrylates); — salts of hydroxy carboxylic acids (e.g. gluconates, citrates); — sugar-based acrylic acid copolymers; — methylglycinediacetic acid (MGDA), L-glutamic acid N,N-diacetic acid (GLDA) and iminodisuccinic acid (IDS); — phosphonates (e.g. aminotris methylene phosphonic acid (ATMP), diethylenetriamine pentamethylene phosphonic acid (DTPMP) and 1-hydroxyl ethylidene-1,1-diphosphonic acid (HEDP)).	Generally applicable.
c.	Substitution of mineral-oil-based antifoaming agents	Mineral-oil-based antifoaming agents are substituted by biodegradable substances, e.g. antifoaming agents based on synthetic ester oil.	Generally applicable.

1.1.6. Emissions to water

BAT 18. In order to reduce the waste water volume, to prevent or reduce the pollutant loads discharged to the waste water treatment plant and the emissions to water, BAT is to use an integrated strategy for waste water management and treatment that includes an appropriate combination of the techniques given below with the following order of priority:

- process-integrated techniques (see BAT 10 and BAT conclusions in Sections 1.2 to 1.7);
- techniques to recover and reuse process liquors (see BAT 10 (j) and BAT 39), separate collection of waste water streams and pastes (e.g. printing and coating) containing high loads of pollutants that cannot be adequately treated by biological treatment; these waste water streams and pastes are either pretreated (see BAT 19) or handled as waste (see BAT 30);
- (final) waste water treatment techniques (see BAT 20).

Description

The integrated strategy for waste water management and treatment is based on the information provided by the inventory of inputs and outputs (see BAT 2).

BAT 19. In order to reduce emissions to water, BAT is to pretreat (separately collected) waste water streams and pastes (e.g. printing and coating) containing high loads of pollutants that cannot be treated adequately by biological treatment.

Description

Such waste water streams and pastes include:

- spent dyeing, coating or finishing padding liquors from continuous and/or semi-continuous treatments;
- desizing liquors;
- spent printing and coating pastes.

The pre-treatment is carried out as part of an integrated strategy for waste water management and treatment (see BAT 18) and is generally necessary to:

- protect the (downstream) biological waste water treatment against inhibitory or toxic compounds;
- remove compounds that are insufficiently abated during biological waste water treatment (e.g. toxic compounds, poorly biodegradable organic compounds, organic compounds that are present in high loads or metals);
- remove compounds that could otherwise be stripped to air from the collection system or during biological waste water treatment (e.g. sulphide);
- remove compounds that have other negative effects (e.g. corrosion of equipment, unwanted reaction with other substances; contamination of waste water sludge).

The above-mentioned compounds to be removed include organophosphorus and brominated flame retardants, PFAS, phthalates and chromium-(VI)-containing compounds.

The pre-treatment of these waste water streams is generally carried out as close as possible to the source in order to avoid dilution. The pre-treatment techniques used depend on the pollutants targeted and may include adsorption, filtration, precipitation, chemical oxidation or chemical reduction (see BAT 20).

The bioeliminability/biodegradability of the waste water streams and pastes before they are sent to the downstream biological treatment is at least:

- 80 % after 7 days (for adapted sludge), when determined according to standard EN ISO 9888, or
- 70 % after 28 days when determined according to standard EN ISO 7827.

The associated monitoring is given in BAT 7.

BAT 20. In order to reduce emissions to water, BAT is to use an appropriate combination of the techniques given below.

Technique ⁽¹⁾		Typical pollutants targeted	Applicability
<i>Pre-treatment of individual waste water streams, e.g.</i>			
a.	Adsorption	Adsorbable dissolved non-biodegradable or inhibitory pollutants (e.g. AOX in dyestuffs, organophosphorus flame retardants)	Generally applicable.
b.	Precipitation	Precipitable dissolved non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	
c.	Coagulation and flocculation	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	
d.	Chemical oxidation (e.g. oxidation with ozone, hydrogen peroxide or UV light)	Oxidisable dissolved non-biodegradable or inhibitory pollutants (e.g. optical brighteners and azo dyestuffs, sulphide)	
e.	Chemical reduction	Reducible dissolved non-biodegradable or inhibitory pollutants (e.g. hexavalent chromium (Cr(VI)))	
f.	Anaerobic pre-treatment	Biodegradable organic compounds (e.g. azo dyestuffs, printing pastes)	

g.	Filtration (e.g. nanofiltration)	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants	
Pre-treatment of combined waste water streams, e.g.			
h.	Physical separation (e.g. screens, sieves, grit separators, grease separators, oil-water separation, or primary settlement tanks)	Gross solids, suspended solids, oil/grease	Generally applicable.
i.	Equalisation	All pollutants	
j.	Neutralisation	Acids, alkalis	
Primary treatment, e.g.			
k.	Sedimentation	Suspended solids and particulate-bound metals or non-biodegradable or inhibitory pollutants	Generally applicable.
l.	Precipitation	Precipitable dissolved non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	
m.	Coagulation and flocculation	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	Generally applicable.
Secondary treatment (biological treatment), e.g.			
n.	Activated sludge process	Biodegradable organic compounds	Generally applicable.
o.	Membrane bioreactor		
p.	Nitrification/ denitrification (when the treatment includes a biological treatment)	Total nitrogen, ammonium/ammonia	Nitrification may not be applicable in the case of high chloride concentrations (e.g. above 10 g/l). Nitrification may not be applicable when the temperature of the waste water is low (e.g. below 12 °C).
Tertiary treatment, e.g.			
q.	Coagulation and flocculation	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	Generally applicable.
r.	Precipitation	Precipitable dissolved non-biodegradable or inhibitory pollutants (e.g. metals in dyestuffs)	
s.	Adsorption	Adsorbable dissolved non-biodegradable or inhibitory pollutants (e.g. AOX in dyestuffs)	

t.	Chemical oxidation (e.g. oxidation with ozone, hydrogen peroxide or UV light)	Oxidisable dissolved non-biodegradable or inhibitory pollutants (e.g. optical brighteners and azo dyestuffs, sulphide)	
u.	Flotation	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants	
v.	Filtration (e.g. sand filtration)		
<i>Advanced treatment for recycling the waste water, e.g. ⁽²⁾</i>			
w.	Filtration (e.g. sand filtration, or membrane filtration)	Suspended solids and particulate-bound non-biodegradable or inhibitory pollutants	Generally applicable.
x.	Evaporation	Soluble contaminants (e.g. salts)	

⁽¹⁾ The descriptions of the techniques are given in Section 1.9.3.

⁽²⁾ Minimal waste water discharge (e.g. 'zero liquid discharge') may be achieved using a combination of techniques including advanced treatment techniques for recycling the waste water.

Table 1.3

BAT-associated emission levels (BAT-AELs) for direct discharges

Substance/Parameter		Activities/processes	BAT-AEL ⁽¹⁾ (mg/l)
Adsorbable organically bound halogens (AOX) ⁽²⁾		All activities/processes	0,1–0,4 ⁽³⁾
Chemical oxygen demand (COD) ⁽⁴⁾			40–100 ⁽⁵⁾ ⁽⁶⁾
Hydrocarbon oil index (HOI) ⁽²⁾			1–7
Metals/metalloids	Antimony (Sb)	Pre-treatment and/or dyeing of polyester textile materials	0,1–0,2 ⁽⁷⁾
		Finishing with flame retardants using antimony trioxide	
	Chromium (Cr)	Dyeing with chromium mordant or chromium-containing dyes (e.g. metal-complex dyes)	0,01–0,1 ⁽⁸⁾
	Copper (Cu)	Dyeing Printing with dyes	0,03–0,4
	Nickel (Ni)		0,01–0,1 ⁽⁹⁾
	Zinc (Zn) ⁽²⁾	All activities/processes	0,04–0,5 ⁽¹⁰⁾
Sulphide, easily released (S ²⁻)		Dyeing with sulphur dyes	< 1
Total nitrogen (TN)		All activities/processes	5–15 ⁽¹¹⁾
Total organic carbon (TOC) ⁽⁴⁾			13–30 ⁽⁶⁾ ⁽¹²⁾
Total phosphorus (TP)			0,4–2
Total suspended solids (TSS)			5–30

- (¹) The averaging periods are defined in the general considerations.
- (²) The BAT-AELs only apply when the substance/parameter concerned is identified as relevant in the waste water stream based on the inventory of inputs and outputs mentioned in BAT 2.
- (³) The higher end of the BAT-AEL range may be higher and up to 0,8 mg/l when dyeing polyester and/or modacrylic fibres.
- (⁴) Either the BAT-AEL for COD or the BAT-AEL for TOC applies. The BAT-AEL for TOC is the preferred option because TOC monitoring does not rely on the use of very toxic compounds.
- (⁵) The higher end of the BAT-AEL range may be up to 150 mg/l:
- when the specific amount of waste water discharged is less than 25 m³/t of treated textile materials as a rolling yearly average; or
 - when the abatement efficiency is ≥ 95 % as a rolling yearly average.
- (⁶) No BAT-AEL applies for biochemical oxygen demand (BOD). As an indication, the yearly average BOD₅ level in the effluent from a biological waste water treatment plant will generally be ≤ 10 mg/l.
- (⁷) The higher end of the BAT-AEL range may be higher and up to 1,2 mg/l when dyeing polyester and/or modacrylic fibres.
- (⁸) The higher end of the BAT-AEL range may be higher and up to 0,3 mg/l when polyamide, wool or silk fibres are dyed using metal-complex dyes.
- (⁹) The higher end of the BAT-AEL range may be higher and up to 0,2 mg/l when dyeing or printing with nickel-containing reactive dyes or pigments.
- (¹⁰) The higher end of the BAT-AEL range may be higher and up to 0,8 mg/l when treating viscose fibres or when dyeing using zinc-containing cationic dyes.
- (¹¹) The BAT-AEL may not apply when the temperature of the waste water is low (e.g. below 12 °C) for prolonged periods.
- (¹²) The higher end of the BAT-AEL range may be up to 50 mg/l:
- when the specific amount of waste water discharged is less than 25 m³/t of treated textile materials as a rolling yearly average; or
 - when the abatement efficiency is ≥ 95 % as a rolling yearly average.

The associated monitoring is given in BAT 8.

Table 1.4

BAT-associated emission levels (BAT-AELs) for indirect discharges

Substance/Parameter		Activities/processes	BAT-AEL (¹) (²) (mg/l)
Adsorbable organically bound halogens (AOX) (³)		All processes	0,1–0,4 (⁴)
Hydrocarbon oil index (HOI) (³)		All processes	1–7
Metals/metalloids	Antimony (Sb)	Pre-treatment and/or dyeing of polyester textile materials	0,1–0,2 (⁵)
		Finishing with flame retardants using antimony trioxide	
	Chromium (Cr)	Dyeing with chromium mordant or chromium-containing dyes (e.g. metal-complex dyes)	0,01–0,1 (⁶)
	Copper (Cu)	Dyeing Printing with dyes	0,03–0,4
	Nickel (Ni)	Dyeing Printing with dyes	0,01–0,1 (⁷)
	Zinc (Zn) (³)	All processes	0,04–0,5 (⁸)
Sulphide, easily released (S ²⁻)		Dyeing with sulphur dyes	< 1

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- (¹) The averaging periods are defined in the general considerations.
- (²) The BAT-AELs may not apply if the downstream waste water treatment plant is designed and equipped appropriately to abate the pollutants concerned, provided this does not lead to a higher level of pollution in the environment.
- (³) The BAT-AELs only apply when the substance/parameter concerned is identified as relevant in the waste water stream based on the inventory of inputs and outputs mentioned in BAT 2.
- (⁴) The higher end of the BAT-AEL range may be higher and up to 0,8 mg/l when dyeing polyester and/or modacrylic fibres.
- (⁵) The higher end of the BAT-AEL range may be higher and up to 1,2 mg/l when dyeing polyester and/or modacrylic fibres.
- (⁶) The higher end of the BAT-AEL range may be higher and up to 0,3 mg/l when polyamide, wool or silk fibres are dyed using metal-complex dyes.
- (⁷) The higher end of the BAT-AEL range may be higher and up to 0,2 mg/l when dyeing or printing with nickel-containing reactive dyes or pigments.
- (⁸) The higher end of the BAT-AEL range may be higher and up to 0,8 mg/l when treating viscose fibres or when dyeing using zinc-containing cationic dyes.
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The associated monitoring is given in BAT 8.

1.1.7. Emissions to soil and groundwater

BAT 21. In order to prevent or reduce emissions to soil and groundwater and to improve the overall performance of the handling and storage of process chemicals, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Techniques to reduce the likelihood and environmental impact of overflows and failures of process and storage tanks	This includes: — slow immersion into and withdrawal of textile materials from the process liquor to avoid spillages; — automatic level adjustment of process liquor (see BAT 4); — avoiding direct injection of water to heat or cool the process liquor; — overflow detectors; — channelling overflows to another tank; — locating tanks for liquids (process chemicals or liquid waste) in a suitable secondary containment; their volume is sized to accommodate at least the complete loss of the liquid of the largest tank that is within the secondary containment; — isolation of tanks and secondary containment (e.g. by closing valves); — ensuring that the surfaces of the process and storage areas are impermeable to the liquids concerned.	Generally applicable.
b.	Regular inspection and maintenance of plant and equipment	The plant and the equipment are regularly inspected and maintained to ensure proper functioning; this includes in particular checking the integrity and/or leak-free status of valves, pumps, pipes, tanks and containments/bunds as well as the proper functioning of warning systems (e.g. overflow detectors).	

c.	Optimised storage location of process chemicals	The storage areas are located in such a way as to eliminate or minimise the unnecessary transport of process chemicals within the plant (e.g. the transport distances on site are minimised).	The applicability to existing plants may be restricted by a lack of space.
d.	Dedicated area for unloading process chemicals containing hazardous substances	Process chemicals containing hazardous substances are unloaded in a bunded area. Occasional spillages are collected and sent for treatment.	Generally applicable.
e.	Segregated storage of process chemicals	Incompatible process chemicals are kept separated. This segregation relies on physical separation and on the chemicals inventory (see BAT 15).	
f.	Handling and storage of packaging containing process chemicals	Packaging containing liquid process chemicals is completely emptied by gravity or by mechanical means (e.g. brushing, wiping) without the use of water. Packaging containing process chemicals in powder is emptied by gravity for small packaging and using suction for large packaging. Empty packaging is stored in a dedicated area.	

1.1.8. Emissions to air

BAT 22. In order to reduce diffuse emissions to air (e.g. VOCs from the use of organic solvents), BAT is to collect diffuse emissions and send the waste gases to treatment.

Applicability

In the case of existing plants, the applicability may be restricted by operational constraints or by the high volume of air to be extracted.

BAT 23. In order to facilitate the recovery of energy and the reduction of channelled emissions to air, BAT is to limit the number of emission points.

Description

The combined treatment of waste gases with similar characteristics ensures more effective and efficient treatment compared to the separate treatment of individual waste gas streams. The extent to which the number of emission points can be limited depends on technical (e.g. compatibility of the individual waste gas streams) and economic factors (e.g. distance between different emission points). Care is taken that limiting the number of emission points does not lead to the dilution of emissions.

BAT 24. In order to prevent emissions of organic compounds to air from dry cleaning and from scouring with organic solvent, BAT is to extract the air from these processes, to treat it using adsorption with activated carbon (see Section 1.9.2) and to fully recirculate it.

BAT 25. In order to reduce emissions of organic compounds to air from the pre-treatment of knitted synthetic textile materials, BAT is to wash them prior to thermofixation or heat-setting.

Applicability

Applicability may be limited by the fabric construction.

BAT 26. In order to prevent or reduce channelled emissions of organic compounds to air from singeing, thermal treatment, coating and lamination, BAT is to use one or a combination of the techniques given below.

Technique	Typical pollutants target	Description
<i>Prevention techniques</i>		
a.	Selection and use of mixtures of chemicals ('recipes') leading to low emissions of organic compounds	Organic compounds
		Mixtures with low emissions of organic compounds are selected and used taking into consideration product specifications (see BAT 14, BAT 17, BAT 50, BAT 51). As an example, emission factors may be used for selection (see Section 1.9.1).
<i>Reduction techniques</i>		
b.	Condensation	Organic compounds excluding formaldehyde
c.	Thermal oxidation	Organic compounds
d.	Wet scrubbing	Organic compounds
e.	Adsorption	Organic compounds excluding formaldehyde
		See Section 1.9.2.

