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⁽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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/208**of 14 December 2021****amending Regulation (EU) No 139/2014 as regards the requirements for all-weather operations****(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 39(1) thereof,

Whereas:

- (1) Commission Regulation (EU) No 139/2014 ⁽²⁾ lays down requirements and administrative procedures related to aerodromes, including provisions addressing the surface movement guidance and control system and low-visibility operations at aerodromes.
- (2) In order to align those provisions with Annexes 6 and 14 to the Convention on International Civil Aviation and Doc 9365 of the International Civil Aviation Organization ('ICAO') it is necessary to lay down rules on the implementation of all-weather operations at aerodromes, by ensuring the availability of the appropriate visual and non-visual aids as well as other aerodrome equipment, the availability of the required information, and the implementation of appropriate procedures.
- (3) Annex I (Definitions) to Regulation (EU) No 139/2014 should be amended as regards to the definitions of decision altitude, instrument runway, low visibility operations, low visibility procedures, low visibility take-off, operation with operational credits and Type B instrument approach operation.
- (4) Annex III (Part-ADR.OR) to Regulation (EU) No 139/2014 lays down organisation requirements for aerodrome operators. That Annex has become outdated as regards the regulatory framework regarding visual and non-visual aids, notably as regards meteorological equipment and should therefore be amended to include specific requirements as regards the availability and maintenance of visual and non-visual aids and any other equipment necessary to support all-weather operations.

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 139/2014 of 12 February 2014 laying down requirements and administrative procedures related to aerodromes pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 44, 14.2.2014, p. 1).

- (5) Annex IV (Part-ADR.OPS) to Regulation (EU) No 139/2014 lays down the requirements for the operation of aerodromes. That Annex should be amended to include specific operational procedures applicable to the aerodrome operator that address the surface movement guidance and control system and low-visibility operations at aerodromes.
- (6) Regulation (EU) No 139/2014 should therefore be amended accordingly.
- (7) Pursuant to Article 75(2), points (b) and (c) and Article 76(1) of Regulation (EU) 2018/1139 the European Union Aviation Safety Agency prepared and submitted to the Commission Opinion No 02/2021 ⁽³⁾ as regards draft implementing rules.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 139/2014 is amended in accordance with the Annex to this Regulation.

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*.

It shall apply from 1 August 2022.

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

Done at Brussels, 14 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ <https://www.easa.europa.eu/document-library/opinions>

ANNEX

Regulation (EU) No 139/2014 is amended as follows:

(1) Annex I is amended as follows:

(a) the following point (16a) is inserted:

“(16a) ‘decision altitude’ (‘DA’) or ‘decision height’ (‘DH’) means a specified altitude or height in a 3D instrument approach operation at which a missed approach procedure must be initiated if the required visual reference to continue the approach has not been established;”;

(b) point (22) is replaced by the following:

“(22) ‘instrument runway’ means one of the following types of runways intended for the operation of aircraft using instrument approach procedures:

1. ‘non-precision approach runway’: a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type A instrument approach operation;
2. ‘precision approach runway, category I’: a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT I instrument approach operation;
3. ‘precision approach runway, category II’: a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT II instrument approach operation;
4. ‘precision approach runway, category III’: a runway served by visual aids and at least one non-visual aid, intended for landing operations following a type B CAT III instrument approach operation;”;

(c) the following point (24c) is inserted:

“(24c) ‘low-visibility operations (LVOs)’ means approach or take-off operations on a runway with a runway visual range less than 550 m or a decision height less than 200 ft;”;

(d) point (25) is replaced by the following:

“(25) ‘low-visibility procedures’ means procedures applied at an aerodrome for the purpose of ensuring safety during low-visibility operations;”;

(e) point (26) is replaced by the following:

“(26) ‘low-visibility take-off (LVTO)’ means a take-off with a runway visual range less than 550 m;”;

(f) point (27) is deleted;

(g) the following point (34c) is inserted:

“(34c) ‘operation with operational credits’ means an operation using specific aircraft or ground equipment, or a combination of aircraft and ground equipment which allows any of the following elements:

- (a) the application of lower than standard aerodrome operating minima for a particular classification of operation;
- (b) visibility requirements can be satisfied or reduced;
- (c) fewer ground facilities are required;”;

(h) point (35) is deleted;

(i) point (47b) is replaced by the following:

“(47b) ‘Type B instrument approach operation’ means an instrument approach operation with a decision height below 75 m (250 ft) categorised as follows:

1. Category I (CAT I): a decision height not lower than 60 m (200 ft) and with either a visibility not less than 800 m or a runway visual range not less than 550 m;

2. Category II (CAT II): a decision height lower than 60 m (200 ft), but not lower than 30 m (100 ft) and a runway visual range not less than 300 m;
3. Category III (CAT III): a decision height lower than 30 m (100 ft) or no decision height and a runway visual range less than 300 m or no runway visual range limitations.”;

