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Legislation

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Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2022/158 of 4 February 2022 amending Implementing Regulation (EU) 2020/1641 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America ⁽¹⁾ 1**
- ★ **Commission Implementing Regulation (EU) 2022/159 of 4 February 2022 approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 ⁽¹⁾ 7**
- ★ **Commission Implementing Regulation (EU) 2022/160 of 4 February 2022 laying down uniform minimum frequencies of certain official controls to verify compliance with Union animal health requirements in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and repealing Regulations (EC) No 1082/2003 and (EC) No 1505/2006 ⁽¹⁾ 11**

DECISIONS

- ★ **Commission Implementing Decision (EU) 2022/161 of 3 February 2022 terminating the examination procedure concerning obstacles to trade within the meaning of Regulation (EU) 2015/1843 applied by the United Mexican States consisting of measures affecting the import of Tequila 17**
- ★ **Commission Implementing Decision (EU) 2022/162 of 4 February 2022 laying down rules for the application of Directive (EU) 2019/904 of the European Parliament and of the Council as regards the calculation, verification and reporting on the reduction in the consumption of certain single-use plastic products and the measures taken by Member States to achieve such reduction ⁽¹⁾ 19**

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/158

of 4 February 2022

amending Implementing Regulation (EU) 2020/1641 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America

(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 129(1) 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 Article 238(3) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down general rules for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing, to acceptable levels, the risks to which humans and animals are exposed either directly or through the environment.
- (2) In particular, Regulation (EU) 2017/625 lays down general conditions for the entry into the Union of animals and goods from third countries or regions thereof, including food intended for human consumption. Article 129 of Regulation (EU) 2017/625 empowers the Commission to recognise that measures applied by third countries, or regions thereof, are equivalent to the requirements laid down in certain rules referred to in Article 1(2) of that Regulation, if the third countries offer objective proof in this respect. It also empowers the Commission to set out the conditions governing the entry into the Union of such animals and goods from such third countries or regions thereof, in particular with regard to the nature and content of the official certificates or attestations that are to accompany those commodities.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ OJ L 84, 31.3.2016, p. 1.

- (3) In accordance with Commission Implementing Regulation (EU) 2020/1641 ⁽³⁾, the measures applied in the States of Massachusetts and Washington of the United States for the protection of public health in relation to the production and placing on the market of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption are equivalent to the requirements laid down in rules as regards food safety referred to in Article 1(2)(a) of Regulation (EU) 2017/625.
- (4) Implementing Regulation (EU) 2020/1641 establishes a model official certificate for imports from the United States of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption. The model official certificate requires an official inspector to certify that the measures applied to the production and placing on the market of those commodities are equivalent to the requirements laid down in rules as regards food safety referred to in Article 1(2)(a) of Regulation (EU) 2017/625.
- (5) In line with the measures agreed with the department of the Food and Drug Administration of the United States responsible for the export to the Union of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption, the model official certificate established in Implementing Regulation (EU) 2020/1641 should be adapted to the appropriate format for the export to the Union of those commodities. In particular, the model official certificate should inform about the date of departure of the consignments. Furthermore, information should be provided on whether the commodities are certified for human consumption or for the final consumer.
- (6) In addition to the public health requirements of the model official certificate established in Implementing Regulation (EU) 2020/1641, live bivalve molluscs of species listed in Commission Implementing Regulation (EU) 2018/1882 ⁽⁴⁾, which are intended for human consumption, and products of animal origin from those molluscs, which are intended for further processing in the Union before human consumption, should enter the Union only if they are accompanied by an official certificate that includes the appropriate animal health attestations. Consequently, in order to fulfil animal health requirements that provide guarantees equivalent to those provided for in Union legislation, the model official certificate should include the general animal health requirements for entry into the Union, as set out in Article 6(1), points (a) and (b), Articles 6(2) and 7(1) and Article 8 of Commission Delegated Regulation (EU) 2020/692 ⁽⁵⁾, and the specific animal health requirements for entry into the Union of those commodities as set out in Article 167, points (a), (c)(ii), (c)(iii) and (d), and Article 169(1) and (2) of Delegated Regulation (EU) 2020/692.
- (7) Implementing Regulation (EU) 2020/1641 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2020/1641 is replaced by the text set out in the Annex to this Regulation.

⁽³⁾ Commission Implementing Regulation (EU) 2020/1641 of 5 November 2020 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America (OJ L 370, 6.11.2020, p. 4).

⁽⁴⁾ 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).

⁽⁵⁾ 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).

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, 4 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

MODEL OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF LIVE, CHILLED, FROZEN OR PROCESSED
BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN
CONSUMPTION FROM THE UNITED STATES OF AMERICA

Part I: Details of dispatched consignment	I.1. Consignor/Exporter				I.2. Certificate reference number		I.2.a.
	Name				I.3. Central Competent Authority		
	Address						
	Postal code						
	Tel No.						
	I.5. Consignee/Importer				I.6.		
	Name						
	Address						
	Postal code						
	Tel No.						
I.7. Country of origin	ISO code	I.8. State of origin	Code	I.9. Country of destination	ISO code	I.10.	
USA	US	SEE BOX I.28	SEE BOX I.28				
I.11. Place of dispatch				I.12.			
Name							
Approval number							
Address							
I.13. Place of loading				I.14. Date of departure			
I.15. Means of transport				I.16. Entry BCP in EU			
Airplane ☐ Ship ☐ Railway wagon ☐							
Identification				I.17			
Documentary references:							
I.18. Description of commodity				I.19. Commodity code (HS code)			
				I.20. Quantity			
I.21. Temperature of product				I.22. Number of packages			
Ambient ☐ Chilled ☐ Frozen ☐							
I.23. Identification of container/Seal number				I.24. Type of packaging			
I.25. Commodities certified for							
☐ Human consumption ☐ Final consumer							

I.26.	I.27. For import or admission into EU ☐						
I.28. Identification of the commodities							
Species (Scientific name)	Nature of commodity	Treatment type	Manufacturing plant name and approval number	Harvest location/ Establishment of Origin	Batch No.	Number of packages	Net Weight