Table 1.5

BAT-associated emission levels (BAT-AELs) for channelled emissions of organic compounds and formaldehyde to air

Substance/Parameter	Activities/Processes (including associated thermal treatments)	BAT-AEL (Average over the sampling period) (mg/Nm ³)
Formaldehyde	Coating ⁽¹⁾	1–5 ⁽²⁾ ⁽³⁾
	Flame lamination	
	Printing ⁽¹⁾	
	Singeing	
	Finishing ⁽¹⁾	
TVOC	Coating	3–40 ⁽²⁾ ⁽⁴⁾ ⁽⁵⁾
	Dyeing	
	Finishing	
	Lamination	
	Printing	
	Singeing	
	Thermofixation or heat-setting	

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- (¹) The BAT-AEL only applies when formaldehyde is identified as relevant in the waste gas stream based on the inventory of inputs and outputs mentioned in BAT 2.
- (²) For activities listed under points 3 and 9, Part 1 of Annex VII to the IED, the BAT-AEL ranges only apply to the extent that they lead to lower emission levels than the emission limit values in Parts 2 and 4 of Annex VII to the IED.
- (³) For finishing processes with easy-care agents, water-/oil-/soil-repellents and/or flame retardants, the higher end of the BAT-AEL range may be higher and up to 10 mg/Nm³.
- (⁴) The lower end of the BAT-AEL range is typically achieved when using thermal oxidation.
- (⁵) The BAT-AEL does not apply when the TVOC mass flow is below 200 g/h for emission point(s) where:
- abatement techniques are not used, and
 - no CMR substances are identified as relevant in the waste gas stream based on the inventory of inputs and outputs mentioned in BAT 2.
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The associated monitoring is given in BAT 9.

BAT 27. In order to reduce channelled dust emissions to air from singeing and thermal treatments, excluding thermofixation and heat-setting, BAT is to use one or a combination of the techniques given below.

Technique		Description
a.	Cyclone	See Section 1.9.2 Cyclones are mainly used as pretreatment before further dust abatement (e.g. for coarse dust).
b.	Electrostatic precipitator (ESP)	See Section 1.9.2.
c.	Wet scrubbing	

Table 1.6

BAT-associated emission level (BAT-AEL) for channelled dust emissions to air from singeing and thermal treatments, excluding thermofixation and heat-setting

Substance/Parameter	BAT-AEL (Average over the sampling period) (mg/Nm ³)
Dust	< 2–10 (¹)

(¹) The BAT-AEL does not apply when the dust mass flow is below 50 g/h for emission point(s) where:

- abatement techniques are not used, and
 - no CMR substances are identified as relevant in the waste gas stream based on the inventory of inputs and outputs mentioned in BAT 2.
-

The associated monitoring is given in BAT 9.

BAT 28. In order to prevent or reduce channelled ammonia emissions to air from coating, printing and finishing, including thermal treatments associated with these processes, BAT is to use one or a combination of the techniques given below.

Technique		Description
<i>Prevention techniques</i>		
a.	Selection and use of mixtures of chemicals ('recipes') leading to low emissions of ammonia	Mixtures with low emissions of ammonia are selected and used taking into consideration product specifications (see BAT 14, BAT 17, BAT 46, BAT 47, BAT 50, BAT 51). As an example, emission factors may be used for selection (see Section 1.9.1).

Reduction techniques

b.	Wet scrubbing	See Section 1.9.2.
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Table 1.7

BAT-associated emission level (BAT-AEL) for channelled ammonia emissions to air from coating, printing and finishing, including thermal treatments associated with these processes

Substance/Parameter	BAT-AEL ⁽¹⁾ (Average over the sampling period) (mg/Nm ³)
NH ₃	3–10 ⁽²⁾

⁽¹⁾ The BAT-AEL only applies when NH₃ is identified as relevant in the waste gas stream based on the inventory of inputs and outputs mentioned in BAT 2.

⁽²⁾ The higher end of the BAT-AEL range may be higher and up to 20 mg/Nm³ when ammonium sulphamate is used as a flame retardant or ammonia is used for curing (see BAT 50).

The associated monitoring is given in BAT 9.

1.1.9. Waste

BAT 29. In order to prevent or reduce the generation of waste and to reduce the quantity of waste sent for disposal, BAT is to use all of the techniques given below.

Technique	Description	Applicability
a.	Waste management plan A waste management plan is part of the EMS (see BAT 1) and is a set of features aiming to: — minimise the generation of waste, — optimise the reuse, regeneration, recycling and/or recovery of waste, and — ensure the proper disposal of waste.	The level of detail of the waste management plan will generally be related to the nature, scale and complexity of the plant.
b.	Timely use of process chemicals Criteria are clearly established associated for example with maximum storage time of process chemicals, and relevant parameters are monitored to avoid process chemicals perishing.	Generally applicable.
c.	Reuse/recycling of packaging Process chemicals packaging is selected to facilitate its complete emptying (e.g. considering the size of the packaging aperture or the nature of the packaging material). After emptying (see BAT 21), the packaging is reused, returned to the supplier or sent for material recycling.	
d.	Return of unused process chemicals Unused process chemicals (i.e. which remain in their original containers) are returned to their suppliers.	Generally applicable.

BAT 30. In order to improve the overall environmental performance of the handling of waste, especially to prevent or reduce emissions to the environment, BAT is to use the technique given below before waste is sent for disposal.

Technique	Description
Separate collection and storage of wastes contaminated with hazardous substances and/or substances of very high concern	Wastes contaminated with hazardous substances and/or substances of very high concern (e.g. finishing chemicals such as flame retardants, oil-, water- and soil-repellents) are collected and stored separately. These wastes may contain high loads of pollutants such as organophosphorus and brominated flame retardants, PFAS, phthalates and chromium-(VI)-containing compounds (see BAT 18) and include in particular: — liquid waste (e.g. first rinsing water in flame retardance finishing), coating and printing pastes; — waste paper, cloths, absorbent material; — laboratory waste; — sludge from waste water treatment.

1.2. **BAT conclusions for the pre-treatment of raw wool fibres by scouring**

The BAT conclusions in this section apply to the pre-treatment of raw wool fibres by scouring and apply in addition to the general BAT conclusions in Section 1.1.

BAT 31. In order to use resources efficiently as well as to reduce water consumption and waste water generation, BAT is to recover wool grease and recycle waste water.

Description

Waste water from wool scouring is treated (e.g. by a combination of centrifugation and sedimentation) to separate grease, dirt and water. Grease is recovered, water is partially recycled to scouring and dirt is sent for further treatment.

Table 1.8

BAT-associated environmental performance levels (BAT-AEPLs) for the recovery of wool grease from the pre-treatment of raw wool fibres by scouring

Type of wool	Unit	BAT-AEPL (Yearly average)
Coarse wool (i.e. wool fibre diameter typically higher than 35 µm)	kg of recovered grease per tonne of raw wool fibres pretreated by scouring	10–15
Extra- and super-fine wool (i.e. wool fibre diameter typically lower than 20 µm)		50–60

The associated monitoring is given in BAT 6.

BAT 32. In order to use energy efficiently, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Covered scouring bowls	Scouring bowls are fitted with covers to prevent heat losses by convection or evaporation (see BAT 11 (c)).	Only applicable to new plants or major plant upgrades.
b.	Optimised temperature of the last scouring bowl	The temperature of the last scouring bowl is optimised to increase the efficiency of the subsequent mechanical wool dewatering (see BAT 13 (a)) and drying.	Generally applicable.
c.	Direct heating	Scouring bowls and dryers are directly heated in order to avoid the heat losses which occur in the generation and distribution of steam.	Only applicable to new plants or major plant upgrades.

BAT 33. In order to use resources efficiently and to reduce the amount of waste sent for disposal, BAT is to biologically treat organic residues from the pre-treatment of raw wool fibres by scouring (e.g. dirt, waste water treatment sludge).

Description

The organic residues are treated, for example by composting.

1.3. BAT conclusions for the spinning of fibres (other than man-made fibres) and the production of fabric

The BAT conclusions presented in this section apply to the spinning of fibres (other than man-made fibres) and the production of fabric and apply in addition to the general BAT conclusions in Section 1.1.

BAT 34. In order to reduce emissions to water from the use of sizing chemicals, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Selection of sizing chemicals	Sizing chemicals with improved environmental performance in terms of quantity needed, washability, recoverability and/or bioeliminability/biodegradability (e.g. modified starches, certain galactomannans and carboxymethyl cellulose) are selected (see BAT 14) and used.	Generally applicable.
b.	Pre-wetting of the cotton yarns	The cotton yarns are dipped into hot water prior to sizing. This allows a reduction of the amounts of sizing chemicals used.	The applicability may be restricted by product specifications (e.g. when high tension is required on the fibre during weaving).
c.	Compact spinning	The fibre strands are compressed by suction or by mechanical or magnetic compacting. This allows a reduction of the amounts of sizing chemicals used.	The applicability may be restricted by product specifications (e.g. level of hairiness or technical properties of the yarn).

BAT 35. In order to improve the overall environmental performance of spinning and knitting, BAT is to avoid the use of mineral oils.

Description

Mineral oils are substituted by synthetic oils and/or ester oils, with improved environmental performance in terms of washability and bioeliminability/biodegradability.

BAT 36. In order to use energy efficiently, BAT is to use technique (a) and one or both of techniques (b) and (c) given below.

Technique		Description	Applicability
a.	Use of general energy-saving techniques for spinning and weaving	This includes: — reducing, as much as possible, the volume of the production area (e.g. by installing a suspended ceiling) to reduce the amount of energy needed for humidifying the ambient air; — using advanced sensors that detect thread breaks to stop the spinning or weaving machines.	Generally applicable.
b.	Use of energy-saving techniques for spinning	This includes: — using lighter spindles and bobbins in ring frames; — using spindle oil with optimal viscosity; — maintaining an optimal oiling level of the yarn; — optimising the ring diameter with respect to the yarn diameter in ring frames; — gradual start-up of the ring spinning machines; — using vortex spinning; — optimising the movement of empty bobbin conveyors in cone winding machines.	Generally applicable.
c.	Use of energy-saving techniques for weaving	This includes: — avoiding excessive air pressure for air-jet weaving; — using a double-width loom for large-volume batches.	A double-width loom may only be applicable to new plants or major plant upgrades.

1.4. BAT conclusions for the pre-treatment of textile materials other than raw wool fibres

The BAT conclusions in this section apply to the pre-treatment of textile materials other than raw wool fibres and apply in addition to the general BAT conclusions in Section 1.1.

BAT 37. In order to use resources and energy efficiently as well as to reduce water consumption and waste water generation, BAT is to use both techniques (a) and (b), in combination with technique (c) or in combination with technique (d) given below.

Technique		Description	Applicability
a.	Combined pre-treatment of cotton textile	Various pre-treatment operations of cotton textiles (e.g. washing, desizing, scouring and bleaching) are carried out simultaneously.	Generally applicable.
b.	Cold pad-batch treatment of cotton textiles	Desizing and/or bleaching are carried out with the cold pad-batch technique (see Section 1.9.4).	Generally applicable.
c.	Single or limited number of desizing liquors	The number of desizing liquors for removing different types of sizing chemicals is limited. In some cases, e.g. for various cellulosic materials, a single oxidative desizing liquor may be used.	Generally applicable.
d.	Recovery and reuse of water-soluble sizing chemicals	When desizing is carried out by washing with hot water, water-soluble sizing chemicals (e.g. polyvinyl alcohol and carboxymethyl cellulose) are recovered from the washing water by ultrafiltration. The concentrate is reused for sizing, whereas the permeate is reused for washing.	Only applicable where sizing and desizing are carried out at the same plant. May not be applicable for synthetic sizing chemicals (e.g. containing polyester polyols, polyacrylates or polyvinyl acetate).

BAT 38. In order to prevent or reduce emissions to water of chlorine-containing compounds and complexing agents, BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Chlorine-free bleaching	Bleaching is carried out with chlorine-free bleaching chemicals (e.g. hydrogen peroxide, peracetic acid or ozone), often combined with pre-treatment with enzymes (see BAT 16 (c)).	May not be applicable to the brightening of flax and other bast fibres.
b.	Optimised hydrogen peroxide bleaching	The use of complexing agents can be completely avoided or minimised by reducing the concentration of hydroxyl radicals during bleaching. This is achieved by: — using soft/softened water; — prior removal of metal impurities from textile materials (e.g. by magnetic separation, chemical treatment or pre-washing); — controlling the pH and the hydrogen peroxide concentration during bleaching.	Generally applicable.

BAT 39. In order to use resources efficiently and to reduce the amount of alkali discharged to waste water treatment, BAT is to recover caustic soda used for mercerisation.

Description

Caustic soda is recovered from the rinsing water by evaporation and further purified, if needed. Before evaporation, the impurities in the rinsing water are removed by using, for example, screens and/or microfiltration.

Applicability

Applicability may be restricted by a lack of suitable recovered heat and/or by a low amount of caustic soda.

Table 1.9

BAT-associated environmental performance level (BAT-AEPL) for the recovery of caustic soda used for mercerisation

Unit	BAT-AEPL (Yearly average)
% of caustic soda recovered	75–95

The associated monitoring is given in BAT 6.

1.5. **BAT conclusions for dyeing**

The BAT conclusions in this section apply to dyeing and apply in addition to the general BAT conclusions in Section 1.1.

BAT 40. In order to use resources efficiently and to reduce emissions to water from dyeing, BAT is to use one or a combination of the techniques given below.

Technique		Description
<i>Techniques for batch and continuous dyeing</i>		
a.	Selection of dyes	Dyes with dispersing agents that are biodegradable (e.g. based on fatty acid esters) are selected.
b.	Dyeing with levelling agents made from recycled vegetable oil	Levelling agents made from recycled vegetable oil are used in high-temperature dyeing of polyester and in dyeing of protein and polyamide fibres.
<i>Techniques for batch dyeing</i>		
c.	pH-controlled dyeing	For textile materials with zwitterionic characteristics, dyeing is carried out at constant temperature and controlled by gradually lowering the pH of the dyeing liquor below the isoelectric point of the textile materials.
d.	Optimised removal of unfixed dyestuff in reactive dyeing	Unfixed dyestuff is removed from the textile materials by using enzymes (e.g. laccase, lipase) (see BAT 16 (c)) and/or vinyl polymers. This reduces the number of rinsing steps needed.
<i>Techniques for batch dyeing</i>		
e.	Low-liquor-ratio systems	See Section 1.9.4.
<i>Techniques for continuous dyeing</i>		
f.	Low-volume application systems	See Section 1.9.4.

BAT 41. In order to use resources efficiently and to reduce emissions to water from the dyeing of cellulosic materials, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
<i>Technique for dyeing with sulphur and vat dyes</i>			
a.	Minimised use of sulphur-based reducing agents	Dyeing is carried out without sodium sulphide or hydrosulphite as reducing agents. Where this is not possible, partially chemically pre-reduced dyes (e.g. indigo dyes) are used so that less sodium sulphide or hydrosulphite is added for dyeing.	The applicability may be restricted by product specifications (e.g. shade).
<i>Technique for continuous dyeing with vat dyes</i>			
b.	Selection of vat dyes	Vat dyes that are not prone to emissions during the use phase of the textile are selected. Auxiliaries (e.g. polyglycols) are used to enable dyeing with less or without subsequent steaming, oxidising and washing and to ensure appropriate colour fastness.	May not be applicable to dyeing with dark shades.
<i>Techniques for dyeing with reactive dyes</i>			
c.	Use of poly-functional reactive dyes	Poly-functional reactive dyes with more than one reactive functional group are used to provide a high level of fixation in exhaust dyeing.	Generally applicable.
d.	Cold pad-batch dyeing	Dyeing is carried out with the cold pad-batch technique (see Section 1.9.4).	Generally applicable.
e.	Optimised rinsing	Rinsing after dyeing with reactive dyes is carried out at a high temperature (e.g. up to 95 °C) and without using detergents. The heat of the rinsing water is recovered (see BAT 11 (i)).	Generally applicable.
<i>Techniques for continuous dyeing with reactive dyes</i>			
f.	Use of concentrated alkali solution	In cold pad-batch dyeing (see Section 1.9.4), concentrated aqueous alkali solutions without sodium silicate are used for the fixation of dyes.	May not be applicable to dyeing with dark shades.
g.	Steam fixation of reactive dyes	The reactive dyes are fixed with steam, which avoids the use of chemicals for fixation.	The applicability may be restricted by the characteristics of the textile materials and by product specifications (e.g. high-quality dyeing of polyester/cotton blends).

BAT 42. In order to reduce emissions to water from the dyeing of wool, BAT is to use one of the techniques given below in the following order of priority.

Technique		Description	Applicability
a.	Optimised reactive dyeing	Wool dyeing is carried out with reactive dyes without chromium mordant.	Generally applicable.
b.	Optimised metal-complex dyeing	Dyeing is carried out with metal-complex dyes under optimised conditions in terms of pH, auxiliaries and acid used, in order to increase the exhaustion of the dyeing liquor and the fixation of the dyes.	May not be applicable to dyeing with dark shades.
c.	Minimised use of chromates	When the use of sodium or potassium dichromate as mordant is authorised, dichromates are dosed as a function of the amount of dye taken up by the wool. Dyeing parameters (e.g. pH and temperature of the dyeing liquor) are optimised to ensure that the dyeing liquor is exhausted as much as possible.	Generally applicable.

