Specifications as regards the listing of third countries and the amendments of the official export certificates

Brussels, 8 June 2023

Listing of third countries

- Letters sent to TCs listed in Annex -1 of Commission Implementing Regulation (EU) 2021/405 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council

- Template annexed to the letter **must be completed** in English and sent within **6 months after reception of the letter**

- To send by email to SANTE-VETERINARY-MEDICINES@ec.europa.eu

European Commission

TEMPLATE ANNEX

GENERAL INFORMATION + 3 SECTIONS

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]
Section 2: Competent authority statement/information – antimicrobials for growth promotion
Section 3: Competent authority statement/information – traceability of food-producing animals/products

All sections/boxes MUST be filled

European Commission

The competent authority response and supporting documents should be e-mailed to: SANTE-VETERINARY-MEDICINES@ec.europa.eu in English

Box 1: Country		**Box 2: Date of provision of information by the competent authority**	

Box 3: Name of competent authority:	
Box 4: Name and position of person responsible for the information submitted in this document	

Box 5: Animal species and commodities intended for export to the EU for human consumption (please tick)	**Bovine**	**Ovine/Caprine**	**Porcine**	**Equine**	**Aquaculture**	**Poultry**	**Milk**	**Eggs**	**Rabbit**	**Farmed Game**	**Honey**	**Casings**
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Section 1: Competent authority statement/information – antimicrobials reserved for human use [1]	**Commission assessment**
Statement 1: Antimicrobial medicinal products containing any of the antimicrobials included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in the Annex to Commission Implementing Regulation (EU) No 2022/1255 are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	

[1] See Annex to Commission Implementing Regulation (EU) No 2022/1255

If you have ticked (a) **(authorised for use)** please specify which of those antimicrobial substances are authorised in your country and for which species of food-producing animals listed in Box 5.	
Response:	
If you have ticked (a) **(authorised for use)** please carefully read each of the statements below and tick only those which apply	
For those animal species or commodities listed in Box 5 and intended for export to the EU for human consumption, are these: Born and reared in your country? Yes ☐ No ☐ Not applicable ☐ Imported into your country from another third country? Yes ☐ No ☐ Not applicable ☐	
Observations, if any:	
<u>Statement 2</u> on food-producing animals born and reared in your country and products derived therefrom which are intended to be exported to the EU, for human consumption There is a **system of regular official controls on food business operators in my country** which is either already in place or which will be put in place (**if so, please specify the date here**) to ensure that antimicrobials reserved for human use [1] have not been administered to those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) which are intended for export to the EU for human consumption. ☐	
<u>Statement 3</u> on food-producing animals or products derived therefrom which are imported into your country and which are intended to be exported from your country to the EU, for human consumption	

Regarding those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) imported into my country from another third country for the purpose of manufacture of food of animal origin for the EU market, **guarantees** have been received from that third country indicating that antimicrobials reserved for human use [1] have not been used in those animals/products imported into my country for that purpose. ☐	
Statement 4 on measures to prevent non-compliant animals & animal products being exported to the EU for human consumption In the event that food business operators are found to have used antimicrobials reserved for human use [1] in food-producing animals intended for export to the EU for human consumption, neither the animals in question, nor the products derived therefrom will be exported to the EU and the operator in question will be prohibited from supplying such animals and products for the EU market until such times as they have rectified the problem and official controls have verified that they are compliant with the rules. ☐	
If you have ticked (b) **(not authorised for use)** please specify if the use is **explicitly prohibited** by national legislation and if so, please provide the name of the legislation and identify the provision giving effect to the prohibition on use in food-producing animals.	
Response:	

Section 2: Competent authority statement/information – antimicrobials for growth promotion	**Commission assessment**
Statement 5: Antimicrobial medicinal products used for the purpose of promoting growth or increasing yield in food-producing animals are either:	
(a) **authorised** for use in food-producing animal species in my country ☐ or	
(b) **not authorised** for use in food producing animal species in my country ☐	
If you have ticked (a) **(authorised for use)** please list those antimicrobial substances which are authorised for such use in your country and for which food-producing animal species listed in Box 5.	
Response:	
If you have ticked (a) **(authorised for use)** please carefully read each of the statements below and tick only those which apply.	
For those animal species or commodities listed in Box 5 and intended for export to the EU for human consumption, are these: Born and reared in your country? Yes ☐ No ☐ Not applicable ☐ Imported into your country from another third country? Yes ☐ No ☐ Not applicable ☐	
Observations, if any:	
Statement 6 on food-producing animals born and reared in your country and products derived therefrom which are intended to be exported to the EU, for human consumption	