United States (US)**Veterinary certificate to EU**

Part II: Certification	II. Health information	II.a. Certificate reference number	II.b.
	II.1. Public health attestation for live, chilled, frozen or processed bivalve molluscs, tunicates and marine gastropods intended for human consumption I, the undersigned hereby certify that: — The herein described products comply with and were produced in accordance with relevant US standards and requirements of the US molluscan shellfish regulatory control program. — The herein described products are labelled as not destined to be immersed or in contact with any EU water — All foreign-sourced shellfish material used in these products originates from third countries/establishments/growing areas approved to export live bivalve molluscs to the EU. (1) (2) II.2. Animal health attestation for live bivalve molluscs⁽³⁾ of listed species intended for human consumption, I, the undersigned official veterinarian, hereby certify that the aquatic animals referred to in Box I.18 of Part I meet: II.2.1. the general animal health requirements for entry into the Union, which are set out in Article 6(1), in points (a)⁽⁴⁾, and (b), Articles 6(2) and 7(1) and Article 8 of Commission Delegated Regulation (EU) 2020/692 ⁽⁴⁾; II.2.2. the specific animal health requirements for entry into the Union of the commodities to which this certificate applies, which are set out in Article 167, points (a), (c)(ii), (c)(iii) and (d), and Article 169(1) and (2) of Delegated Regulation (EU) 2020/692.] <i>Notes</i> n 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 the European Union in this certificate include the United Kingdom in respect of Northern Ireland.		

Part I:

— Box reference I.8: Region of origin: state of US harvest and code of approved production area.

Part II:

- (1) Part II.2. of this certificate applies only to the following commodities of live bivalve molluscs intended for human consumption:
- (a) molluscs of listed species transported without water which are packaged and labelled for human consumption in accordance with the specific requirements for those animals as set out in Regulation (EC) No 853/2004 of the European Parliament and of the Council ^(b) and which are no longer able to survive as living animals if returned to the aquatic environment;
 - (b) molluscs of listed species transported without water which are intended for human consumption without further processing, provided they are packaged for retail sale in compliance with the requirements for such packaging as set out in Regulation (EC) No 853/2004;
 - (c) molluscs of listed species transported without water which are packaged and labelled for human consumption in accordance with the specific requirements for those animals as set out in Regulation (EC) No 853/2004 and which are intended for further processing without temporary storage at the place of processing.
- (2) Part II.2 does not apply, and should be deleted when the consignment consists of wild aquatic animals which are landed from fishing vessels.
- (3) Species listed in columns 3 and 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882 ^(c). Species listed in column 4 of that table shall only be regarded as vectors under the conditions set out in Article 171(1) of Delegated Regulation (EU) 2020/692.
- (4) Where disease is relevant and reportable.
- (5) To be signed by:
- an official veterinarian when the animal health attestation of part II.2 is completed;
 - a certifying officer or an official veterinarian when the animal health attestation in part II.2 is deleted.

[Official veterinarian]⁽⁵⁾ / [Certifying officer]⁽⁵⁾

Name (in capitals) _____

Qualification and title _____

Date _____

Signature _____

Stamp

^(a) 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).

^(b) 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).

^(c) 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).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/159**of 4 February 2022****approving the low-risk active substance *Bacillus amyloliquefaciens* strain IT-45 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, Danstar Ferment AG and Comercial Quimica Masso submitted to France, on 26 June 2017, an application for the approval of the active substance *Bacillus amyloliquefaciens* strain IT-45.
- (2) In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the applicants, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 1 December 2017 of the admissibility of the application.
- (3) On 15 May 2019, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, concluding that the active substance *Bacillus amyloliquefaciens* strain IT-45 could be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority also set a time limit for the applicants to supply additional information to the Member States, the Commission and the Authority
- (5) In its Conclusion, communicated to the applicants, the Member States and the Commission, following a peer review of the pesticide risk assessment pursuant to Article 12 (2) of Regulation (EC) No 1107/2009, the Authority held that the active substance *Bacillus amyloliquefaciens* strain IT-45 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public ⁽²⁾.
- (6) On 21-22 October 2021, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed its review report on the active substance *Bacillus amyloliquefaciens* strain IT-45 and a draft of this Regulation regarding *Bacillus amyloliquefaciens* strain IT-45.
- (7) The applicants were given the possibility to submit comments on the review report.
- (8) It has been established with respect to one representative use of at least one plant protection product containing the active substance, as examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

⁽¹⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁽²⁾ Conclusion on the Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain IT-45. EFSA Journal 2021;19(5):6594 <https://doi.org/10.2903/j.efsa.2021.6594>.

- (9) Since the Commission considers that *Bacillus amyloliquefaciens* strain IT-45 is a low-risk active substance, pursuant to Article 22 of Regulation (EC) No 1107/2009, and since plant protection products containing that substance may be expected to pose only a low risk to human and animal health and the environment, it may be approved for up to 15 years. No critical area of concerns were identified for humans, animals and the environment.
- (10) *Bacillus amyloliquefaciens* strain IT-45 is a microorganism, which also fulfils the conditions established by Article 22 (2) of Regulation (EC) No 1107/2009, in conjunction with point 5.2. of Annex II to that Regulation. It is therefore appropriate to approve *Bacillus amyloliquefaciens* strain IT-45 as a low-risk substance.
- (11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of the active substance

The active substance *Bacillus amyloliquefaciens* strain IT-45, as specified in Annex I, is approved

