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<sup>(1)</sup> 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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<sup>(1)</sup> Text with EEA relevance.

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<sup>(1)</sup> Text with EEA relevance.



## II

*(Non-legislative acts)*

## REGULATIONS

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/997****of 23 May 2023****amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment 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 <sup>(1)</sup>, and in particular Article 60(1) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2021/17 <sup>(2)</sup> sets out a list of variations not requiring assessment.
- (2) The European Medicines Agency ('the Agency') and the Coordination Group on Veterinary Medicinal Products ('CMDv') advised the Commission, on 20 December 2022, to amend points B.12 and B.24 of the Annex to Implementing Regulation (EU) 2021/17 to reflect new developments. Both the Agency and the CMDv received requests for classification of three changes to the terms of a marketing authorisation not listed in the Annex to Implementing Regulation (EU) 2021/17 that had not arisen before as variations not requiring assessment. These changes concern production equipment or processes related to production equipment, and changes in relation to the manufacturer responsible for batch release.
- (3) The Commission took into account the advice of the Agency and the CMDv, the criteria listed in Article 60(2) of Regulation (EU) 2019/6, as well as all necessary conditions and the most current documentation requirements, to ensure that the new variations not requiring assessment do not present a risk to public health, animal health or the environment.
- (4) Implementing Regulation (EU) 2021/17 should therefore be amended accordingly to include these new types of variations currently not listed in the Annex to that Implementing Regulation.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

<sup>(1)</sup> OJ L 4, 7.1.2019, p. 43.<sup>(2)</sup> Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 7, 11.1.2021, p. 22).

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) 2021/17 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*.

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

Done at Brussels, 23 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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In the Annex to Implementing Regulation (EU) 2021/17, point B is amended as follows:

(1) in point 12, the following point is added:

|     |                                                                                                        |                                                                                                                  |                                                       |
|-----|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| 'h) | — to production equipment (when described in the dossier) including processes related to the equipment | The change shall not result in any changes or modifications of the production process or quality of the product. | Amendment of the relevant section(s) of the dossier.' |
|-----|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|

(2) point 24 is replaced by the following:

|     |                                                                                                     |                                                                                                                                                                                                                                                                                                            |                                                                                                                                                        |
|-----|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| '24 | Replacement or addition of a manufacturer responsible for:                                          | The manufacturer or the site shall already be introduced in the Union IT systems storing and providing organisational data.<br><br>The site shall be appropriately authorised and satisfactorily inspected.                                                                                                | Amendment of the relevant section(s) of the dossier, including revised product information, as appropriate.<br><br>Qualified person (QP) declaration.' |
| a)  | — batch release including batch control or testing of a sterile or non-sterile finished product     | The change shall not be applicable to a biological or immunological medicinal product.<br><br>Method transfer from the former to the new site shall have been successfully completed.                                                                                                                      |                                                                                                                                                        |
| b)  | — batch release not including batch control or testing of a sterile or non-sterile finished product | At least one batch control/testing site remains within the EEA or in a country where an operational and suitably scoped GMP mutual recognition agreement (MRA) exists between the country concerned and the EU, that is able to carry out product testing for the purpose of batch release within the EEA. |                                                                                                                                                        |

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/998****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.
- (4) On 30 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 was submitted to Denmark, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26). This Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740, however, according to Article 17 of that Regulation, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (6) The rapporteur Member State prepared a draft renewal assessment report, in consultation with the co-rapporteur Member State, and submitted it to the Authority and the Commission on 20 June 2019. In its draft renewal assessment report, the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation, and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 27 September 2021, the Authority communicated to the Commission its conclusion <sup>(6)</sup>, which indicates that *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 14 October 2022 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351, pay particular attention to the protection of operators and workers.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

<sup>(6)</sup> EFSA Journal. DOI: <https://doi.org/10.2903/j.efsa.2021.6879>. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(7)</sup> extended the approval of *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351 until 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (18) 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

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

For the Commission

The President

Ursula VON DER LEYEN

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<sup>(7)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* *Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

## ANNEX I

| Common Name,<br>Identification Numbers                        | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------|------------|------------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

| Common Name,<br>Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------|------------|-----------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                        |            |                       |                  |                        | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on cabbage and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>3</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in part A, entry 195 is deleted,

(2) in Part B, the following entry is added:

| No.  | Common Name,<br>Identification Numbers                           | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------|------------------------------------------------------------------|------------|------------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '162 | <i>Bacillus thuringiensis</i><br>subsp. <i>kurstaki</i> ABTS-351 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 below 10<sup>5</sup> CFU/g as recommended by EFSA.</li> </ul> |

| No. | Common Name,<br>Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----|----------------------------------------|------------|-----------------------|------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                        |            |                       |                  |                        | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <p>— Data in at least one representative edible crop (i.e. on cabbage and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.</p> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).’