(2) In Annex III, in point ADR.OR.C.005, the following point (e) is added:

”(e) The aerodrome operator, in order to ensure the safe operation of aircraft at the aerodrome, shall provide and maintain, directly or through arrangements with third parties, visual and non-visual aids, meteorological equipment and any other equipment, commensurate with the type of operations conducted at the aerodrome.”;

(3) Annex IV is amended as follows:

- (a) in Subpart A, the following points ADR.OPS.A.070, ADR.OPS.A.075, ADR.OPS.A.080 and ADR.OPS.A.085 are added:

“ADR.OPS.A.070 Information on the aerodrome lighting system

The aerodrome operator shall report to the aeronautical information services the information on the parts of the aerodrome lighting system where light units are light emitting diode (LED) lights.

ADR.OPS.A.075 Charts

The aerodrome operator, either directly or through arrangements with third parties, shall ensure that charts relevant to the aerodrome are published in the AIP by the aeronautical information service provider.

ADR.OPS.A.080 Information on radio navigation and landing aids

- (a) The aerodrome operator shall ensure, either directly or through arrangements with third parties, that information on the radio navigation and landing aids associated with the instrument approach and the terminal area procedures at the aerodrome, are provided to the aeronautical information services.
- (b) The information referred to in point (a) shall include the following:
 - (1) type of aids;
 - (2) magnetic variation to the nearest degree, as appropriate;
 - (3) type of supported operation for ILS/MLS/GLS, basic GNSS and SBAS;
 - (4) classification for ILS;
 - (5) facility classification and approach facility designation(s) for GBAS;
 - (6) for VOR/ILS/MLS also station declination to the nearest degree used for technical line-up of the aid;
 - (7) identification, if required;
 - (8) frequency(-ies), channel number(s), service provider and reference path identifier(s) (RPI(s)), as appropriate;
 - (9) hours of operation, as appropriate;
 - (10) geographical coordinates in degrees, minutes, seconds and tenths of seconds of the position of the transmitting antenna, as appropriate;
 - (11) elevation of the DME transmitting antenna to the nearest 30 m (100 ft) and of the distance-measuring equipment precision (DME/P) to the nearest 3 m (10 ft), elevation of GBAS reference point to the nearest metre or foot, and the ellipsoid height of the point to the nearest metre or foot; for SBAS, the ellipsoid height of the landing threshold point (LTP) or the fictitious threshold point (FTP) to the nearest metre or foot;

- (12) service volume radius from the GBAS reference point to the nearest kilometre or nautical mile; and
- (13) remarks.

ADR.OPS.A.085 Information on visual segment surface (VSS) penetration

The aerodrome operator shall ensure, either directly or through arrangements with third parties, that information on visual segment surface penetration is provided to the aeronautical information services, including procedure and procedure minima affected.”;

(b) Subpart B is amended as follows:

(i) point ADR.OPS.B.030 is amended as follows:

— point (a) is replaced by the following:

”(a) The aerodrome operator shall ensure that a surface movement guidance and control system (SMGCS) is provided at the aerodrome. The SMGCS shall:

(1) take into account the design characteristics and the operational and meteorological conditions of the aerodrome, as well as human factors principles;

(2) be designed to assist in the prevention of:

(i) inadvertent incursions of aircraft and vehicles on an active runway; and

(ii) collisions between aircraft as well as between aircraft and vehicles or objects on any part of the movement area; and

(3) be supported by appropriate means and procedures.”;

— the following point (d) is added:

”(d) The aerodrome operator shall coordinate with the air traffic services provider the development of the SMGCS procedures at the aerodrome.”;

(ii) point ADR.OPS.B.045 is replaced by the following:

‘ADR.OPS.B.045 Low-visibility procedures

(a) The aerodrome operator shall ensure that the aerodrome is provided with appropriate aerodrome equipment and facilities, and that appropriate low-visibility procedures are established and implemented where it is intended to be used for any of the following operations:

(1) low-visibility take-offs;

(2) approach and landing operations with visibility conditions less than 550 m RVR or DH less than 200 ft (60 m);

(3) operations with operational credits where the actual RVR is less than 550 m.

The low-visibility procedures shall coordinate the movement of aircraft and vehicles and shall restrict or prohibit activities on the movement area.

(b) The aerodrome operator shall establish and implement the low-visibility procedures in cooperation with the air traffic services provider. The low-visibility procedures shall include criteria for their preparation, initiation and termination. The criteria shall be based on RVR and cloud ceiling values.

(c) The aerodrome operator shall inform the aeronautical information services provider and air traffic services provider, as appropriate, of any change on the status of the aerodrome equipment and facilities that have an impact on low-visibility operations.