There is a **system of regular official controls on food business operators in my country** which is either already in place or which will be put in place (**if so, please specify the date here**) to ensure that antimicrobials used for the purpose of promoting growth or increasing yield have **not** been administered to those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) which are intended for export to the EU for human consumption. ☐	
Statement 7 on food-producing animals or products derived therefrom which are imported into your country and which are intended to be exported from your country to the EU, for human consumption Regarding those food-producing animal species (listed in Box 5) and products therefrom (listed in Box 5) imported into my country from another third country for the purpose of manufacture of food of animal origin for the EU market, **guarantees** have been received from that third country indicating that antimicrobials used for the purpose of promoting growth or increasing yield have **not** been used in those animals/products imported into my country for that purpose. ☐	
Statement 8 on measures to prevent non-compliant animals & animal products being exported to the EU for human consumption In the event that food business operators are found to have used antimicrobials for the purpose of promoting growth or increasing yield in food-producing animals intended for export to the EU for human consumption, neither the animals in question, nor the products derived therefrom will be exported to the EU and the operator in question will be prohibited from supplying such animals and products for the EU market until such times as they have rectified the problem and official controls have verified that they are compliant with the rules. ☐	
If you have ticked (b) **(not authorised for use)** please specify if the use is **explicitly prohibited** by national legislation and if so, please provide the name of the legislation and identify the provision giving effect to the prohibition on use in food-producing animals.	
Response:	

Section 3: Competent authority statement/information – traceability of food-producing animals/products	Commission assessment
Statement 9 on traceability of animals and products intended to be exported to the EU, for human consumption With regard to the objective of ensuring that the animal species (see Box 5) or commodities (see Box 5) which are intended for export to the EU for human consumption, have not been administered at any time in their lifetime either antimicrobials reserved for human use [1] or antimicrobials for the purpose of promoting growth or increasing yield: (a) **food business operators** already have in place or will have by date **[insert date]** systems to ensure **traceability at all stages** of the production chain in order to meet the above objective. ☐ (b) Official controls are (or will be from **[insert date]**) performed to verify the **appropriateness of food business operators' traceability systems** in meeting the above objective. ☐	
If you are not in a position to tick either of the above boxes, please explain below.	
Response:	

European Commission

General information

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Box 1: Country		Box 2: Date of provision of information by the competent authority	
Box 3: Name of competent authority:			
Box 4: Name and position of person responsible for the information submitted in this document			

Box 3: **all the concerned Competent Authorities MUST be included in this box**

Box 5: Animal species and commodities intended for export to the EU for human consumption (please tick)	Bovine	Ovine/Caprine	Porcine	Equine	Aquaculture	Poultry	Milk	Eggs	Rabbit	Farmed Game	Honey	Casings
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

- **Tick the boxes for the goods that are intended to be exported**
- In order to export into the Union, the country of export, has also to be listed in other EU legislation (e.g. Regulation 2021/404, Regulation 2021/405, etc.) depending on the EU import requirements for the specific type of consignment.
- **After entry into application of Commission Delegated Regulation 2023/905 :** according to its Article 5, third countries, for products falling under the scope of this Delegated Regulation, will also have to be listed in the the list of approved third countries.
- **In order to export to the Union, Third Countries MUST be listed in all the relevant lists.**

NEW STATEMENTS IN THE EXPORT CERTIFICATES

- **Commission Implementing Regulation (EU) …/...of XXX amending Annex III to Implementing Regulation (EU) 2020/2235 and Annex II to Implementing Regulation (EU) 2021/403 as regards model certificates for entry into the Union of consignments of certain products of animal origin and certain categories of terrestrial animals**

European Commission

Example of the possible wording of the new attestation/ Commission Regulation (EU) 2020/2235 (PAO)

PUBLIC HEALTH SECTION

DRAFT TEXT

‘(x) (xx) [II.x.xx. I, the undersigned [official veterinarian/certifying officer/ the undersigned] declare that, **I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2023/905** and hereby certify that [product] described in Part I was produced in accordance with these requirements, and in particular, that the animals from which the [*PRODUCT CONCERNED*] is derived **have not been administered antimicrobial medicinal products for growth promotion and/or yield increase or antimicrobials reserved for the treatment of certain infections in humans** laid down in Commission Implementing Regulation (EU) 2022/1255 and originates from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]’

;

(ii) in the Notes to Part II, the following footnote is inserted:

‘(xx) Applicable to consignments entering the Union as from [***Exact Date to be inserted by the Service responsible for the publication***].’

Commission Delegated Regulation (EU) 2023/905 shall apply as from 24 months after the day of application of the amended Commission Regulation (EU) 2020/2235

European Commission

Example of the possible wording of the new attestation/ Commission Regulation (EU) 2021/403 (ANIMALS)

DRAFT TEXT

‘(x) (xx) [II.x.x. fulfil the requirements provided for in **Article 3 of Commission Delegated Regulation (EU) 2023/905**, and in particular, that **the animals have not been administered antimicrobial medicinal products for growth promotion and/or yield increase or antimicrobials reserved for the treatment of certain infections in humans** laid down in Commission Implementing Regulation (EU) 2022/1255 and originates from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]’

;

(ii) in the Notes to Part II, the following footnote is inserted:

‘(xx) Applicable to consignments entering the Union as from [***Exact Date to be inserted by the Service responsible for the publication***].’

Commission Delegated Regulation (EU) 2023/905 shall apply as from 24 months after the day of application of the amended Commission Regulation (EU) 2021/403

European Commission