State of play concerning the implementation of Commission Delegated Regulation (EU) 2023/905

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Eva ZAMORA ESCRIBANO

DG SANTE, Directorate Medical products and innovation

Unit Veterinary Medicines

Commission Delegated Regulation (EU) 2023/905 of 27 February 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

published on 4th May 2023

European Commission

Commission Delegated Regulation (EU) 2023/905

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.**

Article 5
List of approved third countries

European Commission

Commission Delegated Regulation (EU) 2023/905

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.**

Process for listing of approved third countries (or region/s)

- In May 2023, the Commission formally requested the **98 third countries listed in Annex -I of Regulation 2021/405** (which establishes the list of authorised countries that have an approved control plan for the use of pharmacologically active substances) to provide the necessary guarantees of compliance with the requirements of Article 118.
- **A six-month period** was given to provide the data (template was developed), which came to an end on 23 November. Following the necessary exchanges with third countries, the Commission has completed the evaluation of the written guarantees provided. The implementing regulation listing third countries authorised to export to the EU will be drafted on the basis of this assessment
- On the basis of **available evidence and guarantees provided by third countries** 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) a **draft Regulation is under preparation**

Process for listing of approved third countries (or region/s)

2 steps process:

- A first list including the third countries which have **already** provided the requested written guarantees (certainty, transparency).
- A revised list to be published before the date of application of the new import requirements.

The list may be **combined with other lists** developed under Article 127 of Regulation (EU) 2017/625. The first list will be a standalone legal act to be merged at a later stage with Regulation (EU) 2021/405 (i.e. residues, public health list):

The **list will be revised periodically** (as necessary). **Third countries must report if any relevant changes in their legislation.**

Process for listing of approved third countries (or region/s)

- Following “technical” opinion of the SCoPAFF the draft Regulation will be **notified to the WTO/SPS**
- Some countries have **not provided guarantees for all commodities** they are authorised to export under the residue list: **countries will only be listed for the commodities for which they have submitted guarantees.**
- If a country intends **to export a new commodity** to the EU, the necessary guarantees should be ideally submitted in parallel to the requests to be included in the residues list and provide the necessary information

Country ISO Code	Third country or regions thereof	Bovine	Ovine/ caprine	Porcine	Equine	Poultry	Aquaculture[17]	Milk	Eggs	Rabbit	Farmed game	Honey	Casings
A	Abcd	X	X					X					X
B	Bcdf											X	
C	Cdef						X[14]						
D	Defg	X	X	X	X	X	X M	X	X	X	X	X	X
E	Efgh							Δ	Δ				
F	Fghi						X				X		
G	Ghij	X	X	X[5]		X	X[15]						X

*Wild animals and composite products are excluded from this table as these commodities fall out of scope of Commission Delegated Regulation (EU) 2023/905

(…)