- (d) The aerodrome operator shall provide information on low-visibility procedures to the aeronautical information services provider, for publication in the AIP.
 - (e) Low-visibility procedures, and any changes thereto, shall require prior approval by the competent authority.”.
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COMMISSION IMPLEMENTING REGULATION (EU) 2022/209**of 16 February 2022****establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 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) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ⁽¹⁾, and in particular Article 57(4) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2021/578 ⁽²⁾ sets out the requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.
- (2) In order for Member States to be able to collect and report such data to the European Medicines Agency ('the Agency'), the format of such data should be clearly defined.
- (3) The required format of the data should apply to the data collected for the antimicrobials referred to in Articles 1 to 4 of Delegated Regulation (EU) 2021/578 in order to have harmonised and comparable data. The required format of the data should equally apply to data collected on antimicrobials contained in medicated feed and intermediate products, in line with Article 4(4) of Regulation (EU) 2019/4 of the European Parliament and of the Council ⁽³⁾.
- (4) The format, which Member States are to use for reporting antimicrobial sales and use data to the Agency, should take into account specific data variables that need to be provided per product presentation in order to enable the Agency to calculate the quantity of antimicrobial active substances from veterinary medicinal products sold per Member State for use on its territory during the year of data collection. Those data variables should also enable the Agency to calculate the quantity of antimicrobial active substances from medicinal products used in designated animal species or categories per Member State on its territory during the year of data collection. Additional data variables should be provided by Member States to the Agency, per reporting year, in order to allow for an accurate analysis and interpretation of the data.
- (5) The Agency should provide the necessary supporting information to Member States in order to facilitate the harmonised calculation of the volume of sales and of the use of antimicrobials and to facilitate subsequent data validation by Member States before reporting to the Agency. Such supporting information is to be provided to Member States by the Agency through the web interface for collated data reporting referred to in Article 10 of Delegated Regulation (EU) 2021/578.

⁽¹⁾ OJ L 4, 7.1.2019, p. 43.

⁽²⁾ Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals (OJ L 123, 9.4.2021, p. 7).

⁽³⁾ Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).

- (6) In addition, the Agency should minimise the efforts required by Member States to enter data in the web interface, by pre-filling data entry fields whenever data is already available from existing databases under the remit of the Agency. At the same time, in line with Article 6 of Delegated Regulation (EU) 2021/578, Member States remain responsible for the fulfilment of the data quality requirements with respect to the information provided on the antimicrobial medicinal products authorised at national level, including the accuracy of the information provided by the Agency in those pre-filled data entry fields.
- (7) To ensure that the data collected on the sales and the use of antimicrobials is comparable year-over-year within Member States and within the Union and that those data are adequately analysed, the format for reporting of the data should take into account the size of the animal population that is likely to be treated with antimicrobials. This should also facilitate the comparison of data reported at national level and at Union level with data available from non-Union countries and at global level. It is therefore important to define the format according to which the animal population data should be referred to. Any comparison of data across Member States should take into account the diversity of practices within the Union and the differences in national legal contexts.
- (8) The most appropriate format for the animal population data as regards terrestrial animals should be the number of living animals or the number of slaughtered animals, depending on the animals species or categories concerned, while the most appropriate format for the animal population data as regards farmed fish should be the produced biomass. However, in order to appropriately reflect each Member State's animal population data in the context of the collection of data on the volume of sales and on the use of antimicrobials in animals, so that it can be effectively used by the Agency, the animal population data should be adjusted according to so-called denominators, such as the population correction unit or other denominators, as appropriate. Such adjustments are necessary for the Agency to identify trends in the volume of sales and the use of antimicrobials in animals and make relevant analyses.
- (9) This Regulation is necessary for the application of Regulation (EU) 2019/6, which applies from 28 January 2022. Therefore, and in accordance with Article 153(1) of Regulation (EU) 2019/6, this Regulation should apply from that same date.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

Data to be reported to the Agency on the volume of sales of veterinary antimicrobial medicinal products

1. Data on the volume of sales of veterinary antimicrobial medicinal products shall be reported by the Member States to the Agency using the format specified in Annex I.
2. The Agency shall include the format of the data referred to in paragraph 1 in the protocols and templates it makes available to the Member States, as provided for in Article 8 of Delegated Regulation (EU) 2021/578. The terminology used in the Agency's protocols and templates for reporting shall be based on controlled terms defined in existing catalogues of terms maintained by the Agency, as much as possible.

Article 2

Data to be reported to the Agency on the use of antimicrobial medicinal products in animals

1. Data on the use of veterinary antimicrobial medicinal products shall be reported by the Member States to the Agency through the web interface referred to in Article 10 of Delegated Regulation (EU) 2021/578, using the format specified in Annex II.