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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, 4 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Bacillus amyloliquefaciens</i> IT-45	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> IT-45 in the technical product and formulation is: minimum: 2×10^{13} CFU/kg, maximum: 6×10^{14} CFU/kg. No relevant impurities	27 February 2022	27 February 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> IT-45 shall be taken into account.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the review report.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'35	<i>Bacillus amyloliquefaciens</i> IT-45	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> IT-45 in the technical product and formulation is: minimum: 2×10^{13} CFU/kg, maximum: 6×10^{14} CFU/kg. No relevant impurities	27 February 2022	27 February 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> IT-45 shall be taken into account.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the review report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2022/160**of 4 February 2022****laying down uniform minimum frequencies of certain official controls to verify compliance with Union animal health requirements in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and repealing Regulations (EC) No 1082/2003 and (EC) No 1505/2006****(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 20, paragraph 3, first subparagraph, point (a), thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down general rules for official controls performed by the competent authority for the verification of compliance with rules in a number of areas, including animal health, on a risk basis and with appropriate frequencies. That Regulation also lays down methods and techniques for official controls, which include, among others, inspections of premises, animals and goods under the control of operators.
- (2) Regulation (EU) 2017/625 provides for uniform practical arrangements for the performance of official controls regarding uniform minimum frequencies of official controls to be laid down, where necessary to respond to specific hazards and risks to animal health and to verify compliance with disease prevention and control measures.
- (3) Before the entry into application of Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽²⁾, a number of legal acts on animal health laid down rules for minimum frequencies for official controls, in particular inspections. Regulation (EU) 2016/429 repealed those legal acts with effect from 21 April 2021.
- (4) Commission Delegated Regulation (EU) 2019/2035 ⁽³⁾ lays down requirements for approval, among others, of hatcheries and establishments keeping poultry, establishments for assembly operations for ungulates and poultry, assembly centres of dogs, cats and ferrets, animal shelters for dogs, cats and ferrets, control posts, environmentally isolated production establishments for bumble bees, quarantine establishments and confined establishments of terrestrial animals.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ 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 084 31.3.2016, p. 1).

⁽³⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).

- (5) Commission Delegated Regulation (EU) 2020/686 ⁽⁴⁾ lays down requirements for approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals may be moved to another Member State.
- (6) Commission Delegated Regulation (EU) 2020/691 ⁽⁵⁾ lays down requirements for approval of certain aquaculture establishments and groups of aquaculture establishments keeping aquatic animals posing a significant animal health risk.
- (7) It is important that the competent authority verifies by way of regular official controls, in particular by way of inspections referred to in Article 14, point (b), of Regulation (EU) 2017/625, that the animals and germinal products are continued to be kept and produced under the uniform approval conditions for establishments, that are intended to mitigate risks and hazards associated with diseases listed in Regulation (EU) 2016/429 and with emerging diseases. To respond to those uniform hazards and risks to human and animal health posed by those diseases, uniform minimum frequencies for inspections in certain approved establishments should be laid down in this Regulation.
- (8) For approved germinal product establishments any uniform minimum frequency for inspections should take into account the non-seasonal nature of collecting semen of bovine and porcine animals.
- (9) Any uniform minimum frequency for inspections in certain approved aquaculture establishments and approved groups of aquaculture establishments should take into account the risk ranking of that establishment or group of establishments in accordance with Commission Delegated Regulation (EU) 2020/689 ⁽⁶⁾.
- (10) As regards identification and registration of certain animals, Commission Regulations (EC) No 1082/2003 ⁽⁷⁾ and Commission Regulation (EC) No 1505/2006 ⁽⁸⁾ lay down the minimum level of controls or checks to be carried out in establishments keeping bovine, ovine and caprine animals each year as well as the number of animals to be inspected in each of those establishment.
- (11) Delegated Regulation (EU) 2019/2035 also lays down detailed requirements for the identification and registration of bovine, ovine and caprine animals to ensure their traceability.
- (12) Bovine, ovine or caprine animals that are not identified or registered in accordance with the requirements laid down in Delegated Regulation (EU) 2019/2035 may play a role in spreading diseases listed in Regulation (EU) 2016/429 and in emerging diseases. To mitigate that uniform hazard and risk to human and animal health, to regularly verify compliance of operators with the requirements laid down in Delegated Regulation (EU) 2019/2035 and to ensure the uniform implementation of Regulation (EU) 2017/625, uniform minimum frequencies for inspections during the performance of official controls on identification and registration of bovine, ovine, and caprine animals should be laid down.

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals (OJ L 156, 25.6.2003, p. 9).

⁽⁸⁾ Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals (OJ L 280, 12.10.2006, p. 3).

- (13) Delegated Regulation (EU) 2019/2035 did not explicitly repeal Regulations (EC) No 1082/2003 and (EC) No 1505/2006. To ensure legal certainty, this Regulation should repeal those Regulations.
- (14) The rules laid down in this Regulation should apply to the United Kingdom in respect of Northern Ireland, in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to 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 in conjunction with Annex 2 to that Protocol.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down uniform minimum frequencies for official controls, in particular, inspections of animals and germinal products, and the conditions under which they are kept or produced in the following establishments:

- (a) approved establishments for kept terrestrial animals and hatching eggs referred to in Article 1(1), point (a), of Delegated Regulation (EU) 2019/2035;
- (b) approved germinal product establishments referred to in Article 3 of Delegated Regulation (EU) 2020/686;
- (c) certain aquaculture establishments approved pursuant to Article 176(1), of Regulation (EU) 2016/429 and groups of aquaculture establishments approved pursuant to Article 177, of that Regulation;
- (d) registered establishments for kept terrestrial animals referred to in Article 1(1) point (a), of Delegated Regulation (EU) 2019/2035 that keep bovine, ovine or caprine animals.

Article 2

Definitions

For the purposes of this Regulation, the following definitions laid down in Regulation (EU) 2016/429, in Delegated Regulation (EU) 2019/2035, Delegated Regulation (EU) 2020/686, Delegated Regulation (EU) 2020/688 ⁽⁹⁾ and Delegated Regulation (EU) 2020/990 ⁽¹⁰⁾ shall apply:

- (a) 'establishment' as defined in Article 4, point (27), of Regulation (EU) 2016/429;
- (b) 'hatchery' as defined in Article 4, point (47), of Regulation (EU) 2016/429;
- (c) 'assembly operation' as defined in Article 4, point (49), of Regulation (EU) 2016/429;
- (d) 'assembly centre of dogs, cats and ferrets' as defined in Article 2, point (7), of Delegated Regulation (EU) 2019/2035;
- (e) 'animal shelter' as defined in Article 2, point (8), of Delegated Regulation (EU) 2019/2035;
- (f) 'control post' as defined in Article 2, point (9), of Delegated Regulation (EU) 2019/2035;
- (g) 'environmentally isolated production establishment' as defined in Article 2, point (10), of Delegated Regulation (EU) 2019/2035;

⁽⁹⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

⁽¹⁰⁾ Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L 221, 10.7.2020, p. 42).