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/999****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.
- (4) On 27 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 was submitted to Sweden, the rapporteur Member State and to Spain, the co-rapporteur Member State in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 27 July 2018. In its draft renewal assessment report the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 12 November 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup> which indicates that *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012 <sup>(7)</sup>, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009 in case of applications for authorisation of uses for edible crops. It is then, in particular, appropriate as a precautionary approach for consumer dietary protection to require that Member States, when assessing applications for authorisations of products containing *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 for uses in edible crop, to set a minimum time period between the application of these products and the harvest of edible crops used for fresh consumption.
- (14) Furthermore, it is appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52, pay particular attention to the protection of operators and workers.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2023/689 <sup>(8)</sup> extended the approval period of *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

<sup>(6)</sup> EFSA (European Food Safety Authority). Conclusion on the peer review of the pesticide risk assessment of the active substance *B. thuringiensis* subsp. *israelensis* strain AM65-52. *EFSA Journal*, 2020, DOI: 10.2903/j.efsa.2020.6317.

<sup>(7)</sup> This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

<sup>(8)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *israelensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* *Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinepaxap, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

- (17) 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*

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3*

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

| Common Name, Identification Numbers                                                                       | IUPAC Name     | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------|----------------|------------------------|------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52<br>Culture collection No ATCC 1276 | Not applicable | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the renewal report on <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52, and in particular Appendices I and II thereof, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the protection of wild pollinators and of aquatic organisms (e.g. aquatic invertebrates from Diptera taxon in particular) in case of uses in open field. Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> <p>Conditions of use shall include risk mitigation measures, such as:</p> <ul style="list-style-type: none"> <li>— adequate personal protective equipment for operators using products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52;</li> <li>— In case of authorisation of uses on edible crops, a minimum time period of 3 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

## ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 194 on *Bacillus thuringiensis* subsp. *israelensis* strain AM65-52 is deleted;
- (2) in Part B, the following entry is added:

| No.  | Common Name, Identification Numbers                                                                       | IUPAC Name     | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------|-----------------------------------------------------------------------------------------------------------|----------------|------------------------|------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '161 | <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52<br>Culture collection No ATCC 1276 | Not applicable | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the renewal report on <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52, and in particular Appendices I and II thereof, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> <li>— the protection of wild pollinators and of aquatic organisms (e.g. aquatic invertebrates from Diptera taxon in particular) in case of uses in open field. Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> <p>Conditions of use shall include risk mitigation measures, such as:</p> <ul style="list-style-type: none"> <li>— adequate personal protective equipment for operators using products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52;</li> <li>— In case of authorisation of uses on edible crops, a minimum time period of 3 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 below 10<sup>3</sup> CFU/g at harvest.'</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu)

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1000****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* GC-91 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009, of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.
- (4) On 29 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 was submitted to the Netherlands, the rapporteur Member State and to Germany, the co-rapporteur Member State in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 31 July 2018. In its draft renewal assessment report the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 30 September 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup> which indicates that *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012 <sup>(7)</sup>, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is also appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, pay particular attention to the protection of operators and workers, and to the protection of wild pollinators.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

<sup>(6)</sup> EFSA (European Food Safety Authority). Conclusion on the peer review of the pesticide risk assessment of the active substance *B. thuringiensis* subsp. *aizawai* strain GC-91. *EFSA Journal*, 2020, DOI: 10.2903/j.efsa.2020.6293.