2. The Agency shall include the format of the data referred to in paragraph 1 in the protocols and templates it makes available to the Member States, as provided for in Article 8 of Delegated Regulation (EU) 2021/578. The terminology used in the Agency's protocols and templates for reporting shall be based on controlled terms defined in existing catalogues of terms maintained by the Agency, as much as possible.

Article 3

Information to be provided by the Agency for calculation and validation purposes

When providing the information necessary for the purposes of calculating the volume of sales and of the use of antimicrobials and validating data, the Agency shall use the variables specified in Annex III.

Article 4

Animal population data

1. Data identified by the Agency or reported by the Member States on the relevant animal populations, as specified in Article 16(5) of Delegated Regulation (EU) 2021/578, shall take into account animal species, categories and stages thereof as listed in Article 15 of Delegated Regulation (EU) 2021/578 according to the following format:

- (a) for terrestrial animals: the number of animals per year (living animals or slaughtered animals, depending on the animal species or categories concerned, as specified in the Agency's protocols and templates for the reporting of data);
- (b) for farmed fish: the biomass produced per year (live weight at slaughter).

2. While identifying or reporting the data on the relevant animal populations, the Agency or the Member States, as specified in Article 16(5) of Delegated Regulation (EU) 2021/578, shall take into account the number of animals brought in from other Member States and sent to other Member States for fattening or slaughter, for the relevant animals species, categories and stages thereof, when appropriate, in accordance with the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

3. When Member States report the data on the relevant animal populations in their territories, they shall submit to the Agency a detailed description of the methodologies they used to generate the relevant animal population data.

Article 5

Adjustments to the animal population data for analysis purposes

1. The Agency shall adjust the data for the relevant animal populations referred to in Article 4 according to so-called denominators, which are calculated on the basis of a combination of the number of animals slaughtered and of the number of live animals present in a Member State during the data collection period, multiplied by standardised animal weights.

2. Depending on the data concerned, the most appropriate denominator to be used shall be indicated in the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

3. The data sources and the methodology for the calculation by the Agency of the different denominators shall be specified in the Agency's protocols and templates referred to in Article 8 of Delegated Regulation (EU) 2021/578.

Article 6

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

It shall apply from 28 January 2022.

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

Done at Brussels, 16 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

Format for the reporting of data to the Agency on the volume of sales of veterinary antimicrobial medicinal products

Number	Name of the data variable	Description
1. Data to be reported per product presentation		
1	ISO Country Code	Two-letter code (alpha-2 code), according to the International Standard for country codes (ISO, 2013); XI for Northern Ireland.
2	Year	Four-digit number.
3	Allowed for use under Article 116 of Regulation (EU) 2019/6	A choice of yes/no to be selected to indicate whether the product is allowed for use under Article 116 of Regulation (EU) 2019/6.
4	Identification from the Union product database of the veterinary medicinal product presentation	Structured data field to indicate the permanent and unique identification from the Union product database of the veterinary antimicrobial medicinal product presentation, in line with Article 12(1) of Delegated Regulation (EU) 2021/578.
5	Reference number from other relevant database(s) of the veterinary medicinal product presentation	Open-text field to indicate the reference number from other relevant database(s), such as national database(s), of the veterinary antimicrobial medicinal product presentation. Optional for Member States.
6	Name of the medicinal product	Open-text field to include the name of the veterinary antimicrobial medicinal product as per product information.
7	Product form	Product form, to be selected from a pre-defined list, in line with the Agency's latest protocols and templates.
8	Pack size	Numerical value only, to indicate the content quantity in the pack size.
9	Pack size unit	Unit of measurement of the pack size content, to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of the pack size content shall correspond to the unit of measurement of strength of the antimicrobial active substance.
10	ATCvet code: Anatomical Therapeutic Chemical classification code for veterinary medicinal products	Code to be selected as per the latest version of the ATCvet index.
11	Authorised for companion animals only	A choice of yes/no, to be selected to indicate if the veterinary antimicrobial medicinal product is authorised for use in companion animals only.
12	Number of packages sold	Numerical value to indicate the number of packages of product presentation sold within the reporting year in the reporting Member State.

13	Name of the antimicrobial active substance	Name to be selected from a pre-defined list of antimicrobial active substances, in line with the Agency's latest protocols and templates, which includes International Non-proprietary Name (INN) of antimicrobial substances, as presented according to the latest version of the ATCvet Index. In case of fixed combination products, all the antimicrobial active substances shall be reported individually.
14	Name of the salt of the antimicrobial active substance when strength expressed in international unit (IU)	Name of the salt to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the conversion to mass of active substance in a standardised manner.
15	Name of the derivative or compound of the antimicrobial active substance	Name of the derivative or compound to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, to enable the calculation of the mass of the antimicrobial active moiety in a standardised manner.
16	Strength	Numerical value of the strength or the quantity of the antimicrobial active substance(s), as declared in the product information, in order to enable the calculation of the quantity of antimicrobial active substance(s) in each product presentation.
17	Unit of measurement of strength	Unit of measurement of strength to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of strength shall correspond to the unit of measurement of the pack size.