- (h) 'approved quarantine establishment' as defined in Article 3, point (9), of Delegated Regulation (EU) 2020/688;
- (i) 'confined establishment' as defined in Article 4, point (48), of Regulation (EU) 2016/429;
- (j) 'approved germinal product establishment' as defined in Article 2, point (2), of Delegated Regulation (EU) 2020/686;
- (k) 'approved aquaculture establishment' as defined in Article 2, point (10), of Delegated Regulation (EU) 2020/990;
- (l) 'approved group of aquaculture establishments' as defined in Article 2, point (11), of Delegated Regulation (EU) 2020/990.

Article 3

Uniform minimum frequency of inspections in certain approved establishments

The competent authorities of Member States ⁽¹⁾ shall perform at least once every calendar year, official controls on, in particular inspections of, animals and hatching eggs and the conditions under which those animals and hatching eggs are kept or produced in the following types of establishments on its territory that have obtained approval from the competent authority:

- (a) hatcheries and establishments keeping poultry;
- (b) establishments for assembly operations for ungulates and poultry;
- (c) assembly centres of dogs, cats and ferrets;
- (d) animal shelters for dogs, cats and ferrets;
- (e) control posts;
- (f) environmentally isolated production establishments for bumble bees;
- (g) approved quarantine establishments;
- (h) confined establishments.

Article 4

Uniform minimum frequency of inspections in approved germinal product establishments

The competent authorities of the Member States shall perform official controls on, and in particular, inspections of, germinal products, except hatching eggs, and the conditions under which those germinal products are produced every calendar year in the following types of establishments on its territory that have obtained approval from the competent authority:

- (a) at least twice every calendar year, semen collection centres for bovine and porcine animals;
- (b) at least once every calendar year:
 - (i) semen collection centres for ovine, caprine and equine animals;
 - (ii) embryo collection or production teams;
 - (iii) germinal product processing establishments;
 - (iv) germinal product storage centres.

⁽¹⁾ 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, for the purposes of this Regulation references to 'Member States' include the United Kingdom in respect of Northern Ireland.

*Article 5***Uniform minimum frequency of inspections in certain approved aquaculture establishments and in certain approved groups of aquaculture establishments**

The competent authority of a Member State shall perform official controls on, and in particular, inspections of, aquaculture animals and the conditions under which those animals are kept in certain approved aquaculture establishments and approved groups of aquaculture establishments on its territory. Those official controls shall take into account the risk ranking of the approved aquaculture establishment or the approved group of aquaculture establishments determined by the competent authority pursuant to Part 1, Chapter 1, point 1.2, of Annex VI to Delegated Regulation (EU) 2020/689 or the risk ranking of the establishments in dependent compartments referred to in Article 73(3), point (b), of that Regulation, as follows:

- (a) high-risk establishments shall be inspected at least once every calendar year;
- (b) medium-risk establishments shall be inspected at least once every two calendar years;
- (c) low-risk establishments shall be inspected at least once every three calendar years.

*Article 6***Uniform minimum frequency of inspections in establishments keeping bovine, ovine and caprine animals**

The competent authority of a Member State shall perform official controls on, and in particular, inspections of, the identification and registration of bovine, ovine and caprine animals every calendar year in at least 3 % of establishments on its territory keeping those animals.

*Article 7***Repeals**

1. Regulations (EC) No 1082/2003 and (EC) No 1505/2006 are repealed.
2. References to the repealed Regulations shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex.

*Article 8***Entry into force**

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, 4 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Correlation tables referred to in Article 7(2)

1. Regulation (EC) No 1082/2003

Regulation (EC) No 1082/2003	This Regulation
Article 1	-
Article 2(1)	Article 6
Article 2(2)	-
Article 2(3)	-
Article 2(4)	-
Article 2(5)	-
Article 2(6)	-
Article 3	-
Article 4	-
Article 5	-
Annex I	-

2. Regulation (EC) No 1505/2006

Regulation (EC) No 1505/2006	This Regulation
Article 1	-
Article 2	-
Article 3	-
Article 4	-
Article 5(1), first subparagraph	Article 6
Article 5(1), second subparagraph	-
Article 5(2), first subparagraph	-
Article 5(2), second subparagraph	-
Article 6	-
Article 7	-
Annex	-

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/161

of 3 February 2022

terminating the examination procedure concerning obstacles to trade within the meaning of Regulation (EU) 2015/1843 applied by the United Mexican States consisting of measures affecting the import of Tequila

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/1843 of the European Parliament and the Council of 6 October 2015 laying down Union procedures in the field of the common commercial policy in order to ensure the exercise of the Union's rights under international trade rules, in particular those established under the auspices of the World Trade Organization ⁽¹⁾, and in particular Articles 5(2) and 12(1) thereof,

Whereas:

1. PROCEDURE

- (1) On 23 July 2020, the European Commission initiated an examination procedure concerning obstacles to trade applied by the United Mexican States consisting of the refusal to grant export certificates in respect of Tequila by publishing a notice of initiation in the *Official Journal of the European Union* ⁽²⁾.
- (2) The investigation was initiated following a complaint lodged by the Brewers of Europe Association on behalf of the Union industry. The complaint contained sufficient evidence of trade restriction and of a resulting injury to justify the initiation of the investigation.
- (3) On 16 April 2021, the Commission services informed the Committee established by Article 7(1) of Regulation (EU) 2015/1843 of the results of the examination procedure. The report concluded that, while there was no immediate interest of the EU to pursue the matter to dispute settlement, the procedure should remain open and further developments in the United Mexican States should be monitored.

