Meeting with Third Countries on the Draft Commission Delegated Regulation supplementing Regulation (EU) 2019/6 as regards the application of Article 118

Brussels, 12 January 2023

Dr. Eva ZAMORA ESCRIBANO
Head of Unit Veterinary Medicines,
Health and Food Safety Directorate-General

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

Article 118: Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.

2. The Commission shall adopt **delegated acts** in accordance with Article 147 in order to supplement this Article by **providing the necessary detailed rules on the application of paragraph 1 of this Article**

Article 107: Use of antimicrobial medicinal products

2. Antimicrobial medicinal products **shall not be used in animals for the purpose of promoting growth nor to increase yield**

Article 37: Decisions refusing marketing authorisation

5. The Commission shall, by means of implementing acts, **designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)

Article 37: Decisions refusing marketing authorisation

4. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Regulation by **establishing the criteria for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans** in order to preserve the efficacy of those antimicrobials

5. The Commission shall, by means of implementing acts, **designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans**.

Commission Delegated Regulation (EU) 2021/ 1760 (criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans)

Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

- **It shall apply from 9 February 2023**

The VMP Regulation: **no provisions for official controls on imports of animals and animal products**

To provide a **Union single framework for official controls** to third countries Regulation (EU) 2017/625 was amended : Regulation **(EU) 2021/1756** of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards **official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials** and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs

Article 1

Subject matter and scope

4. This Regulation shall not apply to official controls for the verification of compliance with:

(c) Regulation (EU) 2019/6 of the European Parliament and of the Council (2); however, **this Regulation shall apply to official controls for the verification of compliance with Article 118(1) of that Regulation**

European Commission

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

"Same scope as the residues legislation" except for composite products (Commission Delegated Regulation 2022/2292)

Article 1

Subject matter and scope

1. This Regulation lays down detailed **rules on the application of the prohibition of use, in animals or products of animal origin that are exported from third countries into the Union, of antimicrobial medicinal products for growth promotion and yield increase, and antimicrobials reserved for treatment of certain infections in humans.**

2. This Regulation applies to live **food-producing animals** for which Combined Nomenclature codes ('CN codes') have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87.

   This Regulation also applies to **products of animal origin intended for human consumption**, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16, of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings have been laid down under headings 3501, 3502 and 3504.

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

3. This Regulation **does not apply** to the following:

(a) gelatine and raw materials for the production thereof referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council;

(b) collagen and raw materials for the production thereof referred to in Section XV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(c) highly refined products referred to in Section XVI, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

(d) wild animals and products derived therefrom;

(e) insects, frogs, snails and reptiles, including products derived therefrom;

(f) composite products;

(g) animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the Union;

(h) animals or products of animal origin intended for human consumption only for transit through the Union without being placed on the market;

(i) products of animal origin intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market.

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 3

Restrictions on the use of certain antimicrobial medicinal products in animals or products derived therefrom entering the Union

Animals or products referred to in Article 1(2) **that are exported from third countries** into the Union shall not have been administered, or originate from animals that have been administered any of the following:

(a) an antimicrobial medicinal product used for the purpose of promoting growth or to increase yield;

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255.

European Commission

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 4

Conditions for the entry into the Union

1. Consignments of the animals or products referred to in Article 1(2) shall only enter the Union where the following conditions are met:

(a) they originate from a **third country or region thereof included in the list of countries** referred to in Article 5, and

(b) they are **accompanied by an official certificate** referred to in Article 6 attesting that the consignment complies with the requirements in Article 3.

2. By way of **derogation** from paragraph 1, point (a), consignments of the animals or products referred to in Article 1(2) may enter the Union from third countries that are not included in the list referred to in Article 5(1), where such third countries ensure that the consignments entering the Union originate from a Member State or from a third country included in the list.

European Commission

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 5

List of approved third countries

1. The list referred to in Article 4(1), point (a), is **to be established by means of an implementing act adopted by the Commission** in accordance with Article 127 of Regulation (EU) 2017/625. If appropriate, that list may be combined with other lists developed under Article 127 of Regulation (EU) 2017/625.