BAT 43. In order to reduce emissions to water from the dyeing of polyester with disperse dyes, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Batch dyeing without dyestuff carriers	Batch dyeing of polyester and wool-free polyester blends is carried out at high temperature (e.g. 130 °C) without the use of dyestuff carriers.	Generally applicable.
b.	Use of environmentally friendly dyestuff carriers in batch dyeing	Batch dyeing of polyester-wool blends is carried out with chlorine-free and biodegradable dyestuff carriers.	
c.	Optimised desorption of unfixed dye in batch dyeing	This includes: — using a desorption accelerator based on carboxylic acid derivatives; — using a reducing agent that can be used in the acidic conditions of the spent dyeing liquor; — using disperse dyes that can be desorbed in alkaline conditions by hydrolysis instead of reduction.	The use of a reducing agent that can be used in acidic conditions may not be applicable to polyester-elastane blends. The use of dyes that are desorbable in alkaline conditions may be restricted by product specifications (e.g. colour fastness and shade).

1.6. **BAT conclusions for printing**

The BAT conclusions in this section apply to printing and apply in addition to the general BAT conclusions in Section 1.1.

BAT 44. In order to reduce water consumption and waste water generation, BAT is to optimise the cleaning of the printing equipment.

Description

This includes:

- mechanical removal of the printing paste;
- automatic start and stop of the cleaning water supply;
- reuse and/or recycling of cleaning water (see BAT 10 (i)).

BAT 45. In order to use resources efficiently, BAT is to use a combination of the techniques given below.

Technique	Description	Applicability
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Selection of printing technology

a.	Digital jet printing	Computer-controlled injection of dye onto textile materials.	Only applicable to new plants or major plant upgrades.
b.	Transfer printing on synthetic textile materials	The design is first printed on an intermediate substrate (e.g. paper) using selected disperse dyes and is subsequently transferred to the fabric by applying high temperature and pressure.	

Design and operation technique

c.	Optimised use of printing paste	This includes: — minimisation of the volume of the printing paste supply system (e.g. minimising pipe lengths and diameters); — ensuring a uniform paste distribution over the whole width of the printing machine; — stopping the supply of printing paste shortly before the end of the printing; — manual addition of printing paste for small-scale usage.	Generally applicable.
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Recovery and reuse of printing paste

d.	Recovery of residual printing paste in rotary screen printing	Residual printing paste in the supply system is pushed back to its original container.	Applicability in existing plants may be restricted by the equipment.
e.	Reuse of residual printing paste	The residual printing paste is collected, sorted by type, stored and reused. The degree of reuse of printing paste is limited by its perishability.	Generally applicable.

BAT 46. In order to prevent ammonia emissions to air and to prevent the generation of urea-containing waste water from printing with reactive dyes on cellulosic materials, BAT is to use one of the techniques given below.

	Technique	Description
a.	Reduction of urea content in printing pastes	Printing is carried out with a reduced amount of urea in printing pastes and by controlling the moisture content of textile materials.
b.	Two-step printing	Printing is carried out without urea by two padding steps with intermediate drying and addition of fixation agents (e.g. sodium silicate).

BAT 47. In order to reduce emissions of organic compounds (e.g. formaldehyde) and ammonia to air from printing with pigments, BAT is to use printing chemicals with improved environmental performance.

Description

This includes:

- thickeners with no or low contents of volatile organic compounds;
- fixation agents with low potential for formaldehyde releases;
- binders with low contents of ammonia and low potential for formaldehyde releases.

1.7. **BAT conclusions for finishing**

The BAT conclusions in this section apply to finishing and apply in addition to the general BAT conclusions in Section 1.1.

1.7.1. **Easy-care finishing**

BAT 48. In order to reduce emissions of formaldehyde to air from easy-care finishing of textile materials made of cellulosic fibres and/or blends of cellulosic and synthetic fibres, BAT is to use cross-linking agents with no or low potential for formaldehyde releases.

1.7.2. **Softening**

BAT 49. In order to improve the overall environmental performance of softening, BAT is to use one of the techniques given below.

	Technique	Description
a.	Low-volume application of softening agents	See Section 1.9.4. Softening agents are not added to the dyeing liquor but applied in a separate process step by padding, spraying or foaming.
b.	Softening of cotton textile materials with enzymes	See BAT 16 (c). Enzymes are used for softening, possibly in combination with washing or dyeing.

1.7.3. Flame retardance finishing

BAT 50. In order to improve the overall environmental performance, especially to prevent or reduce emissions to the environment and waste, of flame retardance finishing, BAT is to use one or both of the techniques given below, giving priority to technique (a).

Technique		Description	Applicability
a.	Use of textile materials with inherent flame retardance properties	Textiles that do not require finishing with flame retardants are used.	The applicability may be restricted by product specifications (e.g. flame retardance).
b.	Selection of flame retardants	Flame retardants are selected considering: — the risks associated with them, in particular in terms of persistence and toxicity, including the potential for substitution (e.g. brominated flame retardants, see BAT 14 point I.(d)); — the composition and form of the textile materials to be treated; — the product specifications (e.g. combined flame retardance and oil-/water-/soil-repellence, wash durability).	Generally applicable.

1.7.4. Oil-, water- and soil-repellence finishing

BAT 51. In order to improve the overall environmental performance, especially to prevent or reduce emissions to the environment and waste, of oil-, water- and soil-repellence finishing, BAT is to use oil-, water- and soil-repellents with improved environmental performance.

Description

Oil-, water- and soil-repellents are selected considering:

- the risks associated with them, in particular in terms of persistence and toxicity, including the potential for substitution (e.g. PFAS, see BAT 14 point I.(d));
- the composition and form of the textile materials to be treated;
- the product specifications (e.g. combined oil-, water-, soil-repellence and flame retardance).

1.7.5. Shrink-proof finishing of wool

BAT 52. In order to reduce emissions to water from shrink-proof finishing of wool, BAT is to use chlorine-free antifelting chemicals.

Description

Inorganic salts of peroxymonosulphuric acid are used for shrink-proof finishing of wool.

Applicability

The applicability may be restricted by product specifications (e.g. shrinkage).

1.7.6. Mothproofing

BAT 53. In order to reduce the consumption of mothproofing agents, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Selection of dyeing auxiliaries	When mothproofing agents are added directly in the dyeing liquor, dyeing auxiliaries (e.g. levelling agents) that do not hinder the uptake of mothproofing agents are selected.	Generally applicable.
b.	Low-volume application of mothproofing agents	see Section 1.9.4. In the case of spraying, the excess mothproofing solution is recovered from the textile materials by centrifugation and reused.	Generally applicable.

1.8. BAT conclusions for lamination

The BAT conclusion presented in this section applies to lamination and applies in addition to the general BAT conclusions in Section 1.1.

BAT 54. In order to reduce emissions of organic compounds to air from lamination, BAT is to use hot-melt lamination instead of flame lamination.

Description

Molten polymers are applied to textiles without the use of a flame.

Applicability

May not be applicable to thin textiles and may be restricted by the strength of the bond between the laminate and textile materials.

1.9. Description of techniques

1.9.1. Technique to select process chemicals, prevent or reduce emissions to air

Technique	Description
Emission factors	Emission factors are representative values that attempt to relate the quantity of a substance emitted to a process associated with the emission of that substance. Emission factors are derived from emission measurements according to a predefined protocol considering the textile materials and the reference processing conditions (e.g. curing time and temperature). They are expressed as the mass of a substance emitted divided by the mass of textile materials treated at the reference processing conditions (e.g. grams of organic carbon emitted per kg of textile materials treated at a waste gas flow of 20 m ³ /h). The quantity, hazardous properties and composition of the mixture of the process chemicals and their pick-up by the textile material are considered.

1.9.2. **Techniques to reduce emissions to air**

Technique	Description
Adsorption	The removal of pollutants from a waste gas stream by retention on a solid surface (activated carbon is typically used as an adsorbent). Adsorption may be regenerative or non-regenerative. In non-regenerative adsorption, the spent adsorbent is not regenerated but disposed of. In regenerative adsorption, the adsorbate is subsequently desorbed, e.g. with steam (often on site), for reuse or disposal and the adsorbent is reused. For continuous operation, typically more than two adsorbers are operated in parallel, one of them in desorption mode.
Condensation	Condensation is a technique that eliminates vapours of organic and inorganic compounds from a waste gas stream by reducing its temperature below its dew point.
Cyclone	Equipment for the removal of dust from a waste gas stream based on imparting centrifugal forces, usually within a conical chamber.
Electrostatic precipitator (ESP)	Electrostatic precipitators (ESPs) operate such that particles are charged and separated under the influence of an electrical field. Electrostatic precipitators are capable of operating under a wide range of conditions. Abatement efficiency may depend on the number of fields, residence time (size), and upstream particle removal devices. They generally include between two and five fields. Electrostatic precipitators can be of the dry or of the wet type depending on the technique used to collect the dust from the electrodes.
Thermal oxidation	The oxidation of combustible gases and odorants in a waste gas stream by heating the mixture of contaminants with air or oxygen to above its auto-ignition point in a combustion chamber and maintaining it at a high temperature long enough to complete its combustion to carbon dioxide and water.
Wet scrubbing	The removal of gaseous or particulate pollutants from a waste gas stream via mass transfer to water or an aqueous solution. It may involve a chemical reaction (e.g. in an acid or alkaline scrubber).

1.9.3. **Techniques to reduce emissions to water**

Technique	Description
Activated sludge process	The biological oxidation of dissolved organic pollutants with oxygen using the metabolism of microorganisms. In the presence of dissolved oxygen (injected as air or pure oxygen), the organic components are transformed into carbon dioxide, water or other metabolites and biomass (i.e. the activated sludge). The microorganisms are maintained in suspension in the waste water and the whole mixture is mechanically aerated. The activated sludge mixture is sent to a separation facility from where the sludge is recycled to the aeration tank.

Adsorption	Separation method in which compounds in a fluid (e.g. waste water) are retained on a solid surface (typically activated carbon).
Anaerobic treatment	The biological transformation of dissolved organic and inorganic pollutants in the absence of oxygen using the metabolism of microorganisms. Transformation products include methane, carbon dioxide, and sulphide. The process is carried out in an airtight stirred reactor. The most commonly used reactor types are: — anaerobic contact reactor; — upflow anaerobic sludge blanket; — fixed-bed reactor; — expanded-bed reactor.
Chemical oxidation	Organic compounds are oxidised to less harmful and more easily biodegradable compounds. Techniques include wet oxidation or oxidation with ozone or hydrogen peroxide, optionally supported by catalysts or UV radiation. Chemical oxidation is also used to degrade organic compounds causing odour, taste and colour nuisances and for disinfection purposes.
Chemical reduction	Chemical reduction is the conversion of pollutants by chemical reducing agents into less harmful compounds.
Coagulation and flocculation	Coagulation and flocculation are used to separate suspended solids from waste water and are often carried out in successive steps. Coagulation is carried out by adding coagulants with charges opposite to those of the suspended solids. Flocculation is carried out by adding polymers, so that collisions of microfloc particles cause them to bond to produce larger flocs. The flocs formed are subsequently separated by sedimentation, air flotation or filtration.
Equalisation	Balancing of flows and pollutant loads by using tanks or other management techniques.
Evaporation	The use of distillation to concentrate aqueous solutions of high-boiling substances for further use, processing or disposal (e.g. waste water incineration) by transferring water to the vapour phase. It is typically carried out in multistage units with increasing vacuums, to reduce the energy demand. The water vapours are condensed, to be reused or discharged as waste water.
Filtration	The separation of solids from waste water by passing them through a porous medium, e.g. sand or membrane filtration (see Membrane filtration below).
Flotation	The separation of solid or liquid particles from waste water by attaching them to fine gas bubbles, usually air. The buoyant particles accumulate at the water surface and are collected with skimmers.
Membrane bioreactor	A combination of activated sludge treatment and membrane filtration. Two variants are used: a) an external recirculation loop between the activated sludge tank and the membrane module; and b) immersion of the membrane module in the aerated activated sludge tank, where the effluent is filtered through a hollow fibre membrane, the biomass remaining in the tank.

Membrane filtration	Microfiltration, ultrafiltration, nanofiltration and reverse osmosis are membrane filtration processes that retain and concentrate, on one side of the membrane, pollutants such as suspended particles and colloidal particles contained in waste waters. They differ in terms of membrane pore sizes and hydrostatic pressure.
Neutralisation	The adjustment of the pH of waste water to a neutral level (approximately 7) by the addition of chemicals. Sodium hydroxide (NaOH) or calcium hydroxide (Ca(OH) ₂) may be used to increase the pH, whereas sulphuric acid (H ₂ SO ₄), hydrochloric acid (HCl) or carbon dioxide (CO ₂) may be used to decrease the pH. Some pollutants may precipitate as insoluble compounds during neutralisation.
Nitrification/denitrification	A two-step process that is typically incorporated into biological waste water treatment plants. The first step is aerobic nitrification where microorganisms oxidise ammonium (NH ₄ ⁺) to the intermediate nitrite (NO ₂ ⁻), which is then further oxidised to nitrate (NO ₃ ⁻). In the subsequent anoxic denitrification step, microorganisms chemically reduce nitrate to nitrogen gas.
Oil-water separation	The separation of oil and water including the subsequent oil removal by gravity separation of free oil, using separation equipment or emulsion breaking (using emulsion-breaking chemicals such as metal salts, mineral acids, adsorbents and organic polymers).
Screening and grit separation	The separation of water and insoluble contaminants such as sand, fibre, fluff or other coarse materials from the textile effluent by filtering through screens or gravitational settling in grit chambers.
Precipitation	The conversion of dissolved pollutants into insoluble compounds by adding precipitants. The solid precipitates formed are subsequently separated by sedimentation, air flotation or filtration.
Sedimentation	The separation of suspended particles by gravitational settling.

1.9.4. Techniques to reduce the consumption of water, energy and chemicals

Technique	Description
Cold pad-batch treatment	In cold pad-batch treatment, the process liquor is applied by padding (e.g. with a foulard) and the impregnated fabric is slowly rotated at room temperature for a prolonged period. This technique allows a reduced consumption of chemicals and does not require subsequent steps such as thermal fixation and thereby reduces energy consumption.
Low-liquor-ratio systems (for batch processes)	A low liquor ratio can be achieved by improving the contact between the textile materials and the process liquor (e.g. by creating turbulence in the process liquor), by advanced process monitoring, by improved dosage and application of process liquor (e.g. by jets or spraying) and by avoiding the mixing of process liquor with washing or rinsing water.
Low-volume application systems (for continuous processes)	The fabric is impregnated with process liquor by spraying, vacuum suction through the fabric, foaming, padding, and dipping in nips (process liquor contained in the gap between two rollers) or in reduced-volume tanks, etc.

COMMISSION IMPLEMENTING DECISION (EU) 2022/2509**of 15 December 2022****determining quantitative limits and allocating quotas for substances controlled under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, for the period 1 January to 31 December 2023***(notified under document C(2022) 9109)***(Only the Bulgarian, Croatian, Czech, Dutch, English, Finnish, French, German, Hungarian, Irish, Italian, Latvian, Maltese, Polish, Portuguese, Spanish and Swedish texts are authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer ⁽¹⁾, and in particular Articles 10(2) and 16(1) thereof,

Whereas:

- (1) The release for free circulation in the Union of imported controlled substances is subject to quantitative limits.
- (2) The Commission is required to determine those limits and allocate quotas to undertakings.
- (3) Furthermore, the Commission is required to determine the quantities of controlled substances other than hydrochlorofluorocarbons that may be used for essential laboratory and analytical uses, and the undertakings that may use them.
- (4) The determination of the allocated quotas for essential laboratory and analytical uses has to ensure that the quantitative limits set out in Article 10(6) of Regulation (EC) No 1005/2009 are respected, applying Commission Regulation (EU) No 537/2011 ⁽²⁾. As those quantitative limits include quantities of hydrochlorofluorocarbons licensed for laboratory and analytical uses, the production and import of hydrochlorofluorocarbons for those uses should also be covered by that allocation.
- (5) The Commission has published a notice to undertakings intending to import or export controlled substances that deplete the ozone layer to or from the European Union in 2023 and to undertakings intending to produce or import these substances for laboratory and analytical uses in 2023 ⁽³⁾, and has thereby received declarations on intended imports in 2023.
- (6) The quantitative limits and quotas should be determined for the period 1 January to 31 December 2023, in line with the annual reporting cycle under the Montreal Protocol on Substances that Deplete the Ozone Layer.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 25(1) of Regulation (EC) No 1005/2009,

⁽¹⁾ OJ L 286, 31.10.2009, p. 1.

⁽²⁾ Commission Regulation (EU) No 537/2011 of 1 June 2011 on the mechanism for the allocation of quantities of controlled substances allowed for laboratory and analytical uses in the Union under Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer (OJ L 147, 2.6.2011, p. 4).

⁽³⁾ OJ C 104, 4.3.2022, p. 46.