2. Data to be provided per reporting year

18	Data provider(s)	Data provider(s) to be selected from a pre-defined list including: — Marketing Authorisation Holders; — Wholesalers; — Retailers; — Feed mills; — Pharmacies; — Veterinarians.
19	Contact details of the national contact point and data managers	Open-text field to identify and provide the contact details of the national contact point and of the data managers of the Member State for liaison with the Agency with regards to the reporting of data on the sales of veterinary antimicrobial medicinal products.
20	Actions taken to avoid double reporting of sales	A choice of yes/no to be selected to indicate if necessary actions have been taken or not to avoid double reporting of sales.
21	Correction of the data reported on the sales of veterinary antimicrobial medicinal products, in relation to movements of veterinary medicinal products approved for parallel trade	A choice of yes/not applicable to be selected to confirm whether the data reported on the sales of veterinary antimicrobial medicinal products in the territory of the Member State has been corrected for movements of such products across the Member State's borders as part of parallel trade, in accordance with Article 102 of Regulation (EU) 2019/6.

Format for the reporting of data to the Agency on the use of antimicrobial medicinal products in animals

Number	Name of the data variable	Description
1. Data to be reported per product presentation		
1	Animal species	Animal species, categories and stages thereof, for which data on the use of antimicrobial medicinal products shall be collected and reported, to be selected from a pre-defined list, in line with the requirements set in Article 15 of Delegated Regulation (EU) 2021/578.
2	ISO Country code	Two-letter code (alpha-2 code), according to the International Standard for country codes (ISO, 2013); XI for Northern Ireland.
3	Year	Four-digit number.
4	Identification from the relevant Union database of the medicinal product presentation	Structured data field to indicate: — the permanent and unique identification from the Union product database of the veterinary antimicrobial medicinal product presentation; or — the Packaged Medicinal Product Identifier (PCID) from the Product Management Services (PMS) of the human antimicrobial medicinal product presentation.
5	Reference number from other relevant database(s) of the medicinal product presentation	Open-text field to indicate the reference number from other relevant database(s), such as national database(s), of the antimicrobial medicinal product presentation. Optional for Member States.
6	Name of the medicinal product	Open-text field to include the name of the medicinal product as per product information
7	Product form	Product form to be selected from a pre-defined list, in line with the Agency's latest protocols and templates.
8	Identification of long-acting parenteral products	Two-letter code (LA) for injectable products only, when applicable, in order to identify parenteral products with long acting/prolonged release dosage forms, whose modified release dosage forms are showing slower release than that of the conventional release dosage form administered by the same route. Prolonged release is achieved through special formulation design and/or manufacturing method.
9	Pack size	Numerical value only, to indicate the content quantity in the pack size.
10	Pack size unit	Unit of measurement of the pack size content to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of the pack size content shall correspond to the unit of measurement of strength of the antimicrobial active substance.
11	ATC or ATCvet code: Anatomical Therapeutic Chemical classification code for human and veterinary medicinal products	Code to be selected as per the latest version of the ATC or ATCvet indexes.

12	Number of packages used	Numerical value to indicate the number of packages of product presentation used within the reporting year per Member State and per animal species, animal species category or animal species stage, as specified in Article 15 of Commission Delegated Regulation (EU) 2021/578. In case any data at national level are collected in other units than packages used for each antimicrobial product by the animal species in question, the number of packages used may be calculated by the Member State from the amounts used (expressed in weight or in volume) before reporting to the Agency.
13	Name of the antimicrobial active substance	Name to be selected from a pre-defined list of antimicrobial active substances, in line with the Agency's latest protocols and templates, which includes International Non-proprietary Name (INN) of antimicrobial substances, as presented according to the latest versions of the ATC or ATCvet Indexes, to report antimicrobial use in a standardised manner per antimicrobial classes and active substances. In case of fixed combination products, all the antimicrobial active substances shall be reported individually.
14	Name of the salt of the antimicrobial active substance, when strength is expressed in international unit (IU)	Name of the salt to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the conversion to mass of active substance in a standardised manner.
15	Name of the derivative or compound of the antimicrobial active substance	Name of the derivative or compound to be selected from a pre-defined list, in line with the Agency's latest protocols and templates, when applicable, in order to enable the calculation of the mass of the antimicrobial active moiety in a standardised manner.
16	Strength	Numerical value of the strength or of the quantity of the antimicrobial active substance(s), as declared in the product information, to enable the calculation of the quantity of antimicrobial active substance in each product presentation.
17	Unit of measurement of strength	Unit of measurement of strength to be selected from a pre-defined list, in line with the Agency's latest protocols and templates. The unit of measurement of strength shall correspond to the unit of measurement of the pack size.