2. The Commission shall decide on the inclusion of third countries in the list in accordance with the requirements laid down in Article 127(3), points (a) to (d), and points (f) and (g), of Regulation (EU) 2017/625, on the basis of available evidence and guarantees that the requirements laid down in Article 3 are complied with, including information received on the procedures in place to guarantee the traceability and origin of animals or products referred to Article 1(2).

3. In accordance with Article 127(4) of Regulation (EU) 2017/625, the Commission shall delete the reference to a third country or a region of a third country from the list if the conditions for inclusion in the list cease to be met.

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 6

Certification of compliance

1. **Specific requirements on the official certificates** referred in point (b) of Article 4(1) **are to be laid down by the Commission**, by means of implementing acts, in accordance with the examination procedure referred to in Article 126(3) of Regulation (EU) 2017/625.

2. The official certificates may include details required in accordance with other Union legislation on public and animal health matters.

European Commission

COMMISSION DELEGATED REGULATION (EU) …/...of XXX supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Article 7

Controls

Controls to verify compliance of consignments of the animals or products referred to in Article 1(2) with Article 3 shall be carried out in accordance with Regulation (EU) 2017/625.

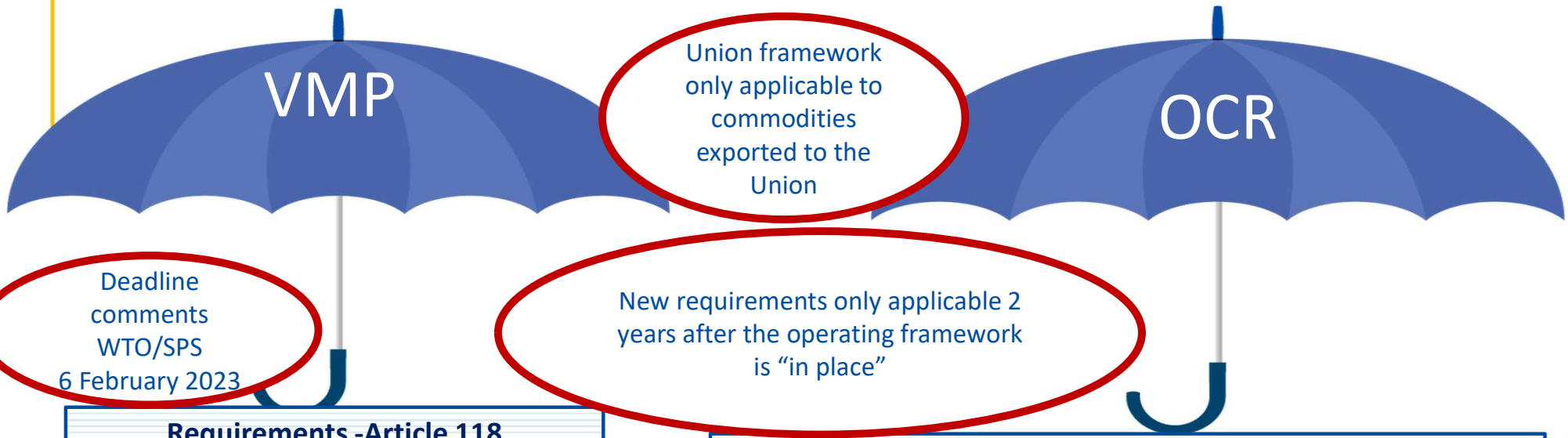
Article 8

Entry into force and application

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

The conditions for entry into the Union of consignments of animals or products set out in this delegated act shall apply as from 24 months after the date of application of the implementing act referred to in Article 6(1). [certificates]

European Commission



Union framework only applicable to commodities exported to the Union

Deadline comments WTO/SPS 6 February 2023

New requirements only applicable 2 years after the operating framework is "in place"