HAS ADOPTED THIS DECISION:

Article 1

Quantitative limits for release for free circulation

The quantities of controlled substances subject to Regulation (EC) No 1005/2009 which may be released for free circulation in the Union in 2023 from sources outside the Union shall be the followings:

Controlled substances	Quantity (in ozone depleting potential (ODP) kilograms)
Group I (chlorofluorocarbons 11, 12, 113, 114 and 115) and group II (other fully halogenated chlorofluorocarbons)	500 550,00
Group III (halons)	26 559 050,00
Group IV (carbon tetrachloride)	385 552,20
Group V (1,1,1-trichloroethane)	2 500 000,00
Group VI (methyl bromide)	588 835,20
Group VII (hydrobromofluorocarbons)	4 788,16
Group VIII (hydrochlorofluorocarbons)	4 878 559,75
Group IX (bromochloromethane)	264 024,00

Article 2

Allocation of quotas for release for free circulation

1. The allocation of quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex I.
2. The allocation of quotas for halons during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex II.
3. The allocation of quotas for carbon tetrachloride during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex III.
4. The allocation of quotas for 1,1,1-trichloroethane during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex IV.
5. The allocation of quotas for methyl bromide during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex V.
6. The allocation of quotas for hydrobromofluorocarbons during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex VI.
7. The allocation of quotas for hydrochlorofluorocarbons during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex VII.
8. The allocation of quotas for bromochloromethane during the period 1 January to 31 December 2023 shall be for the purposes and to the undertakings indicated in Annex VIII.
9. The individual quotas for undertakings shall be as set out in Annex IX.

Article 3

Quotas for laboratory and analytical uses

The quotas for importing and producing controlled substances for laboratory and analytical uses in the year 2023 shall be allocated to the undertakings listed in Annex X.

The maximum quantities that may be produced or imported in 2023 for laboratory and analytical uses allocated to those undertakings are set out in Annex XI.

Article 4

Period of validity

This Decision shall apply from 1 January 2023 until 31 December 2023.

Article 5

Addressees

This Decision is addressed to the following undertakings:

1	A-Gas Deutschland GmbH Bei den Kämpen 22 21220 Seevetal Germany	2	A-Gas Italia s.r.l. Via Cavour 96 67051 Avezzano Italy
3	Abcr GmbH Im Schlebert 10 76187 Karlsruhe Germany	4	AGC Pharma Chemicals Europe Cami de la Pomereda 13 08380 Malgrat de Mar Spain
5	Agilent Technologies Deutschland GmbH Hewlett-Packard-Str. 8 D-76337 Waldbronn Germany	6	Airsense Analytics GmbH Hagenower Str. 73 19061 Schwerin Germany
7	Albemarle Europe SPRL Parc Scientifique Einstein, Rue du Bosquet 9 B-1348 Louvain-la-Neuve Belgium	8	Arkema France Rue Estienne d'Orves 420 92705 Colombes Cedex France
9	Ateliers Bigata SASU Rue Jean-Baptiste Perrin 10 33320 Eysines France	10	BASF Agri-Production S.A.S. Rue de Verdun 32 76410 Saint-Aubin Les Elbeuf France
11	Bayer AG Alfred-Nobel-Str. 50 40789 Monheim Germany	12	Biovit d.o.o. Varazdinska ulica – Odvojak II 15 HR-42000 Varazdin Croatia
13	BTC B.V. Albert Thijsstraat 65 6471WX Eygelshoven Netherlands	14	Ceram Optec SIA Skanstes street 7 K-1 LV-1013 Riga Latvia
15	Chemours Netherlands B.V. Baanhoekweg 22 3313LA Dordrecht Netherlands	16	CPAChem Ltd Ivanka Terzieva 2 6065 Bogomilovo Bulgaria

17	Daikin Refrigerants Frankfurt GmbH Industriepark Hoechst D821 65926 Frankfurt Germany	18	Dyneon GmbH Industrieparkstr. 1 84508 Burgkirchen Germany
19	EAF protect s.r.o. Karlovarská 131/50 35002 Cheb 2 Czech Republic	20	Euroapi France La paterie 4 63480 Vertolaye France
21	Fermion oy Koivu-Mankkaan tie 6 02200 Espoo Finland	22	FOT LTD Ovcha kupel 13 1618 Sofia Bulgaria
23	Gedeon Richter Plc. Gyömrői út 19-21. H-1103 Budapest Hungary	24	GHC Gerling, Holz & Co. Handels GmbH Ruhrstr. 113 22761 Hamburg Germany
25	Gielle Industries di Luigi Galantucci Via Ferri Rocco 32 70022 Altamura Italy	26	Hovione FarmaCiencia SA Quinta de S. Pedro – Sete Casas 2674-506 Loures Portugal
27	Hugen Maintenance for Aircraft B.V. Marketing 43 6921 Duiven Netherlands	28	Hugen Reprocessing Company Dutch Halonbank bv Marketing 43 6921 RE Duiven Netherlands
29	I2 Analytical Limited sp. z o. o. Oddział w Polsce Pionierów 39 41-711 Ruda Śląska Poland	30	ICL Europe Cooperatief U.A. Koningin Wilhelminaplein 30 1062 KR Amsterdam Netherlands
31	Interscience B.V. Tinstraat 16 4823AA Breda Netherlands	32	L'Hotelier SAS Rue Henri Poincaré 4 92160 Antony France
33	Labmix24 GmbH Industriestr. 18A 46499 Hamminkeln Germany	34	Laboratorios Miret S.A. Geminis 4 08228 Terrassa Spain
35	Laboratory Supplies Ltd T/A Lennox JFK Drive D12FP79 Dublin Ireland	36	LGC Standards GmbH Mercatorstr. 51 46485 Wesel Germany
37	Lufthansa Technik AG Weg beim Jäger 193 22335 Hamburg Germany	38	Martec SpA Via dell'industria 1 I-20060 Vignate Italy
39	Mebrom NV Suikerkaai 66 9060 Zelzate Belgium	40	Mebrom Technology NV Antwerpsesteenweg 45 2830 Willebroek Belgium
41	Neochema GmbH Uwe-Zeidler-Ring 10 55294 Bodenheim Germany	42	P.U. Poz-Pliszka Sp. z o.o. Mialki Szlak 52 80-717 Gdansk Poland

43	Philipps-Universität Marburg Biegenstrasse 10 35032 Marburg Germany	44	R.P. Chem s.r.l. Via San Michele 47 31032 Casale sul Sile (TV) Italy
45	Restek France Avenue du General de Gaulle 7 91090 Lisses France	46	Restek GmbH Schaberweg 23 Bad Homburg Germany
47	Restek S.r.l. Via G. Miglioli 2/A 20063 Cernusco sul Naviglio Italy	48	Savi Technologie sp. z o.o. sp. k. Psary Wolnosci 20 51-180 Wroclaw Poland
49	Sigma Aldrich Chimie sarl Rue de Luzais 80 38070 Saint Quentin Fallavier France	50	Sigma-Aldrich Chemie GmbH Riedstraße 2 89555 Steinheim Germany
51	Societe Air France Industries Aéroport de Paris 94290 Villeneuve le Roi France	52	Solvay Fluor GmbH Hans-Boeckler-Allee 20 30173 Hannover Germany
53	Solvay France S.A Rue des Cuirassiers, Immeuble Silex 2 Solvay 9 69003 Lyon France	54	Solvay Specialty Polymers Italy SpA Viale Lombardia 20 20021 Bollate Italy
55	Sterling Chemical Malta Limited Hal Far Industrial Estate HF 51 1504 Floriana Malta	56	Sterling SpA Via della Carboneria 30 06073 Solomeo – Corciano (PG) Italy
57	Tazzetti SAU Calle Roma 2 28813 Torres de la Alameda Spain	58	Tazzetti SpA Corso Europa 600/A 10088 Volpiano Italy
59	Techlab SARL La tannerie 4C 57072 Metz Cedex 3 France	60	TEGA – Technische Gase und Gasetechnik GmbH Werner-von-Siemens-Str. 18 D-97076 Würzburg Germany
61	Ultra Scientific Italia srl Via emilia 51/D 40011 Anzola emilia Italy	62	UTM Umwelt-Technik-Metallrecycling GmbH Alt-Herrenwyk 12 23569 Lübeck Germany
63	Valliscor Europa Limited City Quay 13-18 D02 ED70 Dublin Ireland	64	Vatro-Servis d.o.o. Dravska 61 42202 Trnovec Bartolovecki Croatia

Done at Brussels, 15 December 2022.

For the Commission
Frans TIMMERMANS
Executive Vice-President

ANNEX I

GROUPS I and II

Import quotas for chlorofluorocarbons 11, 12, 113, 114 and 115 and other fully halogenated chlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses during the period 1 January to 31 December 2023.

Company

Abcr GmbH (DE)

Solvay Specialty Polymers Italy SpA (IT)

Tazzetti SAU (ES)

Tazzetti SpA (IT)

TEGA – Technische Gase und Gasetechnik GmbH (DE)

ANNEX II

GROUP III

Import quotas for halons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and critical uses during the period 1 January to 31 December 2023.

Company

A-Gas Deutschland GmbH (DE)
A-Gas Italia s.r.l. (IT)
Abcr GmbH (DE)
Arkema France (FR)
Ateliers Bigata SASU (FR)
BASF Agri-Production S.A.S. (FR)
BTC B.V. (NL)
EAF protect s.r.o. (CZ)
Gielle Industries di Luigi Galantucci (IT)
Hugen Maintenance for Aircraft B.V. (NL)
Hugen Reprocessing Company Dutch Halonbank bv (NL)
L'Hotellier SAS (FR)
Lufthansa Technik AG (DE)
Martec SpA (IT)
P.U. Poz-PLiszka Sp. z o.o. (PL)
Savi Technologie sp. z o.o. sp. k. (PL)
Societe Air France Industries (FR)
UTM Umwelt-Technik-Metallrecycling GmbH (DE)
Vatro-Servis d.o.o. (HR)

ANNEX III

GROUP IV

Import quotas for carbon tetrachloride allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses and process agent uses for the period 1 January to 31 December 2023.

Company

Abcr GmbH (DE)

Arkema France (FR)

Ceram Optec SIA (LV)

ANNEX IV

GROUP V

Import quotas for 1,1,1-trichloroethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2023.

Company

Arkema France (FR)

ANNEX V

GROUP VI

Import quotas for methyl bromide allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2023.

Company

Abcr GmbH (DE)

Euroapi France (FR)

GHC Gerling, Holz & Co. Handels GmbH (DE)

ICL Europe Cooperatief U.A. (NL)

Mebrom NV (BE)

Mebrom Technology NV (BE)

Sigma-Aldrich Chemie GmbH (DE)

ANNEX VI

GROUP VII

Import quotas for hydrobromofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2023.

Company

Abcr GmbH (DE)

Euroapi France (FR)

Fermion oy (FI)

Hovione FarmaCiencia SA (PT)

R.P. Chem s.r.l. (IT)

Sterling Chemical Malta Limited (MT)

Sterling SpA (IT)

Valliscor Europa Limited (IE)

ANNEX VII

GROUP VIII

Import quotas for hydrochlorofluorocarbons allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2023.

Company

Abcr GmbH (DE)

Arkema France (FR)

Bayer AG (DE)

Chemours Netherlands B.V. (NL)

Dyneon GmbH (DE)

Solvay Fluor GmbH (DE)

Solvay France S.A (FR)

Solvay Specialty Polymers Italy SpA (IT)

Tazzetti SAU (ES)

Tazzetti SpA (IT)

ANNEX VIII

GROUP IX

Import quotas for bromochloromethane allocated to importers in accordance with Regulation (EC) No 1005/2009 for feedstock uses for the period 1 January to 31 December 2023.

Company

Albemarle Europe SPRL (BE)

ICL Europe Cooperatief U.A. (NL)

Laboratorios Miret S.A. (ES)

Sigma-Aldrich Chemie GmbH (DE)

Valliscor Europa Limited (IE)

ANNEX IX

(Commercially sensitive - in confidence - not to be published)

ANNEX X

Undertakings entitled to produce or import for laboratory and analytical uses in 2023

The quota of controlled substances which may be used for laboratory and analytical uses, are allocated to:

Company
Abcr GmbH (DE)
AGC Pharma Chemicals Europe (ES)
Agilent Technologies Deutschland GmbH (DE)
Airsense Analytics GmbH (DE)
Arkema France (FR)
Bayer AG (DE)
Biovit d.o.o. (HR)
CPAChem Ltd (BG)
Daikin Refrigerants Frankfurt GmbH (DE)
Fot LTD (BG)
Gedeon Richter Plc. (HU)
I2 Analytical Limited sp. z o. o. Oddział w Polsce (PL)
Interscience B.V. (NL)
Labmix24 GmbH (DE)
Laboratory Supplies Ltd T/A Lennox (IE)
LGC Standards GmbH (DE)
Neochema GmbH (DE)
Philipps-Universität Marburg (DE)
Restek France (FR)
Restek GmbH (DE)
Restek S.r.l. (IT)
Sigma Aldrich Chimie sarl (FR)
Sigma-Aldrich Chemie GmbH (DE)
Solvay Fluor GmbH (DE)
Solvay France S.A (FR)
Solvay Specialty Polymers Italy SpA (IT)
Techlab SARL (FR)
Ultra Scientific Italia srl (IT)
Valliscor Europa Limited (IE)

ANNEX XI

(Commercially sensitive - in confidence - not to be published)

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/2510

of 8 December 2022

establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) The European Green Deal ⁽¹⁾ sets out four interlinked policy goals for the transition to a sustainable economy and society: climate neutrality, biodiversity protection, circular economy and a zero pollution ambition for a toxic-free environment.
- (2) The EU sustainable finance strategy ⁽²⁾ aims to support the financing of the transition to a sustainable economy.
- (3) The Taxonomy Regulation ⁽³⁾ sets out four conditions that an economic activity has to fulfil in order to qualify as environmentally sustainable. It also sets out six environmental objectives, including the transition to a circular economy and pollution prevention and control.
- (4) In the Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment ⁽⁴⁾ (the ‘Chemicals Strategy’), the Commission announced that it would develop ‘safe and sustainable by design’ criteria for chemicals and materials. The Commission will also incentivise Member States, industry and other stakeholders to prioritise innovation for substituting, as far as possible, substances of concern ⁽⁵⁾ across sectors, as for example textiles, food contact materials, information and communications technologies, construction materials, low-carbon mobility, batteries or renewable energy sources.
- (5) The European Parliament has adopted a resolution ⁽⁶⁾ on the Chemicals Strategy, stressing the need to develop ‘safe and sustainable by design’ criteria to help prevent and control pollution, improve the tracing of hazardous chemicals in products, and promote their substitution by safer and more sustainable alternatives. The Council conclusions on the Chemicals Strategy ⁽⁷⁾ of 15 March 2021 also call on the Commission to promptly develop, in cooperation with the Member States and in consultation with stakeholders, harmonised, clear and precise definitions and, where adequate, criteria or principles for the concepts that are crucial for the effective implementation of the Chemicals Strategy, such as ‘safe and sustainable by design’ chemicals.
- (6) The Circular Economy Action Plan ⁽⁸⁾ states that the Commission will support the substitution and elimination of hazardous substances through research and innovation.

⁽¹⁾ COM(2019)640 final.

⁽²⁾ COM/2021/390 final.

⁽³⁾ Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (OJ L 198, 22.6.2020, p. 13).

⁽⁴⁾ COM(2020) 667 final.

⁽⁵⁾ As defined in the Chemicals Strategy for Sustainability (COM(2020) 667 final).

⁽⁶⁾ European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)), https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.pdf

⁽⁷⁾ Council Conclusions 6941/21 of 15 March 2021, Sustainable Chemicals Strategy of the Union: Time to Deliver, <https://www.consilium.europa.eu/media/48827/st06941-en21.pdf>

⁽⁸⁾ COM(2020) 98 final.

- (7) The EU Action Plan Towards Zero Pollution for Air, Water and Soil ⁽⁹⁾ and the Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products ⁽¹⁰⁾, emphasise the commitment to ensure that chemicals and materials are as safe and sustainable as possible by design and during their life cycle, so that material cycles are non-toxic.
- (8) A first sector-specific reference to safety and sustainability by design can be found in the EU Strategy for Sustainable and Circular Textiles ⁽¹¹⁾. The strategy highlights the importance of developing 'safe and sustainable by design' criteria for chemicals and materials to support industry to substitute or, if not possible, minimise substances of concern in textile products.
- (9) European citizens also see the need to act. A 2020 Eurobarometer survey ⁽¹²⁾ shows that 84 % of Europeans are worried about the impact on their health of chemicals present in everyday products, and 90 % are worried about chemicals' impact on the environment.
- (10) Several hundred substances have already been identified as substances of very high concern under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006 ⁽¹³⁾, and many more could fall under the definition of substances of concern in the Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products ⁽¹⁴⁾.
- (11) The transition to chemicals and materials that are 'safe and sustainable by design' requires a common understanding of safety and sustainability aspects to be successful ⁽¹⁵⁾. It is therefore necessary to develop a European assessment framework for 'safe and sustainable by design' chemicals and materials, that can assist in the definition of safety and sustainability criteria, to guarantee coherence between actors, sectors and value chains.
- (12) The envisaged framework should make it possible to comprehensively assess the safety and sustainability of chemicals and materials throughout their life cycle and support the design, development, production and use of chemicals and materials that provide a desirable function or service while being safe and sustainable. The application of the framework will make possible the definition of 'safe and sustainable by design' criteria which should help set high standards for the safety and sustainability of chemicals and materials.
- (13) The review of safety and sustainability dimensions, aspects, methods, indicators and tools ⁽¹⁶⁾, that is the root of the Annex to this Recommendation, although referring to a number of additional socioeconomic sustainability aspects, focuses mainly on chemical safety and environmental sustainability. Assessments of socioeconomic aspects, beyond those considered already, may be necessary in order to provide additional information and enable more informed decisions, in particular when promoting substitution. Such considerations can be taken into account in the application of the framework, whenever relevant.
- (14) The aim of the envisaged 'safe and sustainable by design' framework is to be at the forefront of research and innovation, and to promote use of the latest scientific knowledge to meet the highest levels of ambition for safety and sustainability in innovation.