2. WITHDRAWAL OF THE COMPLAINT AND TERMINATION OF THE PROCEEDING

- (4) On 6 October 2021, the Brewers of Europe Association informed the Commission that it wishes to withdraw the complaint.
- (5) Under Article 5(2) of Regulation (EU) 2015/1843, proceedings may be terminated where the complaint is withdrawn, unless such termination would not be in the Union interest. Under Article 12(1) of Regulation (EU) 2015/1843, proceedings shall be terminated when the interests of the Union do not require any action to be taken.
- (6) The investigation had not brought to light any indications that the termination would not be in the Union's interest. In particular, exports of Tequila to the affected European brewer have resumed and the alleged measure does not have a systemic effect on other EU companies.

⁽¹⁾ OJ L 272, 16.10.2015, p. 1.

⁽²⁾ OJ C 265, 13.8.2020, p. 3.

- (7) The Commission therefore concluded that the examination procedure concerning obstacles to trade applied by the United Mexican States consisting of the refusal to grant export certificates in respect of 'Tequila' spirit should be terminated.
- (8) The Decision is in accordance with the opinion of the Committee established by Article 7(1) of Regulation (EU) 2015/1843,

HAS ADOPTED THIS DECISION:

Article 1

The examination procedure regarding the refusal of the United Mexican States to grant export certificates in respect of 'Tequila' spirit is terminated.

Article 2

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

Done at Brussels, 3 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2022/162**of 4 February 2022****laying down rules for the application of Directive (EU) 2019/904 of the European Parliament and of the Council as regards the calculation, verification and reporting on the reduction in the consumption of certain single-use plastic products and the measures taken by Member States to achieve such reduction****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment ⁽¹⁾, and in particular Article 4(2) and Article 13(4), first subparagraph, thereof,

Whereas:

- (1) Directive (EU) 2019/904 lays down an obligation on Member States to take measures to achieve an ambitious and sustained reduction in the consumption of the single-use plastic products listed in Part A of the Annex to that Directive ('single-use plastic products'). The Commission is to lay down the methodology for the calculation and verification of that consumption reduction.
- (2) Directive (EU) 2019/904 also sets out an obligation on Member States to report to the Commission data on the single-use plastic products that have been placed on the market each year and information on the measures taken in order to reduce the consumption of such products, including a quality check report. The Commission is to lay down the format for that reporting.
- (3) Directive (EU) 2019/904 gives Member States a wide margin of discretion in deciding which measures to adopt in order to achieve an ambitious and sustained reduction in the consumption of single-use plastic products. Those measures may vary depending on the environmental impact of the single-use plastic products over their life cycle, including when they become litter, and they shall be proportionate and non-discriminatory.
- (4) Measuring consumption reduction on the basis of the weight of plastic content in single-use plastic products placed on the market is an appropriate measurement method since it reflects the environmental impact of such products in terms of environmental pollution by plastic littering. That method also takes into consideration the measurement methods and reporting formats for packaging and packaging waste set out in Commission Decision 2005/270/EC ⁽²⁾ which are based on weight and material.
- (5) Measuring consumption reduction on the basis of a number of single-use plastic products placed on the market is also an appropriate methodology to monitor the impact, at a product level, of consumption reduction on waste prevention and therefore the potential reduction of plastic pollution in the environment.
- (6) Given the wide margin of discretion given to Member States by Article 4 of Directive (EU) 2019/904, Member States should be given the choice between calculating the consumption reduction based on either the total weight of the plastic contained in the single-use plastic products placed on the market or the number of such products placed on the market. Since both methodologies provide suitable data to monitor consumption trends and the impact of the

⁽¹⁾ OJ L 155, 12.6.2019, p. 1.

⁽²⁾ Commission Decision 2005/270/EC of 22 March 2005 establishing the formats relating to the database system pursuant to Directive 94/62/EC of the European Parliament and of the Council on packaging and packaging waste (OJ L 86, 5.4.2005, p. 6), as amended by Commission Implementing Decision (EU) 2019/665 of 17 April 2019 (OJ L 112, 26.4.2019, p. 26).

measures taken on prevention of waste generation as well as on substitution of the products with alternatives that are re-usable or do not contain plastic, Member States should be given the option to choose from those two methodologies the methodology that is compatible with their consumption reduction policies and measures taken under Article 4 of Directive (EU) 2019/904.

- (7) Where, in a certain Member State, the number or the weight of single-use plastic products placed on the market is not representative for the consumption of single-use plastic products in that Member State due to significant movements within the Union of single-use plastic products at wholesale level, that Member State should be allowed to adjust the weight or number in order to take account of such movements.
- (8) Where a Member State chooses to apply the weight-based methodology, it should also report data on the total weight of single-use plastic products partly made of plastic that have been placed on the market, as such information contributes to data comparability and makes it possible to obtain a broader overview of the impact of the consumption reduction requirement set out in Directive (EU) 2019/904.
- (9) In order to facilitate the Commission's overview of the measures taken by the Member States to achieve a reduction in the consumption of the single-use plastic products in accordance with Directive (EU) 2019/904, the reporting format should contain an indicative list of different categories of such measures. Member States are, however, required to report all the measures undertaken even if not explicitly mentioned in the indicative list.
- (10) In order to ensure accuracy and verification of data, the reporting format should ensure that all the parameters relevant for the calculation and verification of the reduction in the consumption of single-use plastic products, for the reporting of data on such products placed on the market and for the reporting of measures taken to achieve the consumption reduction are identified and should set out the methodology to be applied for the calculation and verification of the consumption reduction.
- (11) The methodology for the calculation and verification of the reduction in the consumption of single-use plastic products, referred to in Article 4(2) of Directive (EU) 2019/904, and the formats for reporting data on the single-use plastic products placed on the market as well as information on the measures taken by the Member States, referred to in Article 13(4) of that Directive, are closely linked in view of their subject-matter. It is therefore appropriate to adopt this act on the basis of both of those provisions in order to ensure coherence between the rules on calculation, verification and reporting of the reduction in the consumption of single-use plastic products and to facilitate access to those rules.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 39 of Directive 2008/98/EC of the European Parliament and of the Council ⁽⁷⁾,

HAS ADOPTED THIS DECISION:

Article 1

Methodology for calculating the reduction in the consumption of single-use plastic products

1. Member States shall calculate the reduction in the consumption of single-use plastic products based on either of the following parameters:

- (a) the total weight of plastic in the single-use plastic products placed on the market in a Member State in a calendar year;
- (b) the number of single-use plastic products placed on the market in a Member State in a calendar year.