2. Data to be provided per reporting year

18	Data source(s)	Data source(s) to select from a pre-defined list including: — Health records; — Treatment logbooks; — Delivery notes; — Invoices from farms; — Prescriptions; — Pharmacy records; — Veterinary practice records.
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19	Data provider(s)	Data provider(s) to select from a pre-defined list including: — Veterinarians; — Retailers; — Pharmacies; — Feed mills; — End-users (including farmers or breeders).
20	Contact details of the national contact point and data managers	Open-text field to identify and provide the contact details of the national contact point and of the data managers of the Member State for liaison with the Agency with regards to the reporting of data on the use of antimicrobial medicinal products in animals.

Information to be provided by the Agency for calculation and validation purposes

Number	Name of the variable to be provided	Description
1	Conversion factor for the antimicrobial active substance, when strength is expressed in international units (IU)	Conversion factor assigned automatically by the Agency in the web interface, when the strength of the antimicrobial active substance is reported in IU and the substance is included in the pre-defined list, in line with the Agency's latest protocols and templates. This information variable shall enable the conversion from IU to mass of the antimicrobial substance sold or used, per each product presentation.
2	Conversion factor for the derivative or compound of the antimicrobial active substance	Conversion factor assigned automatically by the Agency in the web interface, when the strength is reported for the derivative or compound and not for the antimicrobial active moiety, and the derivative or compound is included in the pre-defined list, in line with the Agency's latest protocols and templates. This information variable shall enable the calculation of the mass of the antimicrobial active moiety sold or used, per each product presentation.
3	Content of antimicrobial active substance per presentation	Content of antimicrobial active substance per gram of product presentation. This information variable shall enable the calculation of the volume of sales and of the use.
4	Unit of antimicrobial active substance per product presentation	Unit of measurement of the content of antimicrobial active substance per presentation in grams. This information variable shall enable the calculation of the volume of sales and of the use.
5	Tonnes of antimicrobial active substance sold or used	Volume of sales and use (in tonnes) of antimicrobial active substance per product presentation. This information variable shall enable further analysis and interpretation of data.

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/210

of 8 February 2022

on a common Union toolbox to address semiconductor shortages and an EU mechanism for monitoring the semiconductor ecosystem

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Semiconductors are essential to the functioning of our modern economy and society. Within the past year, the Union has witnessed unprecedented disruptions in their supply which have entailed serious delays and negative effects on important economic sectors and have led to delays to the repair and maintenance of essential products for critical sectors, such as medical and diagnostic equipment.
- (2) The current semiconductor shortage crisis and its ripple effects therefore render critical sectors such as health, transport, energy, defence, security and space under threat of being affected. The Union's green and digital transition is at risk of delay.
- (3) Against that background, the Commission Proposal for a Regulation of the European Parliament and the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act) ⁽¹⁾ aims to address the Union's resilience to disruptions in the semiconductor supply chain, to foster the development of capacities in advanced manufacturing, design and system integration as well as cutting-edge industrial manufacturing within the Union, to address the acute skills shortage, to increase qualified workforce and to contribute to creating a resilient and dynamic semiconductor ecosystem in the Union. The Union is committed to its strategic goal to reach at least 20 % of world production in value of cutting-edge, innovative and sustainable semiconductors by 2030, as set out in the Digital Decade Policy Programme ⁽²⁾.
- (4) This Recommendation accompanies the proposed Regulation as a tool with immediate effect to enable a rapid and coordinated Union response to the current shortage. To that end, it proposes to set up a coordination mechanism to discuss and decide on timely and proportionate crisis response measures.
- (5) In view of the structural deficiencies of the semiconductor supply chain, it additionally recommends measures to enable coordinated monitoring of the semiconductor value chain, focussing on risks that may disrupt, compromise or negatively affect the supply of semiconductors. Those measures should prepare and enable the permanent mechanism for monitoring of the semiconductor supply chain proposed under the Regulation.
- (6) The Commission has set up the European Semiconductor Expert Group, for the purpose of implementing this Recommendation. The European Semiconductor Expert Group will serve as a platform for coordination between Member States and provide advice and assistance to the Commission in the implementation of the forthcoming Regulation. The tasks of the European Semiconductor Expert Group shall be taken over by the European Semiconductor Board to be established in the Regulation.

⁽¹⁾ COM(2022) 46, 8.2.2022.

⁽²⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 2030 Digital Compass: the European way for the Digital Decade, 9.3.2021 COM(2021) 118 final).

