



2024/2563

27.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2563

of 24 September 2024

amending Implementing Regulation (EU) 2022/1646 as regards additional content of the national risk-based control plans and the national randomised surveillance plan, the submission of those plans and data by Member States and minimum sampling frequencies

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 19(3), first subparagraph, points (a) and (b), thereof,

Whereas:

- (1) In accordance with Article 7(1), point (d), of Commission Implementing Regulation (EU) 2022/1646 ⁽²⁾, Member States are to provide in their national risk-based control plans and in their national randomised surveillance plan the type of follow-up measures taken by the competent authorities with regard to animals or products of animal origin in which non-compliant residues have been detected in the previous years. As this information is also part of the data transmitted to the European Food Safety Authority ('EFSA') and to avoid double reporting, this information should be included only in the data transmitted to EFSA.
- (2) Article 7(2), first subparagraph, point (b), of Implementing Regulation (EU) 2022/1646 requires the national risk-based control plans to include an overview of non-compliance data provided by EFSA. Since Member States can retrieve those data themselves, it is no longer needed to refer to EFSA as a provider of that overview.
- (3) In accordance with Article 8, first paragraph, of Implementing Regulation (EU) 2022/1646, Member States are to submit their control plans and their surveillance plan to the Commission. To clarify that also the surveillance plan is to be submitted, the heading of Article 8 of Implementing Regulation (EU) 2022/1646 should be amended.
- (4) In accordance with Article 9, first paragraph, of Implementing Regulation (EU) 2022/1646, Member States are to transmit to EFSA all data gathered under their control plans and their surveillance plan. This obligation should be reflected more explicitly in the wording of that provision.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>.

⁽²⁾ Commission Implementing Regulation (EU) 2022/1646 of 23 September 2022 on uniform practical arrangements for the performance of official controls as regards the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on specific content of multi-annual national control plans and specific arrangements for their preparation (OJ L 248, 26.9.2022, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2022/1646/oj).

- (5) In the framework of the national risk-based control plan for production in the Member States, Member States are to fulfil the provisions of Implementing Regulation (EU) 2022/1646 as regards the mandatory percentage of samples for substance group A(3), point (b) set out in Annex I to Commission Delegated Regulation (EU) 2022/1644 ⁽³⁾. This group covers unauthorised pharmacologically active substances for the veterinary treatment or for use in feed for food-producing animals, which are plant protection products and biocides, and which may be used in animal husbandry of food-producing animals. Since Member States may include the official controls of these substances under the regulatory framework of multiannual national control programmes on pesticide residues in food and feed, set out in Commission Delegated Regulation (EU) 2021/2244 ⁽⁴⁾, the requirement of a minimum sampling frequency of 5 % laid down in the additional provisions in Annex I to Implementing Regulation (EU) 2022/1646 should not apply to substance group A(3), point (b).
- (6) Implementing Regulation (EU) 2022/1646 should therefore be amended accordingly.
- (7) As the rules laid down in Implementing Regulation (EU) 2022/1646 are related, both for the national risk-based control plans and for the national randomised surveillance plan, to the relevant calendar year, this Regulation should apply for the first time to the plans for the year 2025. This Regulation should therefore apply from 1 January 2025.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2022/1646 is amended as follows:

- (1) Article 7 is replaced by the following:

‘Article 7

Additional content of the national risk-based control plans and the national randomised surveillance plan

- 1. The national risk-based control plans, referred to in Articles 4 and 6, and the national randomised surveillance plan, referred to in Article 5, shall specify the following:
 - (a) the species to be sampled and the place of sampling;
 - (b) the national legislation on the use of pharmacologically active substances and, in particular, their prohibition or their authorisation, distribution, placing on the market and administration, in so far as that legislation is not harmonised by Union legislation;
 - (c) the competent authorities responsible for the implementation of the plans.

⁽³⁾ Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof (OJ L 248, 26.9.2022, p. 3, ELI: http://data.europa.eu/eli/reg_del/2022/1644/oj).

⁽⁴⁾ Commission Delegated Regulation (EU) 2021/2244 of 7 October 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific rules on official controls as regards sampling procedures for pesticides residues in food and feed (OJ L 453, 17.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg_del/2021/2244/oj).

2. The national risk-based control plans referred to in Articles 4 and 6 shall, in addition to the information specified in paragraph 1, provide the following:

- (a) a justification for the selected substances, species, products and matrices included in the plans on the basis of the criteria listed in Annexes II and VI to Delegated Regulation (EU) 2022/1644, including a justification on how the criteria listed in those Annexes were taken into account, even if no changes were made compared to the plans of the previous year;
- (b) a justification on how cases of non-compliance in the relevant Member State detected in the previous three calendar years were taken into account for optimising the plans.

Member States are not required to submit information already provided in the general part of MANCPs in accordance with Article 110(2) of Regulation (EU) 2017/625.;

- (2) the heading of Article 8 is replaced by the following:

‘Submission and evaluation of the national risk-based control plans and the national randomised surveillance plan’;

- (3) Article 9 is replaced by the following:

‘Article 9

Submission of data by the Member State

By 30 June each year, Member States shall transmit to the European Food Safety Authority (“EFSA”) all data from the previous year, including compliant results of screening methods where no confirmatory analyses were performed, gathered under the control plans and the surveillance plan referred to in Article 3. Those data shall also contain the type of follow-up measures taken by the competent authorities with regard to animals or products of animal origin in which non-compliant residues were detected in the previous year.

By 31 August each year, Member States shall finalise the data validation, review and final acceptance in the EFSA data repository systems.;

- (4) in Annex I, in the ‘additional provisions’, point (b) is replaced by the following:

‘(b) Controls on each combination of sub-groups of Group A substances and commodity groups as listed in Annex II to Delegated Regulation (EU) 2022/1644 shall be performed annually in minimum 5 % of the samples taken in accordance with the table of this Annex for that commodity group. This minimum percentage does not apply to casings, and it does not apply to substance groups A(3), point (b) and A(3), point (f) for all commodity groups.’.

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 January 2025.

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

Done at Brussels, 24 September 2024.

For the Commission
The President
Ursula VON DER LEYEN