(5) Ovine species only

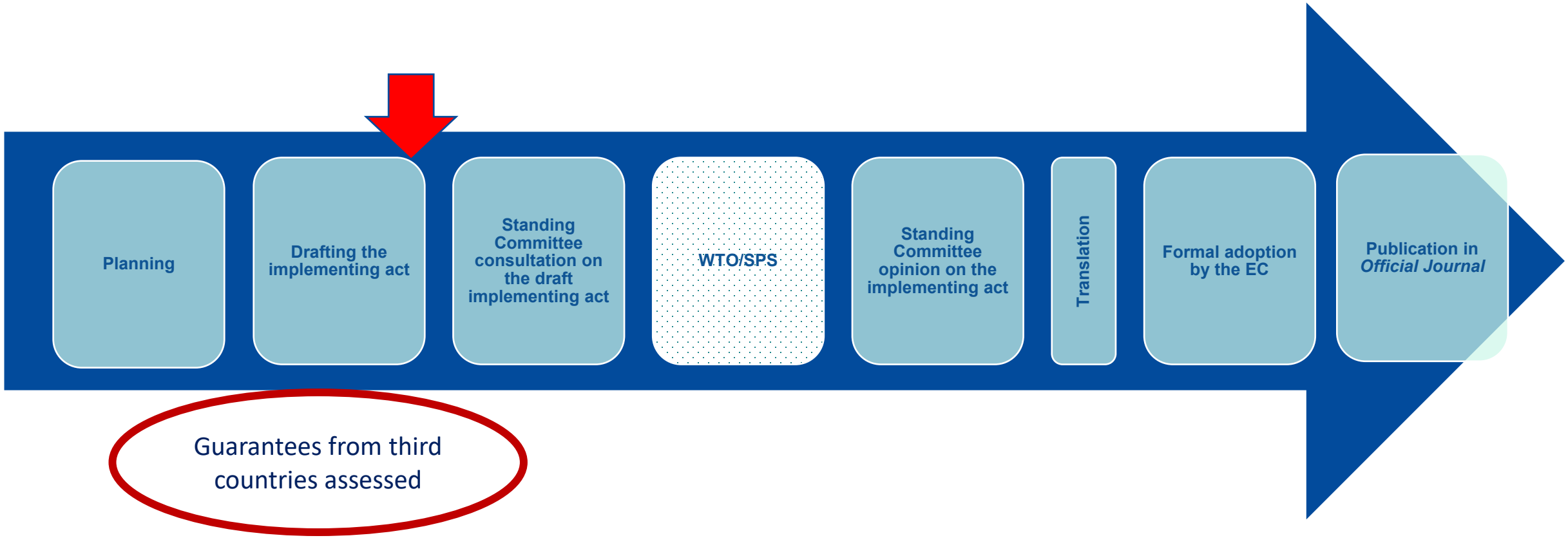
(14) Finfish and finfish products only

(15) Crustaceans only

European Commission

	Number of countries
Countries addressed with a template letter	98
Countries that have submitted information	76
Countries which have not provided information	21
Other countries not currently listed in Annex –I of Regulation 2021/405	1