- (7) The European Semiconductor Expert Group should facilitate rapid and effective information exchange between the Member States and the Commission on market developments that put Union supplies at tangible risk, and foster a uniform and coordinated crisis response.
- (8) As a first measure, Member States are recommended to request information from representative organisations of undertakings or, if necessary, from individual semiconductor and equipment manufacturers. This would increase the ability of the European Semiconductor Expert Group to identify and tailor potential crisis response measures. The data gathered should concern the production capability, production capacity and current primary disruptions and bottlenecks. Any collection or exchange of information should be in line with applicable rules on data sharing and confidentiality of information and data.
- (9) This Recommendation includes suggestions for crisis response measures that Member States are invited to discuss and consider to implement where relevant and proportionate.
- (10) If the assessment of the crisis at hand so requires, Member States could consider entering into a dialogue asking semiconductor manufacturers established in the Union to prioritise contracts with companies who supply products to critical sectors, with a view to ensure that these sectors continue to operate.
- (11) Furthermore, if relevant and appropriate according to the assessment of the crisis at hand, Member States may consider granting a mandate to the Commission to procure certain products on their behalf, in order to create a leverage effect through its purchasing power and to ensure the supply to critical sectors in the public interest.
- (12) Finally, Member States are encouraged to assess whether the Union should exercise surveillance over certain exports for securing supply to the internal market. If they find such protective measures appropriate, necessary and proportionate, they could discuss and request the Commission to assess whether the conditions for protective measures with regard to exports pursuant to Regulation (EU) 2015/479 of the European Parliament and of the Council ⁽⁹⁾ are fulfilled.
- (13) The recommended monitoring action should follow the principles of anticipation, coordination and preparedness with a view to establish an early warning system in order to prevent semiconductor crises and to strengthen the Union's semiconductor ecosystem. To that end, Member States are asked to discuss in the European Semiconductor Expert Group appropriate early warning indicators to anticipate future shortages in the semiconductor supply chain.
- (14) Further in-depth assessment is needed as regards the risks that may disrupt, compromise or negatively affect the value chain, including on the origins and sources of supplies beyond the Union. Therefore, Member States are recommended to gather relevant information and cooperate with a view to enable the Commission to prepare a common risk assessment for the semiconductor value chain in the Union. Factors to be taken into account when preparing the risk assessments should be indicated.
- (15) The Commission sets out in the proposed Regulation a permanent and binding mechanism for a coordinated monitoring and crisis response, which builds upon the measures suggested in this Recommendation. Once the Regulation enters into force, this Recommendation may be repealed.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE OF THIS RECOMMENDATION

- (1) The purpose of this Recommendation is to enable a rapid, effective and coordinated Union response to the current semiconductor shortage and to future similar cases.

⁽⁹⁾ Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports (OJ L 83, 27.3.2015, p. 34).

- (2) This Recommendation will therefore enable a monitoring mechanism in light of the structural deficiencies of the semiconductor supply and the prevailing risk of future shortages or other notable market shocks arising.
- (3) To that end, it is recommended that Member States work together with the Commission through the framework of the European Semiconductor Expert Group, which will coordinate immediate crisis response measures and function as a platform for monitoring the semiconductor value chain, focussing on risks that may disrupt, compromise or negatively affect the supply of semiconductors.

2. DEFINITIONS

- (4) For the purpose of this Recommendation, the definitions set out in the proposed Regulation apply.

3. EUROPEAN SEMICONDUCTOR EXPERT GROUP

- (5) It is recommended that Member States implement this Recommendation through the European Semiconductor Expert Group. The general rules of procedure of this expert group apply.

4. IMMEDIATE CRISIS RESPONSE

- (6) As a matter of urgency, Member States should convene in the European Semiconductor Expert Group in order to exchange information on the current state of the semiconductor crisis in their national markets. In particular, they should assess the concrete products and markets affected by the shortage, as well as discuss any contingency measures that have been implemented at national level.
- (7) Member States should **request information** from representative organisation of undertakings or, if necessary, from individual semiconductor and equipment manufacturers on supply capabilities, which may include information on production capability, production capacity and current primary disruptions, with a view to identify and tailor potential crisis response measures. Any collection or exchange of information should be in line with applicable rules on data sharing and confidentiality of information and data.
- (8) Based on this information, Member States are invited to assess appropriate, effective and proportionate crisis response measures at national and Union level (**crisis toolbox**). These measures could include one or more of the following:
 - (a) engaging in dialogue with and asking manufacturers to prioritize the production of crisis-relevant products to ensure critical sectors continue to operate;
 - (b) considering, where appropriate, to grant to the Commission a mandate to act as a central purchasing body on behalf of two or more Member States for public procurement of crisis-relevant products for certain critical sectors;
 - (c) assessing whether the Union should exercise surveillance over exports of crisis-relevant products and issue a request to the Commission to assess whether the conditions for protective measures with regard to exports pursuant to of Regulation (EU) 2015/479 are fulfilled;
 - (d) entering into coordinated consultations or cooperation with relevant third countries with a view to seeking cooperative solutions to address supply chain disruptions, in compliance with international obligations. This may involve, where appropriate, coordination in relevant international fora.
- (9) To ensure a coordinated approach, Member States should inform the Commission in a timely manner of all national measures taken with regard to the semiconductor supply chain.