⁽⁹⁾ COM(2021) 400 final.

⁽¹⁰⁾ COM(2022) 142 final.

⁽¹¹⁾ COM(2022) 141 final.

⁽¹²⁾ Eurobarometer survey (2020) Attitudes of Europeans towards the Environment – March 2020, <https://europa.eu/eurobarometer/surveys/detail/2257>

⁽¹³⁾ <https://echa.europa.eu/candidate-list-table>

⁽¹⁴⁾ COM(2022) 142 final.

⁽¹⁵⁾ European Commission 2021, Mapping study for the development of Sustainable by Design criteria, <https://op.europa.eu/en/publication-detail/-/publication/f679c200-a314-11eb-9585-01aa75ed71a1/language-en>

⁽¹⁶⁾ Caldeira, C., et al. Safe and Sustainable by Design chemicals and materials. Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, EUR 30991 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6 (online), doi:10.2760/879069 (online), JRC127109. 2022.

- (15) The framework should aim to become a global reference for innovation in pursuit of the green industrial transition; for substituting as much as possible the production and use of substances of concern; for promoting the use of sustainable resources and feedstock for the production of chemicals and materials; for minimising the impact of the production and use of chemicals and materials, throughout their life cycle, on the climate, on the environment, and on human health; and for driving industry's and public authorities' R&I investments in the right direction.
- (16) This Recommendation proposes a European 'safe and sustainable by design' framework as a point of reference for Member States, industry, academia, research and technology organisations (RTOs) and bodies providing benchmarks for safe and sustainable chemicals and materials.
- (17) This Recommendation sets a testing period for the framework with a voluntary reporting mechanism for Member States and stakeholders during this testing period. A revision process of the framework will be launched at the latest by the end of the testing period. Based on feedback collected during the testing period, the Commission will consider including in the assessment additional safety and environmental aspects, as well as economic and social sustainability aspects as an additional facet when relevant.
- (18) As stressed in the Chemicals Strategy, greater public and private investments in providing safe and sustainable chemicals, and a greater capacity to innovate on the part of the chemicals industry, will be vital for developing new solutions and supporting both the green and digital transitions. The vision for 2030 that lies behind this Recommendation should therefore ensure that future European, national and international initiatives for safe and sustainable chemicals and materials are grounded in the proposed framework. The Commission will promote this Recommendation in international fora.
- (19) To provide incentives for testing the framework and, in particular, address substances of concern, the Commission will support the testing period. This will be done in particular through actions in the Horizon Europe framework programme for the development of 'safe and sustainable by design' chemicals and materials, and the development and improvement of testing methods and assessment tools to expand the assessment possibilities the framework has to offer.
- (20) The Commission has also developed a Strategic Research and Innovation Plan for safe and sustainable chemicals and materials ⁽¹⁷⁾, identifying key research and innovation areas in the life cycle (design, production, use and disposal/recycling/remediation) of chemicals and materials to facilitate and support at European and national level the industrial transition towards safe and sustainable chemicals and materials.
- (21) The Commission, aware of the data needed to implement the envisaged framework, will continue promoting findable, accessible, interoperable and reusable (FAIR) data. The Commission is also developing an EU common data platform on chemicals ⁽¹⁸⁾ to facilitate the sharing, access and re-use to existing data used in Union legal acts related to chemicals.
- (22) This Recommendation respects the principle of subsidiarity as the envisaged 'safe and sustainable by design' framework serves the needs of the European Research Area and the single market for chemicals and materials, where there is a need for common understanding at European level of safety and sustainability for chemicals and materials. It also respects the principle of proportionality as it combines the establishment of the framework with a period of testing by non-legally binding means, without detracting from any existing or future (Union) legislation on chemicals and materials,

⁽¹⁷⁾ European Commission, Strategic Research and Innovation Plan for Safe and Sustainable Chemicals and Materials, Publications Office of the European Union, 2022, ISBN 978-92-76-49115-6, doi 10.2777/876851.

⁽¹⁸⁾ COM(2020) 667 final.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE AND SCOPE

- 1.1. This Recommendation proposes that a European framework for 'safe and sustainable by design' chemicals and materials be established for R&I activities. The details of the testing period and the framework, based on technical reports from the Commission's Joint Research Centre ⁽¹⁹⁾, ⁽²⁰⁾, are set out in the Annex to this Recommendation.
- 1.2. The envisaged framework consists of methods for assessing the safety and sustainability aspects of a chemical or material. The results obtained from applying the framework will make it possible to define 'safe and sustainable by design' criteria, including scoring systems and thresholds developed based on the results obtained. The process of criteria definition will be launched in parallel with the revision of the framework. The purpose of this Recommendation is to launch the testing of the assessment framework and get feedback to be able to improve relevance, reliability and operability.
- 1.3. This Recommendation is addressed to Member States, industry, including small and medium-sized enterprises (SMEs), academia and research and technology organisations (RTOs) that contribute to or work on the development of chemicals and materials. It invites them to use the framework in their R&I programmes and activities related to chemicals or materials. They are also encouraged to refer to the framework in relevant policy or strategy documents.
- 1.4. Member States, industry, academia and RTOs should also ensure that the methods, models and data produced and used when applying the framework tally with the findable, accessible, interoperable and reusable (FAIR) guiding principles.

2. USES BY MEMBER STATES

Member States are encouraged to:

- 2.1. Promote the framework in their national R&I programmes, thereby supporting the testing period with applications and use cases.
- 2.2. Increase the availability of high-quality FAIR data for assessing safety and sustainability by incorporating this aspect into their national R&I programmes and into related policies when relevant.
- 2.3. Support the improvement of assessment methods, models and tools, and make new ones available, to integrate into the framework in order to improve the assessment of safety and sustainability.
- 2.4. Support the development of educational curricula to ensure that the skills required to implement the framework are taught.

3. USES BY INDUSTRY, ACADEMIA and RTOs:

Industry (including SMEs), academia and RTOs are encouraged to:

- 3.1. Use the framework in their R&I processes for developing chemicals or materials, thereby supporting the testing period.
- 3.2. Make available high-quality FAIR data for assessing safety and sustainability, without flouting intellectual property rights and, if relevant, security considerations.

⁽¹⁹⁾ Caldeira C., Farcas L., Moretti, C., et al. Safe and Sustainable by Design chemicals and materials. Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6, doi:10.2760/879069.

⁽²⁰⁾ Caldeira C., Farcas L., Garmendia, I., et al., Safe and sustainable by design chemicals and materials: Framework for the definition of safe and sustainable by design criteria for chemicals and materials, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-53264-4, doi: 10.2760/487955.

- 3.3. Support the development and making available of new assessment methods, models and tools that can be integrated into the framework to improve the assessment of safety and sustainability.
- 3.4. Support the development of professional training and educational curricula to ensure the teaching of the skills required to implement the framework.
4. REPORTING ON THE IMPLEMENTATION OF THE RECOMMENDATION:
- 4.1. Member States, industry, academia and RTOs are encouraged to report to the Commission on the implementation of this Recommendation during the testing period.
- 4.2. To facilitate their reporting, the Commission will make a reporting template available. The information transmitted should include the following.
- How Member States, industry, universities and RTOs use the framework in their R&I programmes, activities and elsewhere.
 - Initiatives and use cases for testing the framework.
 - Initiatives for the development of new methods, models and tools for assessing safety and sustainability and how their outcomes can be accessed and used.
 - Initiatives for the development of 'safe and sustainable by design' chemicals and materials.
 - Assessment reports presenting the results obtained from testing the framework.
 - Problems and bottlenecks identified with the use of the framework
 - Information on the establishment of scoring systems and thresholds that can support setting of 'safe and sustainable by design' criteria in a revised framework.

Done at Brussels, 8 December 2022.

For the Commission
Mariya GABRIEL
Member of the Commission

ANNEX

Framework for the future definition of safe and sustainable by design criteria and the procedure for assessing chemicals and materials**Table of contents**

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1. Principles underpinning the safe and sustainable by design framework

A set of principles has been defined for the development of the new 'safe and sustainable by design' (SSbD) framework.

- Define a hierarchy that puts safety first, to avoid regrettable substitutions.
- Define cut-off criteria for the design of chemicals and materials to stimulate sustainable research and innovation (R&I), based not only on data referred to in the requirements of EU legislation on chemicals, but also on data that are outside the scope of those requirements.
- Focus on iteratively minimising environmental pressures, using dynamic boundaries and cut-offs, so that the framework becomes a tool for managing improvements along the innovation process.
- Ensure optimal use of available data on adverse effects. Every (new) chemical or material should be compared to the full spectrum of structurally or functionally similar substances to assess the expected potential to cause negative impact on human health or the environment.
- Communicate SSbD actions taken throughout the supply chain; make all relevant and non-confidential data available in a findable, accessible, interoperable and reusable (FAIR) format, for greater transparency and accountability and to better discharge the duty of care.
- Promote the use of a coherent framework by the various stakeholders, including industry and policymakers.

2. Framework features and structure

The SSbD framework proposed is a general approach to assessing and defining safety and sustainability criteria for chemicals and materials, throughout the innovation process. It can be applied to the development of new chemicals and materials or to the re-assessment of existing ones. In the case of existing chemicals and materials, the framework can be used: i) to support the redesign of their production processes to make them safer and more sustainable by evaluating alternative processes, or ii) to compare them using the SSbD criteria (e.g., for innovation by substitution with better performing chemicals or materials or for selection in downstream applications).

The framework consists of a (re)design stage and a safety and sustainability assessment across the different steps in the life cycle of a chemical or material, considering functionality and end-use(s). Although the framework does not assess the safety and sustainability of products, it does address how the chemicals or materials are used in products.

The SSbD framework comprises the following two components:

1. a **(re)design stage** at which guiding design principles are proposed to support the safe and sustainable design of chemicals and materials;
2. a **safety and sustainability assessment stage** at which the safety and sustainability of the chemical or material in question are assessed.

The SSbD framework can help with the various stages of the innovation process (design, planning, experimental testing and prototyping) where decisions are taken to proceed with, abandon or tweak the innovation approach. The safety and sustainability assessment should start as early as possible in the innovation process to ensure that SSbD principles are being applied to a chemical's or material's design. After that, the assessment should be done iteratively, at the subsequent stages of development, as more information gradually becomes available. The framework should allow for flexibility in its implementation, to ensure alignment with horizontal or product specific legislations or with regulatory exemptions.

The proposed safety and sustainability assessment follows a hierarchical approach in which safety aspects are considered first, before moving on to sustainability aspects.

The first step is to ensure safety by considering chemicals or materials with certain (human health as well as environmental) hazardous properties as non-sustainable by design, even if their design follows recommended design principles or they have a relatively low environmental impact. If the chemical or material in question fulfils the minimum safety criteria, the assessment can proceed to environmental sustainability aspects. In future applications of the framework, socioeconomic sustainability aspects can also be evaluated as a complementary assessment.

This stage-based approach is intended to reduce the burden of the assessment as the initial steps propose to identify 'prohibitive' issues. For example, if the assessment of a chemical or material identifies safety concerns, an LCA would only be done after these had been addressed, e.g., by determining if risk management measures can address the safety concerns. Nevertheless, depending on each organisation's working methods, the different steps could be conducted simultaneously.

3. Stage 1: Guiding (re)design principles

The SSbD framework covers three levels of the term 'by design':

- (1) molecular design, to design new chemicals and materials based on their chemical structure;
- (2) process design, to make the production process safer and more sustainable, both for chemicals and materials being developed and for existing chemicals and materials;
- (3) product design, where the results of the SSbD assessment support the selection of the chemicals or materials to meet the functional demands of the final product in which they are used.

The purpose of this stage is to provide guidance on the principles to be considered at the (re)design stage to maximise the possibilities of a successful safety and sustainability assessment outcome. At this stage, the goal, scope and system boundaries, which will determine the parameters of the assessment of the chemical or material in question, should be defined. This includes choices such as assessing a mixture as a single element or as components of mixtures. Adhering to those principles does not necessarily make it possible to draw conclusions about the safety and sustainability performance of the chemicals and materials in question. This requires an assessment of safety and sustainability in the next stage.

The design principles are summarised in Table 1 (a non-exhaustive list). They are derived from existing best practices, e.g. Green Chemistry Principles ⁽¹⁾, Green Engineering Principles ⁽²⁾, Sustainability Chemistry Criteria ⁽³⁾, German Environment Agency (UBA) Golden Rules ⁽⁴⁾, Circularity Chemistry Principles ⁽⁵⁾. Other principles from those best practices can also be considered.

Table 1

Non-exhaustive list of guiding design principles, associated definitions, and examples of actions at the (re)design stage

Design principle	Definition	Examples of actions
Material efficiency	Incorporating all the chemicals or materials used in a process into the final product or fully recovering them inside the process, thereby using fewer raw materials and generating less waste.	Maximise yield during reaction to reduce chemical or material consumption. Recover more unreacted chemicals or materials. Select materials and processes that minimise the generation of waste. Identify the occurrence of the use of critical raw materials ⁽¹⁾, in order to minimise or substitute them.
Minimise the use of hazardous chemicals or materials	Preserving the functionality of products while reducing or completely avoiding the use of hazardous chemicals or materials where possible. Using the best technology to avoid exposure at all stages of the life cycle of a chemical or material.	Reduce and/or eliminate hazardous chemicals or materials in production processes. Redesign production processes to minimise the use of hazardous chemicals/materials. Eliminate hazardous chemicals or materials in final products.

⁽¹⁾ Anastas, P., and Warner, J. (1998), Green Chemistry: Theory and Practice, Oxford University Press, New York, p. 30.

⁽²⁾ Anastas, P. T. and Zimmerman, J. B. (2003), 'Peer Reviewed: Design Through the 12 Principles of Green Engineering', Environmental Science & Technology 37(5), 94A–101A: <https://doi.org/10.1021/es032373g>

⁽³⁾ UBA (2009), 'Sustainable Chemistry: Positions and Criteria of the Federal Environment Agency', p. 6; <https://www.umweltbundesamt.de/en/publikationen/sustainable-chemistry>

⁽⁴⁾ UBA (2016), 'Guide on sustainable chemicals – A decision tool for substance manufacturers, formulators and end users of chemicals': <https://www.umweltbundesamt.de/en/publikationen/guide-on-sustainable-chemicals>

⁽⁵⁾ Keijer, T., Bakker, V., Slootweg, J. C. (2019), 'Circular chemistry to enable a circular economy', Nature chemistry 11(3), pp. 190–195: <https://doi.org/10.1038/s41557-019-0226-9>

Design principle	Definition	Examples of actions
Design for energy efficiency	Minimising the energy used to produce and use a chemical or material in the production process and/or in the supply chain.	Select or develop (production) processes that: a. involve alternative and less energy-intensive production/separation techniques b. maximise energy re-use (e.g. integration of heat networks and cogeneration) c. have fewer production steps d. use catalysts, including enzymes e. reduce inefficiencies and exploit available residual energy in the process or select lower temperature reaction pathways
Use renewable sources	Conserving resources, by means of resource-closed loops or by using renewable material and energy sources.	Promote the use of feedstocks that: a. are renewable b. are circular c. do not create land competition d. do not negatively affect biodiversity or processes that: a. use renewable energy resources with low-carbon emissions and without adverse effects on biodiversity
Prevent and avoid hazardous emissions	Applying technologies to minimise or avoid hazardous emissions or the release of pollutants into the environment.	Select materials or processes that: a. minimise the generation of hazardous waste and hazardous by-products b. minimise the generation of emissions (e.g. volatile organic compounds, total organic carbon, acidifying and eutrophication pollutants, and heavy metals)
Design for end of life	Design chemicals and materials so that, once they have served their purpose, they break down into chemicals that do not pose any risk to the environment or to humans. Design chemicals and materials in a way that makes them fit for re-use, waste collection, sorting and recycling/upcycling.	Avoid using chemicals or materials that impede end-of-life processes such as recycling. Select materials that are: a. more durable (longer life and less maintenance) b. easy to separate and sort c. valuable even after being used (commercial afterlife) d. fully biodegradable for uses that unavoidably lead to release into the environment or wastewater

Design principle	Definition	Examples of actions
Consider the whole life cycle	Applying the design principles to the entire life cycle, from the raw materials supply chain to the final product's end of life.	Consider: a. using reusable packaging for the chemical or material being assessed and for chemicals or materials in its supply chain b. energy-efficient logistics (e.g., reducing transported quantities, changing the means of transport) c. reducing transport distances in the supply chain

(¹) https://ec.europa.eu/growth/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en

4. Stage 2: Safety and sustainability assessment

Once the design principles have been listed, the next stage is the safety and sustainability assessment composed of four steps. The first three steps mainly cover different aspects of the safety of chemicals or materials. These three steps build on knowledge generated with existing EU chemicals legislation like Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006, Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008 or occupational safety and health (OSH) Directive 89/391/EEC, which is adapted to the R&I application of SSbD. The fourth step covers the environmental aspect of sustainability. Depending on how the SSbD framework is applied, it may also be worthwhile assessing socioeconomic aspects of sustainability – for instance, as an additional element to complement the main safety and sustainability assessment in the framework's future application.