⁽⁷⁾ 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. Member States shall calculate the reduction in the consumption of single-use plastic products placed on the market in a Member State in a calendar year in accordance with the formulas set out in Annex I.
3. Where there are significant exports or imports or other movements within the Union of single-use plastic products before they are made available to the final consumer or user, Member States may adjust the weight or number of single-use plastic products placed on the market, as referred to in paragraph 1, in order to take account of such movements.

Article 2

Reporting of data

1. Member States shall report the data on single-use plastic products placed on the market referred to in Article 13(1), point (a), of Directive (EU) 2019/904, as calculated in accordance with Article 1 of this Decision, in the format laid down in Annex II to this Decision.
2. Member States shall report the information on consumption reduction measures referred to in Article 13(1), point (b), of Directive (EU) 2019/904 in the format laid down in Annex III to this Decision.
3. Member States shall submit the quality check report as regards the data and information referred to in this Article in the format laid down in Annex IV.
4. The Commission shall publish the data reported by the Member States unless, as regards information included in the quality check report, the Member State provides a justified request to withhold the publication of certain data.
5. Member States shall, to the extent possible, use electronic registries to collect and report data to the Commission.

Article 3

Entry into force

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

Done at Brussels, 4 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Formulas for the calculation of the reduction in the consumption of single-use plastic products

For single-use plastic cups for beverages, including their covers and lids, referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 ('cups for beverages'):

$$\text{ConRedCfB} = \frac{\text{PoMCfB}(t) - \text{PoMCfB}(t2022)}{\text{PoMCfB}(t2022)} \times 100$$

For single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 ('food containers'):

$$\text{ConRedFC} = \frac{\text{PoMFC}(t) - \text{PoMFC}(t2022)}{\text{PoMFC}(t2022)} \times 100$$

where:

CfB means cups for beverages;

FC means food containers;

ConRed means consumption reduction in a Member State per calendar year;

PoMCfB means:

- (a) the total weight of plastic (tonnes) contained in cups for beverages placed on the market in a Member State in a given calendar year, where relevant adjusted in accordance with Article 1(3), where the methodology referred to in Article 1(1), point (a), is applied for the calculation of the consumption reduction, or
- (b) the total number of single-use plastic cups for beverages placed on the market in a Member State in a given calendar year, where relevant adjusted in accordance with Article 1(3), where the methodology referred to in Article 1(1), point (b), is applied for the calculation of the consumption reduction;

PoMFC means

- (i) the total weight of plastic (tonnes) contained in food containers placed on the market in a Member State in a given calendar year, where relevant adjusted in accordance with Article 1(3), where the methodology referred to in Article 1(1), point (a), is applied for the calculation of the consumption reduction, or
- (ii) the total number of food containers placed on the market in a Member State in a given calendar year, where relevant adjusted in accordance with Article 1(3), where the methodology referred to in Article 1(1), point (b), is applied for the calculation of the consumption reduction;

t2022 means the reference year which is the calendar year 2022

t means the reference year (the year for which the data is collected and reported).

Format for reporting of data on single-use plastic products placed on the market

	Weight of plastic ⁽¹⁾ (tonnes)	Total weight ⁽²⁾ (tonnes)	Products ⁽³⁾ (thousand units)
Single-use plastic cups for beverages, including their covers and lids, referred to in part A, point (1), of the Annex to Directive (EU) 2019/904 made wholly of plastic			
Single-use plastic food containers referred to in part A, point (2), of the Annex to Directive (EU) 2019/904 made wholly of plastic			
Single-use plastic cups for beverages, including their covers and lids, referred to in part A, point (1), of the Annex to Directive (EU) 2019/904 made partly of plastic			
Single-use plastic food containers referred to in part A, point(2), of the Annex to Directive (EU) 2019/904 made partly of plastic			

⁽¹⁾ Provision of data is mandatory if a Member State applies the methodology laid down in Article 1(1), point (a), and may be adjusted in accordance with Article 1(3). Provision of data is voluntary if a Member State applies the methodology laid down in Article 1(1), point (b).

⁽²⁾ Provision of data is mandatory if a Member State applies the methodology laid down in Article 1(1), point (a), and may be adjusted in accordance with Article 1(3). Provision of data is voluntary if a Member State applies the methodology laid down in Article 1(1), point (b).

⁽³⁾ Provision of data is mandatory if a Member State applies the methodology laid down in Article 1(1), point (b), and may be adjusted in accordance with Article 1(3). Provision of data is voluntary if a Member State applies the methodology laid down in Article 1(1), point (a).

Format for reporting information on consumption reduction measures

1. Measures to achieve reduction in the consumption of single-use plastic cups for beverages, including their covers and lids, referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 (SUP Cfb)

Consumption reduction measures	Specification of the measure (sub-categories)	Quantitative/ qualitative description of the measure	Entry into force of the measure	Legal nature of the measure (voluntary/ mandatory)	Coverage of the measure (local, regional, national or other)	Target group of the measure (producers, importers, vendors, consumers)
Quantitative targets	— Quantitative targets for reducing the share of SUP Cfb placed on the market and made available to consumers. — Quantitative targets for increasing the share of reusable alternatives to SUP Cfb placed on the market and made available to consumers					
Promotion of sustainable alternatives to SUP Cfb (including reusable plastic Cfb)	— Measures promoting reusable alternatives to SUP Cfb in public administrations — Measures establishing obligations or incentives for economic operators to make reusable alternatives to SUP Cfb available to consumers in large public events — Measures establishing “bring-your-own” systems allowing consumers to bring their own cups for beverages. — Promotion of business models that provide reusable alternatives to SUP Cfb — Measures establishing obligations or incentives for economic operators to provide sustainable alternative Cfb at the point of sale to the final consumer — Promotion of free public sources of drinking water encouraging people to bring a refillable cup or drink from the tap.					