5. MONITORING

- (10) Member States should carry out regular monitoring of the semiconductor value chain, focussing on risks that may disrupt, compromise or negatively affect the supply of semiconductors.
- (11) To that end, Member States should identify appropriate early warning indicators with a view to anticipate future disturbances of the semiconductor supply chain.
- (12) Member States should provide to the Commission information for the purpose of mapping factors, trends and events that could lead to significant disruptions of the global semiconductor value chain with repercussions in the Union (**Union risk assessment**). Relevant factors to be taken into account could include:
- (a) availability and integrity of the services or goods of undertakings in the semiconductor sector in the Union the functioning of which is essential for the semiconductor supply chain;
 - (b) the rate at which demand fluctuates for different types of semiconductors, also in relation to available manufacturing capacities;
 - (c) gaps and bottlenecks in manufacturing, packaging and logistics, including shortages in raw materials and available qualified workforce;
 - (d) accidents, attacks, natural disasters or other serious events with the potential of affecting the semiconductor supply chain;
 - (e) technical, regulatory or environmental changes reducing manufacturing yield;
 - (f) concentration of supply with regard to geographical areas and companies, taking into consideration network and lock-in effects;
 - (g) impacts of trade policies, tariffs, trade barriers and other trade related measures;
 - (h) authenticity and integrity of semiconductors, possible impact of counterfeit semiconductors;
 - (i) infringement or theft of intellectual property or trade secrets.
- (13) Member States should identify the main categories of users of semiconductors, especially those from critical sectors. They should invite relevant stakeholder organisations, including industry associations and representatives of the main user categories, to provide information regarding atypical increases in demand and known disruptions of their supply chain, including the unavailability of critical semiconductors or raw materials, longer than average lead-time, delays in delivery and exceptional price surges.
- (14) Member States should immediately alert the Commission where they become aware of a potential disruption of the supply of semiconductor, an atypical increase in demand or have concrete and reliable information of any other risk factor or event materialising.

6. REVIEW

- (15) The Recommendation may be repealed following the entry into force of the proposed Regulation.

Done at Brussels, 8 February 2022.

For the Commission
Thierry BRETON
Member of the Commission

CORRIGENDA

Corrigendum to Council Decision (CFSP) 2021/2160 of 6 December 2021 amending Decision (CFSP) 2020/1999 concerning restrictive measures against serious human rights violations and abuses*(Official Journal of the European Union L 436 of 7 December 2021)*

On page 44, Annex, entry 12 in the table concerning Abderrahim AL-KANI, third column headed 'Names':

for: 'الرحيم الكاني عبد' (Arabic spelling),

read: 'عبد الرحيم الكاني' (Arabic spelling).

**Corrigendum to Council Implementing Regulation (EU) 2021/2151 of 6 December 2021
implementing Regulation (EU) 2020/1998 concerning restrictive measures against serious human
rights violations and abuses**

(Official Journal of the European Union L 436 of 7 December 2021)

On page 5, Annex, entry 12 in the table concerning Abderrahim AL-KANI, third column headed 'Names':

for: 'الرحيم الكاني عبد' (Arabic spelling),

read: 'عبد الرحيم الكاني' (Arabic spelling).

Corrigendum to Commission Implementing Regulation (EU) 2021/2325 of 16 December 2021 establishing, pursuant to Regulation (EU) 2018/848 of the European Parliament and of the Council, the list of third countries and the list of control authorities and control bodies that have been recognised under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for the purpose of importing organic products into the Union

(Official Journal of the European Union L 465 of 29 December 2021)

On page 37, in Annex II, in the entry for '**BAŞAK Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd**', in the third row of the first column of the table in point 3:

for: 'TU-BIO-175',

read: 'TR-BIO-175'.

On page 64, in Annex II, in the entry for '**Food Safety SA**', regarding the digits in the code numbers in all rows of the first column of the table in point 3:

for: '197',

read: '198'.

**Corrigendum to Decision (EU) 2021/1758 of the European Central Bank of 21 September 2021
amending Decision ECB/2007/7 concerning the terms and conditions of TARGET2-ECB
(ECB/2021/43)**

(Official Journal of the European Union L 354 of 6 October 2021)

On page 40, Annex II, point 10:

for: 'paragraph 8(4)(b)',

read: 'paragraph 7(1)(b)'.

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