Requirements -Article 118

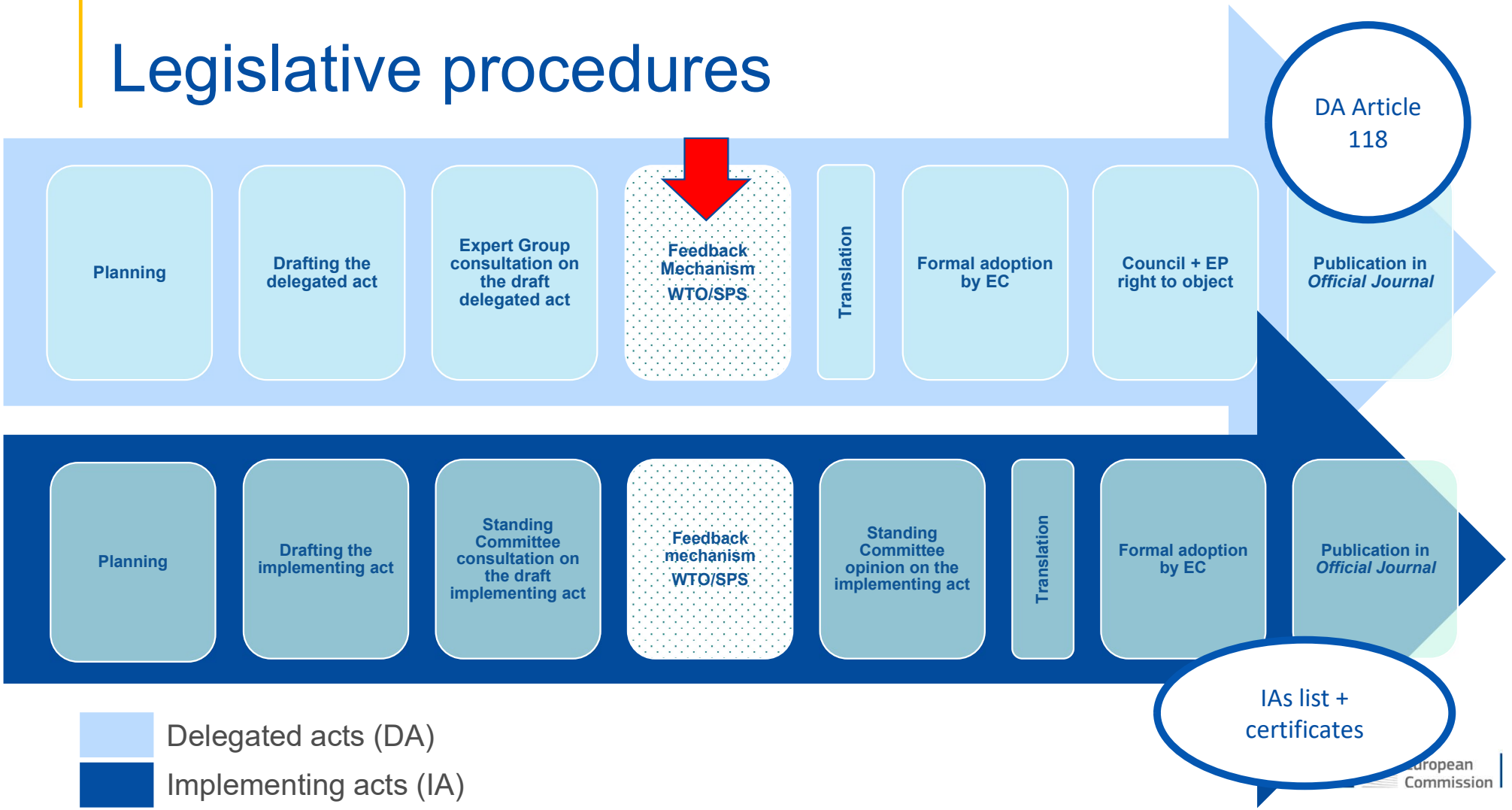
- Ban on use of antimicrobials growth promotion + list of antimicrobials
- Scope food producing animals and PAO
- Conditions: only consignments from listed countries and accompanied by official certificates
- Application date linked to the application date of the amended certificates

Union single framework for official controls : official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials (VMP Regulation)

List of third countries to be developed on the basis of the guarantees provided by TC

Amendments to the current legal acts laying down the relevant models of official certificates for animals and products of animal origin for the entry intro the Union (e.g. Commission Implementing Regulation (EU) 2020/2235, etc): relevant **attestations** to be included (VMP)

Legislative procedures



Where can you follow progress?

https://europa.eu/!rJ63kT

Where can you provide feedback?

https://ec.europa.eu/info/law/better-regulation/have-your-say

European Commission

Thank you