<sup>(7)</sup> This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(8)</sup> extended the approval period of *Bacillus thuringiensis* subsp. *aizawai* strain GC-91 to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (18) 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

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain GC-91, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

For the Commission

The President

Ursula VON DER LEYEN

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<sup>(8)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* *Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

## ANNEX I

| Common Name,<br>Identification Numbers                    | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------|------------|------------------------|------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

| Common Name,<br>Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------|------------|-----------------------|------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                        |            |                       |                  |                        | <p>The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:</p> <p>— data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.</p> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 193 is deleted,

(2) in Part B, the following entry is added:

| No.  | Common Name, Identification Numbers                       | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
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| '160 | <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

| No. | Common Name, Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----|-------------------------------------|------------|-----------------------|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                     |            |                       |                  |                        | <p>The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:</p> <p>— data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.’</p> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1001****of 23 May 2023****renewing the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2007/6/EC <sup>(2)</sup> included *Bacillus amyloliquefaciens* strain QST 713 in Annex I to Council Directive 91/414/EEC <sup>(3)</sup> with the name of *Bacillus subtilis* (Cohn 1872) QST 713.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus amyloliquefaciens* strain QST 713, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.
- (4) An application for the renewal of the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713 was submitted to Germany, the rapporteur Member State, and Denmark, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 4 June 2018. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances (OJ L 43, 15.2.2007, p. 13).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the other Member States for comments in accordance with Article 12(1) of Regulation (EC) No 1107/2009, launched a public consultation and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to public.
- (8) On 16 April 2021, the Authority communicated to the Commission its conclusion <sup>(6)</sup> on whether the active substance *Bacillus amyloliquefaciens* strain QST 713 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and a draft Regulation regarding *Bacillus amyloliquefaciens* strain QST 713 to the Standing Committee on Plants, Animals, Food and Feed on 13 October 2022 and 25 January 2023, respectively.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012 <sup>(7)</sup>, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of least one plant protection product containing the active substance *Bacillus amyloliquefaciens* strain QST 713 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) It is therefore appropriate to renew the approval of *Bacillus amyloliquefaciens* strain QST 713.
- (12) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge, it is necessary to include certain conditions to the renewal of approval of that active substance. In particular, the Commission considers that *Bacillus amyloliquefaciens* strain QST 713 is a micro-organism within the meaning of Regulation (EC) No 1107/2009, for which a critical area of concern was identified as regards bees. For this reason, it is necessary to provide for specific risk mitigation measures in order to ensure a proper protection of bees.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2023/689 <sup>(8)</sup> extended the approval period to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(6)</sup> Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain QST 713 (formerly *Bacillus subtilis* strain QST 713): <https://doi.org/10.2903/j.efsa.2021.6381>.

<sup>(7)</sup> This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

<sup>(8)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* *Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinepaxap, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

HAS ADOPTED THIS REGULATION:

*Article 1*

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus amyloliquefaciens* strain QST 713, as specified in Annex I to this Regulation, is renewed subject to the conditions laid down in that Annex.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3*

**Entry into force and date of application**

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 July 2023.

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

Done at Brussels, 23 May 2023.

*For the Commission*

*The President*

Ursula VON DER LEYEN

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## ANNEX I

| Common Name,<br>Identification Numbers              | IUPAC<br>Name | Purity <sup>(1)</sup>                                                                                                                                                                                                              | Date of approval | Expiration of<br>approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus amyloliquefaciens</i><br>strain QST 713 | n.a.          | The nominal content of<br><i>Bacillus amyloliquefaciens</i> strain<br>QST 713 in the technical<br>product and formulation is<br>Minimum: $1 \times 10^{12}$ CFU/kg<br>Maximum: $3 \times 10^{13}$ CFU/kg<br>No relevant impurities | 1 July 2023      | 30 June 2038              | <p>When authorising plant protection products containing <i>Bacillus amyloliquefaciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall:</p> <ul style="list-style-type: none"> <li>— only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees;</li> <li>— implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles).</li> </ul> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In addition, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the specification of the technical material as commercially manufactured used in plant protection products;</li> <li>— the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

## ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 138 on *Bacillus subtilis* (Cohn 1872) strain QST 713 is deleted.
- (2) in Part B, the following entry is added:

| No.  | Common Name, Identification Numbers              | IUPAC Name | Purity <sup>(1)</sup>                                                                                                                                                                                                  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------|--------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '158 | <i>Bacillus amyloliquefaciens</i> strain QST 713 | n.a.       | The nominal content of <i>Bacillus amyloliquefaciens</i> strain QST 713 in the technical product and formulation is Minimum: $1 \times 10^{12}$ CFU/kg<br>Maximum: $3 \times 10^{13}$ CFU/kg<br>No relevant impurities | 1 July 2023      | 30 June 2038           | <p>When authorising plant protection products containing <i>Bacillus amyloliquefaciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall:</p> <ul style="list-style-type: none"> <li>— only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees;</li> <li>— implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles).</li> </ul> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account. In addition, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup></li> <li>— the specification of the technical material as commercially manufactured used in plant protection products;</li> <li>— the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.'</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1002****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.
- (4) On 29 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 was submitted to the Netherlands, the rapporteur Member State and to Germany, the co-rapporteur Member State in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 11 October 2018. In its draft renewal assessment report the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation and forwarded the comments received to the Commission. The Authority made the supplementary summary dossier available to the public.
- (8) On 30 September 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup> which indicates that *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012 <sup>(7)</sup>, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is also appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, pay particular attention to the protection of operators and workers, and to the protection of wild pollinators.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

<sup>(6)</sup> EFSA (European Food Safety Authority). Conclusion on the peer review of the pesticide risk assessment of the active substance *B. thuringiensis* subsp. *aizawai* strain ABTS-1857. *EFSA Journal*, 2020, DOI: 10.2903/j.efsa.2020.6294.

<sup>(7)</sup> This Regulation was replaced by Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(8)</sup> extended the approval period of *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857 to 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (18) 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

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *aizawai* strain ABTS-1857, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

For the Commission

The President

Ursula VON DER LEYEN

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<sup>(8)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *Aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *Israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *Kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

## ANNEX I

| Common Name, Identification Numbers                                  | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------|------------|------------------------|------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

| Common Name, Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------|------------|-----------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                     |            |                       |                  |                        | <p>The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:</p> <ul style="list-style-type: none"><li>— data in at least one representative edible crop (i.e. peppers and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>3</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.</li></ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 193 is deleted;

(2) in Part B, the following entry is added:

| No.  | Common Name,<br>Identification Numbers                                     | IUPAC Name | Purity <sup>(1)</sup>     | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------|----------------------------------------------------------------------------|------------|---------------------------|------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '159 | <i>Bacillus thuringiensis</i><br>subsp. <i>aizawai</i> strain<br>ABTS-1857 | n.a.       | No relevant<br>impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>;</li> <li>— the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate.</li> </ul> |

| No. | Common Name,<br>Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----|----------------------------------------|------------|-----------------------|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                        |            |                       |                  |                        | <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> <p>The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. peppers and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.'</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1003****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* EG2348 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *kurstaki* EG2348 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* EG2348, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.
- (4) On 28 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* EG2348 was submitted to Denmark, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26). This Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), however, according to Article 17 of that Regulation, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (6) The rapporteur Member State prepared a draft renewal assessment report, in consultation with the co-rapporteur Member State, and submitted it to the Authority and the Commission on 28 June 2019. In its draft renewal assessment report, the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* EG2348.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation, and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 2 March 2021, the Authority communicated to the Commission its conclusion <sup>(6)</sup>, which indicates that *Bacillus thuringiensis* subsp. *kurstaki* EG2348 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *kurstaki* EG2348 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 5 July 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *kurstaki* EG2348 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* EG2348.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* EG2348 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *kurstaki* EG2348 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *kurstaki* EG2348 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *kurstaki* EG2348 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* EG2348, pay particular attention to the protection of operators and workers.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

<sup>(6)</sup> EFSA Journal DOI: <https://doi.org/10.2903/j.efsa.2021.6495>. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(7)</sup> extended the approval of *Bacillus thuringiensis* subsp. *kurstaki* EG2348 until 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (18) 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

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* EG2348, as specified in Annex I, is renewed, subject to the conditions laid down in that Annex.