Legislative procedure



Article 6
Certification of compliance

European Commission

Commission Delegated Regulation (EU) 2023/905

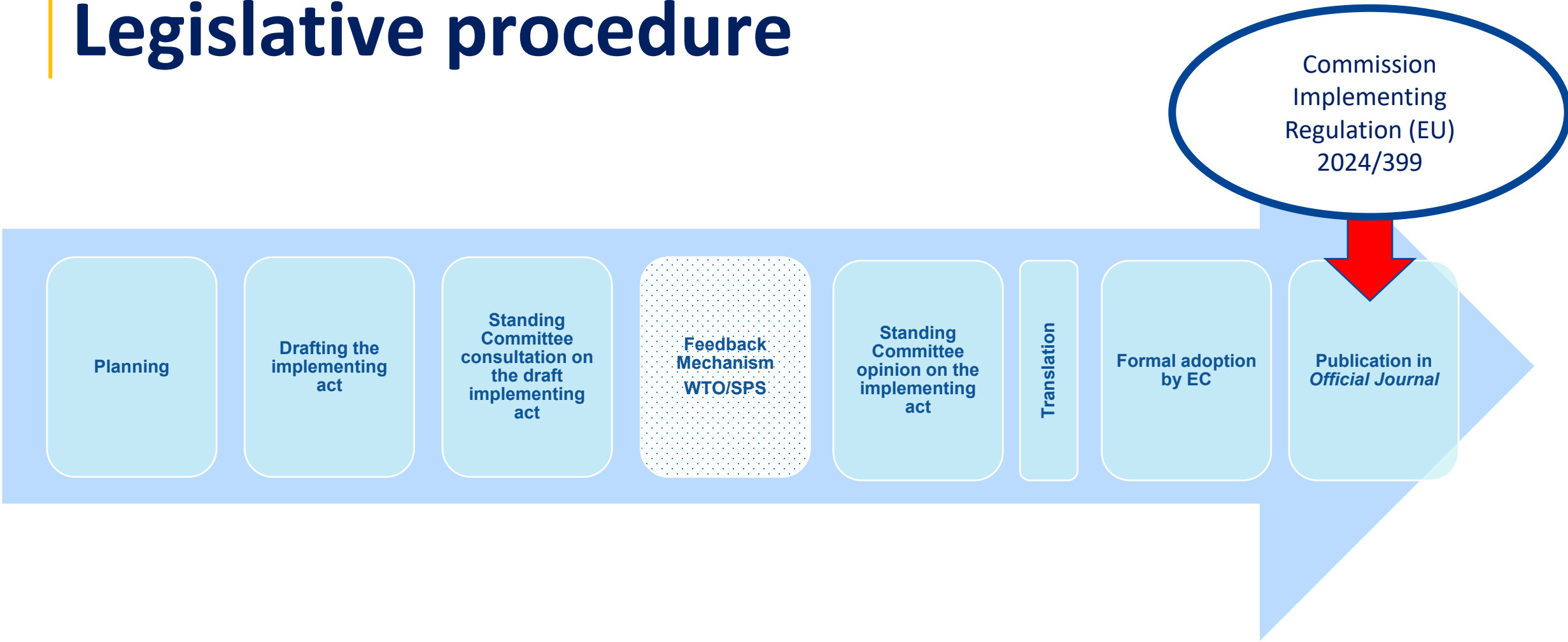
Article 6

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.

Legislative procedure



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2024/399

12.2.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/399

of 29 January 2024

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

(Text with EEA relevance)

Article 3

1. For a transitional period until 3 December 2024, as regards consignments of certain products of animal origin for human consumption, the use of certificates issued in accordance with the models set out in Chapters 1, 2, 3, 4, 5, 7, 10, 11, 12, 13, 15, 19, 20, 23, 24, 25, 26, 27, 28, 33, 34, 35, 36, 37, 38, 45 and 49 of Annex III to Implementing Regulation (EU) 2020/2235, as applicable before the amendments made to that Implementing Regulation by this Regulation, shall continue to be authorised for the entry into the Union provided that those certificates were issued no later than 3 September 2024.

2. For a transitional period until 3 December 2024, as regards consignments of certain categories of food-producing terrestrial animals, the use of certificates issued in accordance with the models set out in Chapters 1, 2, 4, 5, 7, 8, 12, 13, 14, 22, 23, 29, 30 and 31 of Annex II to Implementing Regulation (EU) 2021/403, as applicable before the amendments made to that Implementing Regulation by this Regulation, shall continue to be authorised for the entry into the Union provided that those certificates were issued no later than 3 September 2024.

Article 4

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 3 September 2024.

MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION OF FRESH MEAT INTENDED FOR HUMAN CONSUMPTION, EXCLUDING MECHANICALLY SEPARATED MEAT, OF DOMESTIC BOVINE ANIMALS (MODEL BOV)

COUNTRY			Animal health/Official certificate to the EU		
Consignment	I.1 **Consignor/Exporter** Name Address Country ISO country code		I.2 **Certificate reference**	I.2a **IMSOC reference**	
			I.3 **Central Competent Authority**	**QR CODE**	
			I.4 **Local Competent Authority**		
	I.5 **Consignee/Importer** Name		I.6 **Operator responsible for the consignment** Name		

(1) (16) [**II.1.a. Attestation as regards Commission Delegated Regulation (EU) 2023/905** [Delete when the Union is not the final destination of the fresh meat]