Consumption reduction measures	Specification of the measure (sub-categories)	Quantitative/ qualitative description of the measure	Entry into force of the measure	Legal nature of the measure (voluntary/ mandatory)	Coverage of the measure (local, regional, national or other)	Target group of the measure (producers, importers, vendors, consumers)
Economic instruments	— Levies imposed on economic operators when placing SUP Cfb on the market — Green Public Procurement — Deposit Refund schemes — Subsidies or reduced levies for economic operators placing reusable alternatives to SUP Cfb on the market — Instruments ensuring discounts for consumers buying or bringing their own reusable alternatives to SUP Cfb — Extended producer responsibility obligations for producers of SUP Cfb					
Marketing and use restrictions	— Restrictions on the placing on the market of SUP Cfb in order to ensure that they are substituted with alternatives that are re-usable or do not contain plastic or contain less plastic as referred to in Article 4(1), third subparagraph, of Directive (EU) 2019/904 — Restrictions on the making available of SUP Cfb in certain specific locations (e.g. public beaches or parks) or by certain economic operators and public administrations — Restrictions on the use of SUP Cfb when serving drinks to consumers.					

Consumption reduction measures	Specification of the measure (sub-categories)	Quantitative/ qualitative description of the measure	Entry into force of the measure	Legal nature of the measure (voluntary/ mandatory)	Coverage of the measure (local, regional, national or other)	Target group of the measure (producers, importers, vendors, consumers)
Agreements between competent authorities and economic sectors pursuant to Article 17(3) of Directive (EU) 2019/904	— Agreements containing quantitative targets to reduce the number of SUP Cfb placed on the market. — Agreements containing quantitative targets to place reusable alternatives or plastic-free products on the market. — Agreements containing obligations on the economic operators [of the relevant economic sectors] to inform consumers or encourage consumers to use alternatives to SUP Cfb or reuse systems					<i>Sector concerned and the amount of actors subscribing to the agreements</i>
Awareness raising measures [focused on SUP Cfb]	— Campaigns to raise awareness of the negative environmental impacts of SUP Cfb due to littering and other inappropriate waste disposal, including as part of litter clean-up campaigns — Promotion of sustainable alternatives to SUP Cfb (e.g. reusable beverage cups) — Promotion of venues connected to reusable schemes (e.g. “bring your own cup” schemes)					
Other measures	<i>Please specify</i>					

Add rows as appropriate.

2. Measures to achieve reduction in the consumption of single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 (SUP FC)

Consumption reduction measure	Specification of the measure (sub- categories)	Quantitative/ qualitative description of the measure	Entry into force of the measure	Legal nature of the measure(voluntary/ mandatory)	Coverage of the measure (local, regional, national or other)	Target group of the measure (producers, importers, vendors, consumers)
Quantitative target	— Quantitative targets for reducing the share of SUP FC placed on the market and made available to consumers — Quantitative targets for increasing the share of reusable alternatives to SUP FC placed on the market and made available to consumers					
Promotion of sustainable alternatives to SUP FC (including reusable plastics)	— Measures promoting reusable alternatives to SUP FC in public administrations — Measures establishing obligations or incentives for economic operators to make reusable alternatives to SUP FC available to consumers in large public events — Measures establishing “bring-your-own” systems allowing consumers to bring their own food container — Promotion of business models that provide reusable alternatives to SUP FC, such as deposit systems. Measures establishing obligations or incentives for economic operators to provide sustainable alternative to SUP FC at the point of sale to the final consumer — Promotion of business models that provide for sustainable alternatives to SUP FC					

Economic instruments	— Levies on economic operators placing SUP FC on the market — Subsidies or reduced levies for economic operators placing reusable alternatives to SUP FC on the market. — Green Public Procurement — Deposit Return Schemes — Instruments ensuring discounts for consumers buying reusable alternatives to SUP FC.					
Marketing and use restrictions	— Restrictions on the placing on the market of SUP FC in order to ensure that they are substituted with alternatives that are reusable or do not contain plastic or contain less plastic as referred to in Article 4(1), third subparagraph, of Directive (EU) 2019/904. — Restrictions on the making available of SUP FC in certain specific locations (e.g. public beaches or parks) or by certain economic operators and public administrations — Restrictions on the use of SUP FC when providing food to consumers					
Agreements between competent authorities and economic sectors pursuant to Article 17(3) of Directive (EU) 2019/904	— Agreements containing quantitative targets to reduce the number of SUP FC placed on the market — Agreements containing quantitative targets to place reusable alternatives or plastic-free products on the market — Agreements containing obligations on economic operators [of the relevant economic sectors] to inform consumers or encourage consumers to use alternatives to SUP FC or reuse systems					<i>Sector concerned and the amount of actors subscribing to the agreements</i>

Awareness raising measures [focused on SUP FC]	— Campaigns to raise awareness of the negative environmental impact of SUP FC due to littering and other inappropriate waste disposal, including as part of litter clean-up campaigns — Promotion of sustainable alternatives to SUP FC (e.g. reusable food containers) — Promotion of venues connected to reusable schemes (e.g. “bring your own food container” schemes)					
Other measures	<i>Please specify</i>					

Add rows as appropriate.

Format for the quality check report**1. General Information**

1.1. Member State:

1.2. Organisation submitting the data and the description:

1.3. Contact person / contact details:

1.4. Reference year:

1.5. Delivery date / version:

1.6 Link to data publication by the Member State (if any):

2. Description of the parties involved in the data collection:

Name of institution	Description of key responsibilities

Add rows as appropriate.