The four steps, although presented sequentially, can be performed in parallel, as information becomes available at various points of the life cycle of the chemical or material in question and depending on whether a new or existing chemical or material is being assessed.

Each step consists of aspects that can be measured using indicators. The indicators are assessed with the methods proposed in the framework. For the purposes of the framework a criterion can be formed by an aspect with an assessment method and a minimum threshold or target values (on which a decision about the safety or sustainability of a chemical or material may be based). At this stage thresholds for Step 1 are available as they have been set in EU legislations on chemicals (CLP and REACH).

At this stage the SSbD framework has applicability only in the innovation stage of chemicals and materials development, as explained in stage 1; it does not interfere with Union legal obligations for chemicals and materials.

Step 1 – Hazard assessment (intrinsic properties)

This step looks at the intrinsic properties of the chemical or material in order to understand its hazard (⁽⁶⁾) profile (human health, environment and physical hazards), before assessing the safety during its production, processing and use.

Step 2 – Human health and safety aspects of production and processing

This step assesses the human health and safety aspects of the production and processing of the chemical or material in question. Production means the production process from raw material extraction to production of the chemical or material including recycling or waste management.

The goal is to assess whether the production and processing of the chemical or material in question poses any risk to workers, in line with, or beyond, EU Occupational Health and Safety directives.

(⁶) Hazard is defined as a property or set of properties that make a substance dangerous (definition provided by the terminology portal of ECHA <https://echa-term.echa.europa.eu/>).

Step 3 – Human health and environmental aspects in the final application phase

This step assesses the hazards and risks of the final application of the material or chemical in question. It covers use-specific exposure to the chemical or material and the associated risks.

The goal is to assess whether the use of a chemical or material in its final application poses any risk to human health or the environment.

Step 4 – Environmental sustainability assessment

In the fourth step environmental sustainability impacts along the entire chemical/material life cycle are considered by means of an LCA, assessing several impact categories such as climate change and resource use. Toxicity and ecotoxicity are also considered in this step, referring to impacts due to life cycle emissions to humans and the environment via environmental compartments (e.g., soil, water, air), including mobility between compartments and not via direct exposure (covered in Step 3).

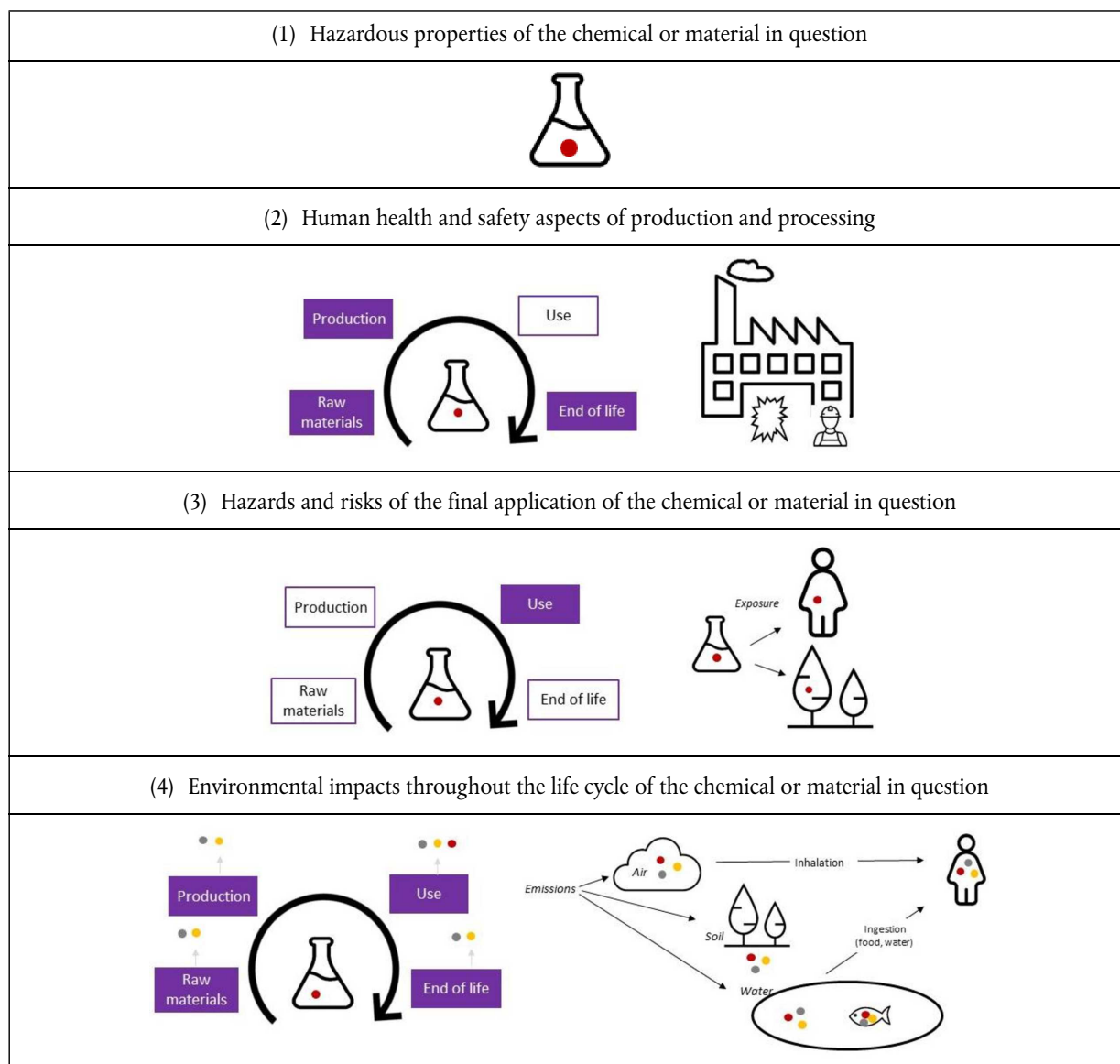


Figure 2: Illustration of the safety and sustainability aspects of the chemical or material covered by the safety and sustainability assessment. Coloured boxes indicate which life cycle stage is covered. The red dot refers to the chemical or material being assessed, while the yellow and grey dots refer to all the other substances emitted during its life cycle (e.g., other toxic chemicals emitted during the extraction of raw material or as a result of the energy used in the production process).

4.1. Hazard assessment (Step 1)

In EU legislation on chemicals (REACH and CLP), chemical hazards are divided in human health hazards, environmental hazards and physical hazards. These hazards are further divided into hazard classes and categories, which are included in the assessment. The aim is to establish a set of SSbD criteria for the intrinsic properties of chemicals and materials that can have adverse effects on humans or the environment. It is based on the hazard classes and categories established in the CLP Regulation. The SSbD assessment is voluntary and linked to R&I activities. Its scope may therefore be broader than the data these Regulations cover. The three main hazard categories are:

1. intrinsic hazardous properties relevant to human health (human health hazards)
2. intrinsic hazardous properties relevant to the environment (environmental hazards)
3. hazard physical properties (physical hazards).

The SSbD classification of the hazardous properties is closely linked to relevant EC initiatives, such as the Chemicals Strategy for Sustainability ⁽⁷⁾, the proposal for a regulation regarding sustainable products ⁽⁸⁾ or the EU sustainable finance ⁽⁹⁾. The classification criteria for substances and mixtures established by the CLP Regulation need to be consulted for any detailed information on the assessment methods.

The test methods Regulation ⁽¹⁰⁾ lays down the test methods to use for generating data for hazard assessment, and the methods are to a large extent based on the OECD Guidelines for the Testing of Chemicals ⁽¹¹⁾, which are one of the main tools for globally assessing the potential adverse effects of chemicals on human health and the environment. Additionally, methods recommended for assessing the hazardous properties are included in the ECHA's Guidance on the Application of the CLP Criteria ⁽¹²⁾, which supports the CLP criteria for hazard properties. Further support on assessment methods is available in the European Chemical Agency's (ECHA's) Guidance on Information Requirements and Chemical Safety Assessment ⁽¹³⁾, that describes the information requirements and how to fulfil them in accordance with the REACH Regulation. Classification for SSbD assessment can already consider further hazard classes like: persistent, bioaccumulative and toxic (PBT), very persistent very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent very mobile (vPvM), endocrine disruption. Even if those hazard classes are not yet in place under CLP, draft criteria under development could already be applied.

For the assessment of aspects in Table 2 ⁽¹⁴⁾, a tiered approach is proposed depending on the data availability. As the information available for new developed chemicals or materials could be limited at the beginning of the process, a tiered approach is beneficial to be able to characterise hazards as early as possible at the innovation stage (i.e. during the design of the chemical or material) by using, for example, new approach methodologies (NAMs) to generate data and knowledge. A tiered approach makes it possible to identify suspected hazardous chemicals or materials early on the innovation process, and take informed decisions (e.g., further assess the hazard, screen out the substance, request more data through the life cycle of the chemical or material in question). High-throughput screening, computer-based models, read-across and other alternative approaches should initially be used so that only the most promising candidates (less hazardous chemicals or materials) are tested at higher tiers in accordance with the regulatory requirements for chemicals to be placed on the market. If the assessment is performed on an existing chemical (e.g., already on the market), NAMs could be used to fill-in any data gaps needed to fulfil the information requirements for the aspects mentioned in Table 2. A screening of available academic data should also be done before deciding on the need for additional studies, in particular those involving laboratory animals.

⁽⁷⁾ COM(2020) 667 final.

⁽⁸⁾ COM(2022) 142 final.

⁽⁹⁾ Technical Working Group, Part B-Annex: Technical Screening Criteria, March 2022. https://www.efeu.awsassets.panda.org/downloads/220330_sustainable_finance_platform_finance_report_remaining_environmental_objectives.pdf

⁽¹⁰⁾ Council Regulation (EC) No 440/2008.

⁽¹¹⁾ <https://www.oecd.org/chemicalsafety/testing/>

⁽¹²⁾ <https://echa.europa.eu/guidance-documents/guidance-on-clp>

⁽¹³⁾ <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

⁽¹⁴⁾ Table 2 will be revised after the testing period.

Table 2

List of aspects (hazardous properties) relevant for Step 1

Group definition	Human health hazards	Environmental hazards	Physical hazards
Group A: Includes the most harmful substances (according to the Chemicals Strategy for Sustainability), including substances of very high concern (SVHC) (i.e., substances meeting the criteria laid down in REACH Art. 57(a-f) and identified in accordance with REACH Art. 59(1) ⁽¹⁾ , ⁽²⁾	— Carcinogenicity Cat. 1A and 1B — Germ cell mutagenicity Cat. 1A and 1B — Reproductive/developmental toxicity Cat. 1A and 1B — Endocrine disruption Cat. 1 (human health) — Respiratory sensitisation Cat. 1 — Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity	— Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) — Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM) ⁽³⁾ — Endocrine disruption Cat. 1 (environment)	
Group B: Includes substances of concern, as described in the Chemicals Strategy for Sustainability and defined in Article 2(28) of the ecodesign proposal for sustainable products ⁽⁴⁾ , but not included in Group A	— Skin sensitisation Cat 1 — Carcinogenicity Cat. 2 — Germ cell mutagenicity Cat. 2 — Reproductive/developmental toxicity Cat. 2 — Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 2 — Specific target organ toxicity – single exposure (STOT-SE) Cat. 1 and 2 — Endocrine disruption Cat. 2 (human health)	— Hazardous for the ozone layer — Chronic environmental toxicity (chronic aquatic toxicity) — Endocrine disruption Cat. 2 (environment)	

Group definition	Human health hazards	Environmental hazards	Physical hazards
Group C: Includes the other hazard classes not in Groups A or B	— Acute toxicity — Skin corrosion — Skin irritation — Serious eye damage/eye irritation — Aspiration hazard (Cat. 1) — Specific target organ toxicity – single exposure (STOT-SE) Cat. 3	— Acute environmental toxicity (acute aquatic toxicity)	— Explosives — Flammable gases, liquids and solids — Oxidising gases, liquids, solids — Gases under pressure — Self-reactive — Pyrophoric liquids, solids — Self-heating — In contact with water emits flammable gas — Organic peroxides — Corrosivity — Desensitised explosives

(¹) Article 57(a) of the REACH Regulation – carcinogenic category 1A or 1B; Article 57(b) of the REACH Regulation – mutagenic category 1A or 1B; Article 57(c) of the REACH Regulation – toxic for reproduction category 1A or 1B; Article 57(d) of the REACH Regulation – persistent, bioaccumulative and toxic (PBT); Article 57(e) of the REACH Regulation – very persistent and very bioaccumulative (vPvB); Article 57(f) of the REACH Regulation – equivalent level of concern with probable serious effects on human health (and/or) the environment.

(²) Some substances with other hazardous properties (e.g. STOT RE) may be classified as substances of very high concern because of their 'equivalent level of concern' (see Article 57(f) of the REACH Regulation).

(³) The inclusion of all PMT and vPvM in the subgroup of most harmful substances will be subject to further assessment.

(⁴) Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products (COM(2022) 142 final)) Article 2(28) – 'Substance of concern' means a substance that:

- (a) meets the criteria in Article 57, and is identified in accordance with Article 59(1), of the REACH Regulation; or
- (b) is classified in Part 3 of Annex VI to the CLP Regulation in one of the following hazard types or hazard categories:
 - carcinogenicity categories 1 and 2,
 - germ cell mutagenicity categories 1 and 2,
 - reproductive toxicity categories 1 and 2,
 - respiratory sensitisation category 1,
 - skin sensitisation category 1,
 - chronic hazard for the aquatic environment categories 1 to 4,
 - hazardous for the ozone layer,
 - specific target organ toxicity – repeated exposure categories 1 and 2,
 - specific target organ toxicity – single exposure categories 1 and 2; or
- (c) negatively affects the reuse and recycling of materials in the product in which it is present.

4.2. Human health and safety aspects of production and processing (Step 2)

The aspects included in this step are related to occupational health and safety during the production and processing of a chemical or material. The risk should be estimated as a combination of the chemical or material hazards, exposure during the different processes and the risk management measures in place.

For this part of the assessment, it is important to identify all the production and processing steps, the substances used in each of them (e.g., raw chemicals or materials, processing aids), the substances that may be produced during the processes (volatile organic compounds, by-products, etc.), and identify their hazards and risks for workers. The operational conditions (how the substance is used in the process, whether its processing is closed/open, its concentration in a preparation) together with the release potential (volatility, dustiness, fugacity, temperature, pressure), and the risk management measures in place (e.g., local exhaust ventilation) will determine the likelihood of workers' exposure and the potential exposure route (inhalation, dermal, oral ingestion).

As in Step 1, a tiered approach can be applied, depending on data availability.

There are various qualitative/simplified models available (also known as control-banding models) for assessing safety and managing risks at the workplace. These models are designed to characterise risk at the workplace using a tier 1 approach, when the whole set of data required to perform a quantitative assessment is not available. The models are based on assigning scores or levels to some of the following variables to be considered during the characterisation of risk:

- hazards of chemicals
- frequency and duration of exposure
- amount of the chemical or material in question that is used or present
- physical properties of the chemical or material in question, such as volatility or dustiness
- operational conditions
- type of risk management measures in place

There are two types of models: models that estimate the potential risk of exposure (they do not include the preventive measures taken as an input variable) and models that estimate the expected risk of exposure (they estimate the final risk, considering the preventive measures implemented, if any).

The result is a categorisation into different risk levels, to determine if the risk is acceptable and, if needed, the types of preventive measures to be applied.

Among the recommended assessment tools for Step 2 is the tiered targeted risk assessment (TRA) tool developed by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). ECETOC TRA ⁽¹⁵⁾, developed to facilitate the registration of chemicals in accordance with the REACH Regulation, and widely used by industry and known by small and medium-sized enterprises. To use this tool, it is recommended to apply ECHA guidance (Chapter R12 Use description ⁽¹⁶⁾) to define the use of the chemical or material in question at the different stages, since the tool uses this guidance as a reference. Other models and tools are also available, e.g., Chesar ⁽¹⁷⁾ (also relevant for Step 3 where more details are provided), the International Labour Organization (ILO) model ⁽¹⁸⁾, the German Hazardous Substances Column Model, supported by the 'Easy-to-use Workplace Control Scheme for Hazardous Substances' (EMKG) tool ⁽¹⁹⁾, the INRS model ⁽²⁰⁾; the Dutch Stoffenmanager model ⁽²¹⁾, or the Belgian REGETOX model ⁽²²⁾.