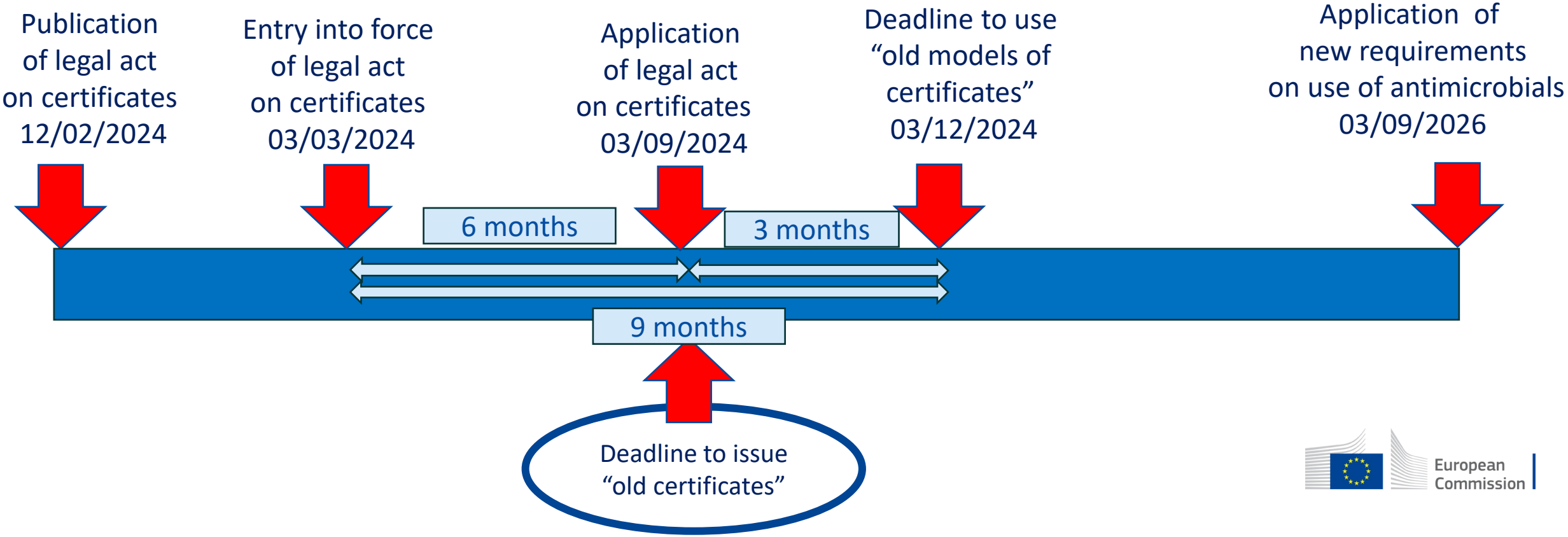
I, the undersigned official veterinarian declare that, I am aware of the relevant requirements of Regulation (EU) 2019/6 of the European Parliament and of the Council and Commission Delegated Regulation (EU) 2023/905 and hereby certify that fresh meat of domestic bovine animals (including *Bison* and *Bubalus* species and their cross-breeds) described in Part I was produced in accordance with these requirements, and in particular, that the animals from which the meat is derived have not been administered antimicrobial medicinal products for growth promotion or yield increase or antimicrobial medicinal products containing an antimicrobial that is included in the list of antimicrobials reserved for the treatment of certain infections in humans laid down in Commission Implementing Regulation (EU) 2022/1255 as set out in Article 3 of Delegated Regulation (EU) 2023/905 and originate from a third country or region thereof listed in accordance with Article 5(2) of Delegated Regulation (EU) 2023/905.]

(1) Delete if not applicable.

(16) Applicable to consignments entering the Union as from 3 September 2026.

Transitional periods

Commission Implementing Regulation (EU) 2024/399



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Article 8
Entry into force and application

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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] APPLICABLE TO CONSIGMENTS ENTERING THE UNION AS FROM 3 SEPTEMBER 2026

	Publication	Application	IMPLEMENTATION OF ARTICLE 118
Commission Implementing Regulation (EU) 2024/399 (certificates)	12 February 2024	3 September 2024	3 September 2026
Commission Delegated Regulation (EU) 2023/905	4 May 2023	24 months after the date of application of the IA	
Regulation (EU) 2019/6 on veterinary medicinal products	7 January 2019	28 January 2022	
Commission Implementing Regulation listing third countries	Q3-2024		

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Thank you

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