3. Description of methods used.

a. **Data sources for calculating data on single-use plastic cups for beverages, including their covers and lids, referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 placed on the market of a Member State**

Data sources	Data source used (yes/no)	Description of the applied methods	Share in the total data
Data from deposit refund schemes			
Extended Producer Responsibility (EPR) scheme data. Data from producers or from organisations implementing EPR obligations on their behalf			
Data from central registries on single-use plastic cups for beverages placed on the market			
Data from municipalities			

Data sources	Data source used (yes/no)	Description of the applied methods	Share in the total data
Surveys			
Electronic registry			
Administrative reporting			
Production statistics - national codes			
Tax statistics			
Industry statistics			
Other sources (specify)			

b. Data sources for calculating data on single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 placed on the market of a Member State

Data sources	Data source used (yes/no)	Description of the applied methods	Share in the total data
Data from deposit refund schemes			
Extended Producer Responsibility (EPR) scheme data. Data from producers or from organisations implementing EPR obligations on their behalf			
Data from central registries on single-use plastic food containers placed on the market			
Data from municipalities			
Surveys			
Compositional analyses			
Electronic registry			
Administrative reporting			
Production statistics - national codes			
Tax statistics			
Industry statistics			
Other sources (specify)			

- c. **Where data is reported by weight using the methodology referred to in Article 1(1), point (a), please indicate whether an estimate for the weight of plastic contained in single-use plastic products placed on the market of a Member State and for the total weight of such products has been used, where data collection does not cover the whole market. If yes, please indicate the added weight of plastics in % of the total weight reported**

Specific issues considered	Description of the applied methods to determine the estimates ⁽¹⁾	%	
Free riders ⁽¹⁾			
Private movements within the Union, imports / exports ⁽²⁾			
On-line sales ⁽³⁾			
De-minimis rules ⁽⁴⁾			
Others (specify)			

⁽¹⁾ A free rider is a producer or distributor that places single-use plastic products on the market but does not fulfil its EPR responsibilities individually or collectively with other producers.

⁽²⁾ Movements within the Union and imports / exports of products after they have been sold to end-users.

⁽³⁾ Placing on the market data must include sale through distance communication.

⁽⁴⁾ De-minimis rules applied for reporting on single-use plastic products placed on the market.

- d. **Where data is reported by the number of products using the methodology referred to in Article 1(1), point (b), please indicate whether an estimate of the number of single-use plastic products placed on the market of a Member State has been used, where data collection does not cover the whole market. If yes, please indicate the added number of products in % of the total number reported**

Specific issues considered	Description of the applied methods to determine the estimates ⁽¹⁾	%
Free riders ⁽¹⁾		
Private intra-EU movements, imports / exports ⁽²⁾		
On-line sales ⁽³⁾		
De-minimis rules ⁽⁴⁾		
Others (specify)		

⁽¹⁾ A free rider is a producer or distributor that places single-use plastic products on the market but does not fulfil its EPR responsibilities individually or collectively with other producers.

⁽²⁾ Movements within the Union and imports / exports of products after they have been sold to end-users.

⁽³⁾ Placing on the market data must include sale through distance communication.

⁽⁴⁾ De-minimis rules applied for reporting on single-use plastic products placed on the market.

4. Data verification and control system

a. Verification of data on single-use plastic products placed on the market of a Member State

Verification and control procedures	Applied for all relevant data on		Additional comments, if relevant
	Single-use plastic cups for beverages, including their covers and lids referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	Single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	
Data completeness checks			
Cross-checks			
Time-series checks			
Audit checks			
Other (specify)			

b. Description of main factors affecting the accuracy of the data on single-use plastic products placed on the market of a Member State

Factors that can affect reliability [accuracy] of data	Factors relevant for any data on		Description of how the accuracy of the data is affected and which methods are applied to minimize such impact
	Single-use plastic cups for beverages, including their covers and lids referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	Single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	
Sampling errors ⁽¹⁾ (e.g. coefficients of variation)			
Coverage errors ⁽²⁾ (e.g. de-minimis rules, regional coverage)			
Measurement errors ⁽³⁾			
Data collection test instruments ⁽⁴⁾ (e.g. questionnaires)			

Factors that can affect reliability [accuracy] of data	Factors relevant for any data on		Description of how the accuracy of the data is affected and which methods are applied to minimize such impact
	Single-use plastic cups for beverages, including their covers and lids referred to in Part A, point (1), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	Single-use plastic food containers referred to in Part A, point (2), of the Annex to Directive (EU) 2019/904 placed on the market (yes/no)	
Processing errors ⁽⁵⁾			
Non-response errors ⁽⁶⁾			
Model assumption errors ⁽⁷⁾			
Other (please specify)			

⁽¹⁾ Describe the estimated coefficients of variation and the methodologies applied for variance estimation.

⁽²⁾ Describe the type and size of coverage errors.

⁽³⁾ Describe the instruments to reduce potential risks and avoid errors.

⁽⁴⁾ Describe the instruments and methodologies applied for securing quality and relevance of data collection instruments.

⁽⁵⁾ Describe the processing steps between data collection and production of statistics and list processing errors identified and their extent.

⁽⁶⁾ Describe the non-response rates for the main variables and the imputation methods (if any).

⁽⁷⁾ Describe the type and size of model assumption errors.

c. Explanation of the scope and validity of surveys to collect data on single-use plastic products placed on the market of a Member State

Add rows as appropriate.

d. Differences from the data reported for the previous reporting years

Significant methodological changes in the calculation method used for the current reference year in relation to the calculation method used for previous reference years, if any (please include in particular retrospective revisions, their nature and whether a break-flag is required for a certain year).

Add rows as appropriate.

- e. **Where the weight of plastic contained in and the total weight of single-use plastic products placed on the market of a Member State or the number of such products placed on the market of a Member State has increased by more than 10 % compared to the previous reporting year, an explanation of the reasons for that differences**

Single-use plastic products placed on the market	Variation (%)	Main reason for the variation

Add rows as appropriate.

5. **Confidentiality**

Justification to withhold the publication of specific parts of this quality check report in accordance with Article 2(4) and listing of the parts that are requested to be withheld.

Add rows as appropriate.

6. **Main national websites, reference documents and publications**

Please provide the name and url of the main websites, reference documents and publications related to this data collection.

Add rows as appropriate.

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