⁽¹⁵⁾ ECETOC's TRA tool: <https://www.ecetoc.org/tools/tra-main/>

⁽¹⁶⁾ https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

⁽¹⁷⁾ Chemical safety assessment and reporting tool, <https://chesar.echa.europa.eu/home>

⁽¹⁸⁾ ILO – International Chemical Control Toolkit, https://www.ilo.org/legacy/english/protection/safework/ctrl_banding/toolkit/icct/

⁽¹⁹⁾ Easy-to-use Workplace Control Scheme for Hazardous Substances (EMKG), https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/EMKG/Easy-to-use-workplace-control-scheme-EMKG_node.html

⁽²⁰⁾ INRS model, <https://www.inrs.fr/media.html?refINRS=ND%202233>

⁽²¹⁾ Stoffenmanager, <https://stoffenmanager.com/en/>

⁽²²⁾ Réseau de Gestion des Risques Toxicologiques (REGETOX 2000), http://www.regetox.med.ulg.ac.be/accueil_fr.htm

Examples of relevant aspects and indicators to be assessed in Step 2 are listed in Table 3. They are adapted from the German Hazardous Substances Column Model developed by the Institute for Occupational Safety and Health of the German Social Accident Insurance Body ⁽²³⁾. For the case of chronic human health hazards, they are linked to the grouping of hazard classes in Step 1. The Column Model has been developed primarily to support the substitution assessment of hazardous substances, but the approach could be adapted for other purposes and by using the same information.

⁽²³⁾ The GHS Column Model 2020 — An aid to substitute assessment, edited by Smola T., Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA), <https://www.dguv.de/ifa/praxishilfen/hazardous-substances/ghs-spaltenmodell-zur-substitution-spruefung/index.jsp>

Table 3

Examples of aspects and indicators relevant for Step 2 adapted from the German Hazardous Substances Column Model.

Aspect	Sub-aspects and indicators				
	Acute human health hazards	Chronic human health hazards	Physical properties	Hazards from release behaviour	Processing-related risk contribution
Very-high-risk process	— Acutely toxic substances or mixtures, Cat. 1 or 2 (H300, H310, H330) — Substances or mixtures that, in contact with acids, liberate highly toxic gases (EUH032)	— Human hazards similar to Group A of Step 1	— Unstable explosive substances or mixtures (H200) — Explosive substances, mixtures or articles, divisions 1.1 (H201), 1.2 (H202), 1.3 (H203), 1.4 (H204), 1.5 (H205) and 1.6 (without H-phrase) — Flammable gases, Cat. 1A (H220, H230, H231, H232) and Cat. 1B and 2 (H221) — Pyrophoric gases (H232) — Flammable liquids, Cat. 1 (H224) — Self-reactive substances or mixtures, Types A (H240) and B (H241) — Organic peroxides, Types A (H240) and B (H241) — Pyrophoric liquids or solids, Cat. 1 (H250) — Substances or mixtures that, in contact with water, emit flammable gases, Cat. 1 (H260) — Oxidising liquids or solids, Cat. 1 (H271)	— Gases — Liquids with a vapour pressure > 250 hPa (mbar) — Dust-generating solids	— Open processing — Possibility of direct skin contact — Large-area application — Open design or partially open design, natural ventilation

Aspect	Sub-aspects and indicators				
	Acute human health hazards	Chronic human health hazards	Physical properties	Hazards from release behaviour	Processing-related risk contribution
High-risk process	— Acutely toxic substances or mixtures, Cat. 3 (H301, H311, H331) — Substances or mixtures that are toxic in contact with the eyes (EUH070) — Substances or mixtures that, in contact with water or acids, liberate toxic gases (EUH029, EUH031) — Substances or mixtures with specific target organ toxicity (single exposure), Cat. 1: Organ damage (H370) — Skin-sensitising substances or mixtures (H317, Sh) — Substances or mixtures that sensitise the respiratory organs (H334, Sa) — Substances or mixtures corrosive to the skin, Cat. 1, 1A (H314)	— Human hazards similar to Group B of Step 1	— Aerosols, Cat. 1 (H222 and H229) — Flammable liquids, Cat. 2 (H225) — Flammable solids, Cat. 1 (H228) — Self-reactive substances or mixtures, Types C and D (H242) — Organic peroxides, Types C and D (H242) — Self-heating substances or mixtures Cat. 1 (H251) — Substances or mixtures that, in contact with water, emit flammable gases, Cat. 2 (H261) — Oxidising gases, Cat. 1 (H270) — Oxidising liquids or solids, Cat. 2 (H272) — Desensitised explosives, Cat. 1 (H206) and Cat. 2 (H207) — Substances or mixtures with certain properties (EUH001, EUH014, EUH018, EUH019, EUH044)	— Liquids with a vapour pressure of 50–250 hPa (mbar)	— Partially open design, processing-related opening with simple extraction, open with simple extraction

Aspect	Sub-aspects and indicators				
	Acute human health hazards	Chronic human health hazards	Physical properties	Hazards from release behaviour	Processing-related risk contribution
Medium-risk process	— Acutely toxic substances or mixtures, Cat. 4 (H302, H312, H332) — Substances or mixtures with specific target organ toxicity (single exposure), Cat. 2: Possible organ damage (H371) — Substances or mixtures corrosive to the skin, Cat. 1B, 1C (H314) — Eye-damaging substances or mixtures (H318) — Substances or mixtures that have a corrosive effect on respiratory organs (EUH071) — Non-toxic gases that can cause suffocation by displacing air (e.g. nitrogen)	— Human hazards similar to Group C of Step 1, except those listed under 'acute human health hazards' (left column).	— Aerosols, Cat. 2 (H223 and H229) — Flammable liquids, Cat. 3 (H226) — Flammable solids, Cat. 2 (H228) — Self-reactive substances or mixtures, Types E and F (H242) — Organic peroxides, Types E and F (H242) — Self-heating substances or mixtures, Cat. 2 (H252) — Substances or mixtures that, in contact with water, emit flammable gases, Cat. 3 (H261) — Oxidising liquids or solids, Cat. 3 (H272) — Gases under pressure (H280, H281) — Corrosive to metals (H290) — Desensitised explosives, Cat. 3 (H207) and Cat. 4 (H208)	— Liquids with a vapour pressure of 10–50 hPa (mbar), with the exception of water	— Closed processing with possibilities of exposure, e.g. during filling, sampling or cleaning — Closed design, tightness not ensured, partially open design with effective extraction

Aspect	Sub-aspects and indicators				
	Acute human health hazards	Chronic human health hazards	Physical properties	Hazards from release behaviour	Processing-related risk contribution
Low-risk process	— Skin-irritant substances or mixtures (H315) — Eye-irritant substances or mixtures (H319) — Skin damage when working in moisture — Substances or mixtures with a risk of aspiration (H304) — Skin-damaging substances or mixtures (EUH066) — Substances or mixtures with specific target organ toxicity (single exposure), Cat. 3: irritation of the respiratory organs (H335) — Substances or mixtures with specific target organ toxicity (single exposure), Cat. 3: drowsiness, dizziness (H336)	— Substances chronically harmful in other ways (no H-phrase)*	— Aerosols, Cat. 3 (H229 without H222, H223) — Not readily flammable substances or mixtures (flash point > 60 ... 100 °C, no H-phrase) — Self-reactive substances/mixtures, Type G (no H-phrase) — Organic peroxides, Type G (no H-phrase)	— Liquids with a vapour pressure 2–10 hPa (mbar)	— Closed design, tightness ensured, partially closed design with integrated extraction, partially open design with highly effective extraction
Negligible risk	Substances of no concern regarding intrinsic hazardous properties, according to Step 1 (i.e., not classified in groups A, B or C)			— Liquids with a vapour pressure < 2 hPa (mbar) — Non-dust-generating solids	

4.3. Human health and environmental aspects of the final application (Step 3)

This step assesses the human health and environmental impacts of the application of the chemical or material in question. As in Step 2, the conditions of use will determine the likelihood of exposure to the chemical or material as well as the potential exposure routes (all relevant pathways) and the related toxicity impacts on human health, including service-life exposure, and the environment (e.g., from wash-off uses, such as shampoo ending up in wastewater treatment plant effluents).

The risk is characterised as a combination of the chemical or material hazards and the assessment of the estimated exposure of human health and the environment to the hazards during the application of the chemical or material in question.

Information on the chemical's or the material's intrinsic properties are necessary for the safety assessment, and mainly covers the same hazard properties as considered in Step 1: physical hazards, environmental hazards and human health hazards.

Information about other physico-chemical properties is also needed to identify the fate of the chemical or material in question, estimate the exposure and identify the exposure pathway(s) and characterise risk (e.g., properties such as the chemical's or material's physical form and vapour pressure relevant for human health, or water solubility and the octanol water partition coefficient ($\text{Log } K_{ow}$) relevant for the environment).

To estimate exposure, it is particularly important to identify/describe the application of the chemical or material in question and define the use conditions by providing information on frequency and duration of exposure, the amount of the chemical or material used or present in the application, the conditions of use of the chemical or material and the instructions for its use. If the chemical or material has several possible uses, ideally the different exposure routes should be considered.

As in previous steps, the approach might be optimised depending on whether a new or existing chemical or material is being assessed, and on what data are available.

As in Step 2, it is recommended to apply ECHA guidance (Chapter R12 Use description²¹) as a starting point to define the use of the chemical or material in question in this step. R12 guidance provides lists of product categories and article categories and many available exposure estimation tools, such as ECETOC TRA²⁰, use these description categories as input for assessing exposure and safety.

The chemical safety assessment and reporting tool (Chesar)²² is another tool recommended for the safety assessment of the chemical/material. The tool was developed by ECHA for assisting companies in producing chemical safety reports (CSR) and exposure scenarios (ES) in a structured, harmonised, transparent and efficient way. This includes reporting the substance-related data (relevant phys-chem, fate and hazard data), describing the uses of the substance, carrying out exposure assessment including identifying conditions of safe use, related exposure estimates and demonstrating control of risks. For carrying out the exposure assessment, a number of exposure estimation tools are included in Chesar: the ECETOC TRA tool for workers' and for consumers' exposure estimation, as well as EUSES for environmental exposure estimation. Those tools require as input the expected conditions of use. Use maps, developed by industry sectors, collect information on the uses and the conditions of use of chemicals in their sector in a harmonised and structured way. They contain the input parameters for workers' exposure assessment (SWEDs), for consumers' exposure assessment (SCEDs) and for environmental exposure assessment (SPERCs). The existing use maps are available in Chesar format at <https://www.echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library>. It is also possible to document in Chesar the exposure estimates obtained from other tools or measured exposure data. Some tools, such as ConsExpo²⁹, can directly export their outputs to Chesar.

As in Step 2, tools from higher tiers (e.g., ConsExpo²⁴) or sector specific tools developed by industry for assessing specific product types and articles, can also be used if the data are available to do so.

4.4. Environmental sustainability assessment (Step 4)

This step covers the assessment of the environmental sustainability aspects of the chemical or material in question, focusing on its environmental impacts throughout the value chain.

(²⁴) <https://www.rivm.nl/en/consexpo>

To assess the environmental sustainability of the chemical or material in question, a function-based LCA, covering the entire life cycle, must be done. If the new chemical or material has several possible uses, or if it can be produced by means of several production routes, different LCAs must be done considering each production, use and its end of life. Ideally, the LCA studies of the different uses of the chemical or material should be conducted following the same modelling principles to ensure harmonisation and allow comparison of results. It is therefore recommended, whenever possible, to use the product environmental footprint method³⁰ as a guiding document for doing the LCA.

The environmental footprint impact assessment method is recommended to be used to assess the life cycle environmental performance of products ⁽²⁵⁾. It consists of a minimum set of impacts to assess. Other aspects, not yet fully covered by current LCA practices, might need to be assessed on a case-by-case basis using possible indicators that could be developed for the purpose.

Given that existing environmental impacts go beyond those the environmental footprint method covers, there could be the possibility of adding other impacts in the future.

The underlying models and characterisation factors for the environmental footprint method, available at <https://eplca.jrc.ec.europa.eu/LCDN/developerEF.xhtml>, should be applied in accordance with the latest environmental footprint package available. The aspects taken into consideration, the indicators and methods in place at the date of the publication of this recommendation are listed in Table 5, which should be regarded solely as an example, given that recommended methods are constantly evolving.

⁽²⁵⁾ C(2021) 9332 final.

Table 5

Aspects, indicators and methods for the environmental footprint method for Step 4

LCA assessment level/aspects	Sub-aspect	Indicator and unit	Recommended default LCIA method
Toxicity	Human toxicity, cancer effects	Comparative Toxic Unit for humans (CTU _h)	based on USEtox2.1 model (Fantke et al., 2017 ⁽¹⁾) adapted as in (Saouter et al., 2018 ⁽²⁾)
	Human toxicity, non- cancer effects	Comparative Toxic Unit for humans (CTU _h)	Based on USEtox2.1 model (Fantke et al., 2017 ⁽¹⁾), adapted as in Saouter et al., 2018 ⁽²⁾
	Ecotoxicity freshwater	Comparative Toxic Unit for ecosystems (CTU _e)	Based on USEtox2.1 model (Fantke et al., 2017 ⁽¹⁾), adapted as in Saouter et al., 2018 ⁽²⁾
Climate change	Climate change	Global warming potential (GWP100, kg CO ₂ eq)	Bern model – Global warming potential (GWP) over a 100-year time horizon (based on IPCC, 2013 ⁽³⁾)
Pollution	Ozone depletion	Ozone depletion potential (ODP) (kg CFC-11eq)	EDIP model based on the ODPs of the World Meteorological Organization (WMO) over an infinite time horizon (WMO, 2014 ⁽⁴⁾ + integrations)
	Particulate matter/respiratory inorganics	Human health effects associated with exposure to PM _{2.5} (Disease incidences ⁽⁵⁾)	PM model (Fantke et al., 2016 ⁽⁶⁾) in UNEP, 2016 ⁽⁷⁾
	Ionising radiation, human health	Human exposure to U ²³⁵ (kBq U ²³⁵)	Human health effect model as developed by Dreicer et al., 1995 (Frischknecht et al, 2000 ⁽⁸⁾)
	Photochemical ozone formation	Tropospheric ozone concentration increase (kg NMVOC eq)	LOTOS-EUROS (Van Zelm et al., 2008 ⁽⁹⁾) as applied in ReCiPe 2008
	Acidification	Accumulated exceedance (mol H ⁺ eq)	Accumulated exceedance (Posch et al., 2008 ⁽¹⁰⁾ ; Seppälä et al., 2006 ⁽¹¹⁾)

LCA assessment level/aspects	Sub-aspect	Indicator and unit	Recommended default LCIA method
	Eutrophication, terrestrial	Accumulated exceedance (mol N eq)	Accumulated exceedance (Seppälä et al., 2006 ⁽¹¹⁾ , Posch et al., 2008 ⁽¹⁰⁾)
	Eutrophication, aquatic freshwater	Fraction of nutrients reaching freshwater end compartment (P, kg P eq)	EUTREND model (Struijs, et al. 2009 ⁽¹²⁾) as implemented in ReCiPe 2008
	Eutrophication, aquatic marine	Fraction of nutrients reaching marine end compartment (N, kg N eq)	EUTREND model (Struijs et al., 2009 ⁽¹²⁾) as implemented in ReCiPe 2008
Resources	Land use	Soil quality index ⁽¹³⁾ (Biotic production, erosion resistance, mechanical filtration and groundwater replenishment), dimensionless	Soil quality index based on the LANCA model (De Laurentiis et al., 2019 ⁽¹⁴⁾) and on the LANCA CF version 2.5 (Horn & Maier, 2018 ⁽¹⁵⁾)
	Water use	User deprivation potential (deprivation-weighted water consumption, m ³ water eq. of deprived water)	Available WAter REMaining (AWARE) model (Boulay et al., 2018 ⁽¹⁶⁾ ; UNEP, 2016 ⁽⁷⁾)
	Resource use, minerals and metals	Abiotic resource depletion (ADP ultimate reserves, kg Sb eq)	CML (Guinée et al., 2002 ⁽¹⁷⁾) and (Van Oers et al. 2002 ⁽¹⁸⁾)
	Resource use, energy carriers	Abiotic resource depletion – fossil fuels (ADP-fossil, MJ) ⁽¹⁹⁾	CML (Guinée et al., 2002 ⁽¹⁷⁾) and (Van Oers et al., 2002 ⁽¹⁸⁾)

- (¹) USEtox® 2.0 Documentation (Version 1), <http://usetox.org>. <https://doi.org/10.11581/DTU:00000011>
- (²) Using REACH and the EFSA database to derive input data for the USEtox model, EUR 29495 EN, Publications Office of the European Union, Luxembourg, 2018, ISBN 978-92-79-98183-8, Joint Research Centre (JRC) 114227, <https://doi.org/10.2760/611799>
- (³) Anthropogenic and Natural Radiative Forcing. In: Climate change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change. T.F. Stocker, D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Doschung, A. Nauels, Y. Xia, V. Bex, and P.M. Midgley, Eds. Cambridge University Press, pp. 659–740, doi:10.1017/CBO9781107415324.018.
- (⁴) Scientific Assessment of Ozone Depletion: 2014, Global Ozone Research and Monitoring Project Report No 55, Geneva, Switzerland. Retrieved from <https://csl.noaa.gov/assessments/ozone/2014/preface.html>
- (⁵) The name of the unit has been changed from 'Deaths' in the original source (UNEP, 2016) to 'Disease incidences'.
- (⁶) Health impacts of fine particulate matter. In: Frischknecht, R., Joliet, O. (Eds.), Global Guidance for Life Cycle Impact Assessment Indicators: Volume 1. UNEP/SETAC Life Cycle Initiative, Paris, 76–99. Retrieved from www.lifecycleinitiative.org/applying-lca/lcia-cf/
- (⁷) Global guidance for life cycle impact assessment indicators: Volume 1, ISBN: 978-92-807-3630-4. Retrieved from <https://www.ecocostsvalue.com/EVR/img/references%20others/global-guidance-lcia-v.1-1.pdf>
- (⁸) Human health damages due to ionising radiation in life cycle impact assessment. Environmental Impact Assessment Review. [https://doi.org/10.1016/S0195-9255\(99\)00042-6](https://doi.org/10.1016/S0195-9255(99)00042-6)
- (⁹) 'European characterisation factors for damage to human health caused by PM10 and ozone in life cycle impact assessment', Atmospheric Environment 42, pp. 441–453. <https://doi.org/10.1016/j.atmosenv.2007.09.072>
- (¹⁰) 'The role of atmospheric dispersion models and ecosystem sensitivity in the determination of characterisation factors for acidifying and eutrophying emissions in LCIA', The International Journal of Life Cycle Assessment, 13, pp. 477–486, <https://doi.org/10.1007/s11367-008-0025-9>
- (¹¹) 'Country-dependent Characterisation Factors for Acidification and Terrestrial Eutrophication Based on Accumulated Exceedance as an Impact Category Indicator', The International Journal of Life Cycle Assessment 11(6), pp. 403–416, <https://doi.org/10.1065/lca2005.06.215>
- (¹²) Aquatic Eutrophication. Chapter 6 in: Goedkoop, M., Heijungs, R., Huijbregts, M.A.J., De Schryver, A., Struijs, J., Van Zelm, R. (2009). ReCiPe 2008.A Life Cycle Impact Assessment Method Which Comprises Harmonised Category Indicators at the Midpoint and the Endpoint Level. Report I: Characterisation Factors, First Edition.
- (¹³) This index is the result of the aggregation by the JRC of the 4 indicators provided by the LANCA model for assessing impacts due to land use as reported in De Laurentiis et al., (2019).
- (¹⁴) 'Soil quality index: Exploring options for a comprehensive assessment of land use impacts in LCA', Journal of Cleaner Production, 215, pp. 63–74, <https://doi.org/10.1016/j.jclepro.2018.12.238>
- (¹⁵) LANCA®- Characterization Factors for Life Cycle Impact Assessment, Version 2.5 November 2018. Retrieved from <http://publica.fraunhofer.de/documents/N-379310.html>
- (¹⁶) 'The WULCA consensus characterization model for water scarcity footprints: assessing impacts of water consumption based on available water remaining (AWARE)', The International Journal of Life Cycle Assessment 23(2), pp. 368–378, <https://doi.org/10.1007/s11367-017-1333-8>
- (¹⁷) 'Handbook on Life Cycle Assessment: Operational Guide to the ISO Standards', Series: Eco-efficiency in industry and science, Kluwer Academic Publishers, Dordrecht: <https://doi.org/10.1007/BF02978897>
- (¹⁸) Abiotic Resource Depletion in LCA. Road and Hydraulic Engineering Institute, Ministry of Transport and Water, Amsterdam.
- (¹⁹) In the ILCD flow list, and for this recommendation, uranium is included in the list of energy carriers. It is measured in MJ.

5. Assessment procedure and reporting

The application of the SSbD framework to a chemical or material will provide three outputs:

1. adherence to SSbD principles during the (re)design stage;
2. a safety and sustainability assessment;
3. the dashboard summarising the results.

Not all current aspects and indicators have thresholds associated (these are mainly in place for regulatory safety aspects). This means that, for aspects and indicators without thresholds, the criteria are not complete. In such cases, a pragmatic approach in the testing is to compare the chemical/material under assessment with the chemical(s) or material(s) that might be replaced, in line with what is currently done using alternative assessment methods. In case of new chemicals or materials the comparison should be based on functionality. This approach will lead to relative improvements, based on the performance of the chemical(s) or material(s) compared.

Templates for presenting the results will be made available online by the Commission, including a proposal for their graphic visualisation.

For **Step 1** of the safety and sustainability assessment, four assessment levels are envisaged.

- Level 0 – chemicals or materials in criteria group A (e.g., considered most harmful substances, including SVHC).
- Level 1 – chemicals or materials in criteria group B (e.g., having chronic human health or environmental effects, substances of concern not included in group A).
- Level 2 – chemicals or materials in criteria group C (e.g., having other hazardous properties).
- Level 3 – chemicals or materials not in any of the hazard categories listed in the previous criteria groups. For these, it should be borne in mind that the chemical or material in question could still be harmful in certain applications from a risk perspective that goes beyond generic hazard criteria and involves the consideration of application-specific exposure settings.

The aspects listed in groups A, B and C (Table 2) are hierarchical, meaning that they need to be assessed one after the other, and the next aspect-related criterion will only be assessed if the previous one has been fulfilled.

If there is evidence that the chemical or material in question possesses one of the hazardous properties included in the group of hazardous properties being assessed, there is, for the SSbD assessment, no need to gather information on the other properties in the same group. This aims to simplify the assessment and make it easier to gather data and to eliminate problematic chemicals or materials faster, early in the research and development process. However, to proceed to assessing the next criterion, evidence on all aspects of the same set of criteria needs to be provided.

For **Steps 2, 3 and 4** of the safety and sustainability assessment it is recommended to report the complete assessment for the case analysed, indicating what methods have been used. It is also recommended to benchmark the results of the steps with the chemical or material that is being replaced, to see if there is an improvement (comparative assessment). The final SSbD report should include an analysis of the results obtained in Steps 2, 3 and 4 and identify the aspects and indicators with the highest impact on safety and sustainability. Criteria for Steps 2, 3 and 4 are to be defined case-by-case on the basis of the results obtained, as not all chemicals and materials will require the same safety and sustainability measures.

6. Overview of data sources to support the safety and sustainability assessment

As a starting point and in addition to the tools mentioned in the description of Steps 1-4, sources such as the ECHA's Information on Chemicals ⁽²⁶⁾ (including C&L Inventory ⁽²⁷⁾ and EUCLEF ⁽²⁸⁾), the European Food Safety Authority's (EFSA's) Chemical Hazards Database (OpenFoodTox) ⁽²⁹⁾, the Organisation for Economic Cooperation and Development's (OECD's) eChemPortal ⁽³⁰⁾, the United States of America Environmental Protection Agency's (EPA's) CompTox ⁽³¹⁾, can be screened first, especially for information on the hazardous properties of existing chemicals.

For the environmental footprint, Life Cycle Inventory (LCI) datasets are available on the European Platform for Life Cycle Assessment ⁽³²⁾, created and managed by the Commission. If available, environmental footprint-compliant datasets should be used. A large platform for searching for data across different databases is the Global LCA Data Access Network ⁽³³⁾. It also provides tools for harmonising datasets from different sources.

For modelling the end-of-life scenario, the variety of data needed depending on the chemical or material being assessed makes it difficult to pinpoint specific data sources. A recommended source for general end-of-life statistics is the Eurostat database ⁽³⁴⁾, which provides data on waste management in Europe. Additional useful information is published by trade associations of producers that often release studies and statistics on their own sector's sustainability.

⁽²⁶⁾ ECHA Information on Chemicals: <https://echa.europa.eu/information-on-chemicals>

⁽²⁷⁾ <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>

⁽²⁸⁾ <https://echa.europa.eu/legislation-finder>

⁽²⁹⁾ EFSA Chemical Hazards Database (OpenFoodTox): <https://www.efsa.europa.eu/en/microstrategy/openfoodtox>

⁽³⁰⁾ OECD eChemPortal: <https://www.chemportal.org/chemportal/>

⁽³¹⁾ US EPA CompTox Chemicals Dashboard: <https://comptox.epa.gov/dashboard/>

⁽³²⁾ European Platform on Life Cycle Assessment: <https://eplca.jrc.ec.europa.eu/LCDN/contactListEF.xhtml>

⁽³³⁾ Global LCA Data Access Network: <https://www.globalcadataaccess.org/>

⁽³⁴⁾ <https://ec.europa.eu/eurostat/web/main/data/database>

III

(Other acts)

EUROPEAN ECONOMIC AREA

EFTA SURVEILLANCE AUTHORITY DELEGATED DECISION No 204/22/COL

of 16 November 2022

amending Decision No 196/22/COL concerning emergency measures in Norway in relation to outbreaks of highly pathogenic avian influenza pursuant to Article 259(1)(c) of Regulation (EU) 2016/429 and Articles 21, 39 and 55 of Delegated Regulation (EU) 2020/687 [2022/2511]

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, in particular Articles 1(2) and 3 of Protocol 1 thereof,

Having regard to the Act referred to at Point 13. of Part 1.1 of Chapter I of Annex I to the Agreement on the European Economic Area ('EEA Agreement'), Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 *on transmissible animal diseases and amending and repealing certain acts in the area of animal health* ('Regulation (EU) 2016/429') ⁽¹⁾, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Articles 257(1), 258(1), (2) and (3) and 259(1)(c) thereof,

Having regard to the Act referred to at Point 13e. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council *as regards rules for the prevention and control of certain listed diseases* ('Delegated Regulation (EU) 2020/687') ⁽²⁾, as amended and as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Articles 21, 39 and 55 thereof,

Having regard to the Act referred to at Point 13a. of Part 1.1 of Chapter I of Annex I to the EEA Agreement, Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 *on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases* ('Implementing Regulation (EU) 2018/1882') ⁽³⁾, as adapted to the EEA Agreement by the specific and the sectoral adaptations referred to in Annex I to that Agreement, and in particular Articles 1 and 2 as well as the Annex thereof,

as adapted to the EEA Agreement by point 4(d) of Protocol 1 to the EEA Agreement,

Whereas:

Highly pathogenic avian influenza ('HPAI') is an infectious viral disease in birds and may have a severe impact on the profitability of poultry farming causing disturbance to trade within the European Economic Area ('EEA'). HPAI viruses can infect migratory birds, which can then spread these viruses over long distances during their autumn and spring migrations. Therefore, the presence of HPAI viruses in wild birds poses a continuous threat for the direct and indirect introduction of these viruses into holdings where poultry or captive birds are kept. In the event of an outbreak of HPAI, there is a risk that the disease agent may spread to other holdings where poultry or captive birds are kept.

⁽¹⁾ Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020.

⁽²⁾ Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 3/2021 of 5 February 2021.

⁽³⁾ Incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020.

Regulation (EU) 2016/429, Delegated Regulation (EU) 2020/687 and Implementing Regulation (EU) 2018/1882 have applied from 21 April 2021.

Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases transmissible to animals or humans. HPAI is referred to in Article 9(1)(a)(i) of Regulation (EU) 2016/429 as a listed disease subject to the disease prevention and control rules laid down therein. The Annex to Implementing Regulation (EU) 2018/1882 lists HPAI as a category A, D and E disease as defined in Article 1 of that Regulation.

Article 259(1) of Regulation (EU) 2016/429 requires the EFTA Surveillance Authority ('the Authority') to review emergency measures taken by the Norwegian competent authorities pursuant to Article 257(1)(a) or 258 of the same Regulation in the event of an outbreak of a listed disease referred to in point (a) of Article 9(1), including HPAI ('Norwegian measures'). Article 259(1)(c) requires the Authority, where it considers it necessary to avoid unjustified disruptions in the movement of animals and products, to adopt emergency measures referred to in Article 257(1) approving the Norwegian measures.

Delegated Regulation (EU) 2020/687 supplements the rules for the control of category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures for HPAI. Article 21 of that Regulation provides for the establishment of protection and surveillance zones in the event of an outbreak of a category A disease, including HPAI. This regionalisation is applied in particular to preserve the health status of birds in the remainder of the territory of Norway by preventing the introduction of the pathogenic agent and ensuring the early detection of the disease.

On 26 October 2022, the Authority adopted Decision 196/22/COL concerning emergency measures in Norway in relation to an outbreak of HPAI. Norway had notified a confirmed outbreak of HPAI in a holding of approximately 7 000 birds laying hatching eggs on its territory on 22 October 2022 ⁽⁴⁾.

On 12 November 2022, Norway notified a new confirmed outbreak of HPAI on its territory in a holding of approximately 7 500 laying hens ("the second HPAI outbreak") ⁽⁵⁾. An update to the notification was received on 15 November 2022 ⁽⁶⁾. The Norwegian competent authorities have taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around the second HPAI outbreak.

In order to prevent any unnecessary disturbance to trade within the EEA, it is necessary to rapidly describe the protection and surveillance zones established by Norway in relation to both outbreaks of HPAI.

Accordingly, the protection and surveillance zones relating to HPAI in Norway, where the disease control measures as laid down in Delegated Regulation (EU) 2020/687 are applied, are listed in the Annex to this Decision approving the Norwegian measures pursuant to Article 259(1)(c) of Regulation (EU) 2016/429 and the duration of that regionalisation specified in that Annex.

The Authority has examined the disease control measures in collaboration with Norway, and it is satisfied that the boundaries of the protection and surveillance zones, established by the competent authorities of Norway, are at a sufficient distance to any holding where an outbreak of HPAI has been confirmed.

Therefore, the areas listed as protection and surveillance zones in the Annex to the Authority's Decision No 196/22/COL should be amended.

⁽⁴⁾ Document No 1322915.

⁽⁵⁾ Document No 1327550.

⁽⁶⁾ Document No 1328618.

On 15 November 2022, the Authority, by its Delegated Decision No 203/22/COL (Document No 1327635), duly submitted the draft Decision to the EFTA Veterinary and Phytosanitary Committee in accordance with Articles 259(1) and 266(2) of Regulation (EU) 2016/429. On 16 November 2022, the EFTA Committee delivered a positive opinion on the draft Decision. Accordingly, the draft Decision is in accordance with the opinion of the Committee,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to the Authority's Decision No 196/22/COL is replaced by the text in the Annex to this Decision.

Article 2

This Decision shall enter into force on the day of its signature.

Article 3

This Decision shall apply until the latest date mentioned in the Annex to this Decision on which disease control measures in any of the protection or surveillance zones cease to be applicable in accordance with Articles 39 or 55 of Delegated Regulation (EU) 2020/687, as relevant.

Article 4

This Decision is addressed to Norway.

Article 5

This Decision shall be authentic in the English language.

Done at Brussels, 16 November 2022.

For the EFTA Surveillance Authority, acting under Delegation Decision No 130/20/COL,

Árni Páll ÁRNASON
Responsible College Member

Melpo-Menie JOSÉPHIDÈS
*Countersigning as Director,
Legal and Executive Affairs*

Part A**Protection zones in Norway as referred to in Articles 1 and 2**

Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687	Adopted by EFTA's Surveillance Authority Decision Number:
The parts of the municipalities Klepp, Sandnes and Sola in the county of Rogaland that are contained within a circle of 3 kilometres radius, centred on GPS coordinates N: 58.80459 E: 5.61203	12.11.2022	196/22/COL
The parts of the municipality of Sola in the county of Rogaland that are contained within a circle of 3 kilometres radius, centred on GPS coordinates N: 58.90047 E: 5.57987	07.12.2022	204/22/COL

Part B**Surveillance zones in Norway as referred to in Articles 1 and 3**

Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687	Adopted by EFTA's Surveillance Authority Decision Number
The parts of the municipalities Klepp, Sandnes, Sola and Time in the County of Rogaland, beyond the area described in the protection zone and within the circle of 10 kilometres radius, centred on GPS coordinates N: 58.80459 E: 5.61203	22.11.2022	196/22/COL
The parts of the municipalities Klepp, Sandnes and Sola in the county of Rogaland that are contained within a circle of 3 kilometres radius, centred on GPS coordinates N: 58.80459 E: 5.61203	From 12.11.2022 until 22.11.2022	196/22/COL
The parts of the municipalities Randaberg, Stavanger, Klepp, Sandnes and Sola in the County of Rogaland, beyond the area described in the protection zone and within the circle of 10 kilometres radius, centred on GPS coordinates N: 58.90047 E: 5.57987	16.12.2022	204/22/COL
The parts of the municipality of Sola in the county of Rogaland that are contained within a circle of 3 kilometres radius, centred on GPS coordinates N: 58.90047 E: 5.57987	From 08.12.2022 until 16.12.2022	204/22/COL

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