Article 2

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

For the Commission

The President

Ursula VON DER LEYEN

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<sup>(7)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *Aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *Israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *Kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

## ANNEX I

| Common Name, Identification Numbers                         | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------|------------|------------------------|------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on pome fruits and solanaceous vegetables during the fruiting period) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability</li> </ul> |

| Common Name, Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                            |
|-------------------------------------|------------|-----------------------|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                     |            |                       |                  |                        | data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025. |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu)

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in part A, entry 195 is deleted;

(2) in Part B, the following entry is added:

| No   | Common Name, Identification Numbers                         | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------|-------------------------------------------------------------|------------|------------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '163 | <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 below 10<sup>5</sup> CFU/g as recommended by EFSA.</li> </ul> |

| No | Common Name, Identification Numbers | IUPAC Name | Purity <sup>(1)</sup> | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----|-------------------------------------|------------|-----------------------|------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                     |            |                       |                  |                        | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on pome fruits and solanaceous vegetables during the fruiting period) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu)

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1004****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-11 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-11 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-11, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.
- (4) On 30 April 2016, an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-11 was submitted to Denmark, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26). This Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740, however, according to Article 17 of that Regulation, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (6) The rapporteur Member State prepared a draft renewal assessment report, in consultation with the co-rapporteur Member State, and submitted it to the Authority and the Commission on 11 January 2019. In its draft renewal assessment report, the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-11.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation, and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 16 September 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup>, which indicates that *Bacillus thuringiensis* subsp. *kurstaki* SA-11 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *kurstaki* SA-11 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-11 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-11.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* SA-11 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *kurstaki* SA-11 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *kurstaki* SA-11 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *kurstaki* SA-11 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* SA-11, pay particular attention to the protection of operators and workers.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(7)</sup> extended the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-11 until 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

<sup>(6)</sup> EFSA Journal DOI: 10.2903/j.efsa.2020.6261. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

<sup>(7)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *Aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *Israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *Kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

- (18) 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*

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-11, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3*

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

| Common Name,<br>Identification Numbers                        | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------------------------|------------|------------------------|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i><br>subsp. <i>kurstaki</i> SA-11 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> |

|  |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--|--|--|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  |  |  |  | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>3</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.</li> </ul> |
|--|--|--|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

(<sup>1</sup>) Further details on the identity and the specification of the active substance are provided in the renewal report.  
 (<sup>2</sup>) pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in part A, entry 195 is deleted,

(2) in Part B, the following entry is added:

|      |                                                            |      |                        |             |              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------|------------------------------------------------------------|------|------------------------|-------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '165 | <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | <p>The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*).</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 below 10<sup>5</sup> CFU/g as recommended by EFSA.</li> </ul> |
|------|------------------------------------------------------------|------|------------------------|-------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |  |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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|  |  |  |  |  |  | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. by 13 December 2025.</li> </ul> |
|--|--|--|--|--|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

(\*) pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).'

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1005****of 23 May 2023****renewing the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/113/EC <sup>(2)</sup> included a reference to the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (2) According to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(4)</sup>.
- (3) The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 August 2024.
- (4) On 30 April 2016 an application for the renewal of the approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12 was submitted to Denmark, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicant also submitted the supplementary dossiers required by Article 6 of Implementing Regulation (EU) No 844/2012 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). The application was found to be admissible by the rapporteur Member State.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (OJ L 330, 9.12.2008, p. 6).

<sup>(3)</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26). This Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), however, according to Article 17 of that Regulation, it continues to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member States and submitted it to the Authority and the Commission on 2 April 2019. In its draft renewal assessment report, the rapporteur Member State proposes to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments, launched a public consultation, and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 16 September 2020, the Authority communicated to the Commission its conclusion <sup>(6)</sup>, which indicates *Bacillus thuringiensis* subsp. *kurstaki* SA-12 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report regarding *Bacillus thuringiensis* subsp. *kurstaki* SA-12 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 May 2021 and on 25 January 2023, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) It is therefore appropriate to renew the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12.
- (13) It is, however, necessary to provide for certain conditions pursuant to Article 14(1), read in conjunction with Article 6, of Regulation (EC) No 1107/2009. It is, in particular, appropriate as a precautionary approach for consumer dietary protection to include a minimum time period between the application of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* SA-12 and the harvest of edible crops used for fresh consumption, unless residues data show levels of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 below 10<sup>5</sup> CFU/g at harvest.
- (14) In addition, in order to increase the confidence in the conclusion that *Bacillus thuringiensis* subsp. *kurstaki* SA-12 does not affect human health, the applicant should provide further data regarding the density decline of viable spores of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g.
- (15) Furthermore, it is appropriate to require that Member States, when assessing applications for authorisations of plant protection products containing *Bacillus thuringiensis* subsp. *kurstaki* SA-12, pay particular attention to the protection of operators and workers.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

<sup>(6)</sup> EFSA Journal. DOI: 10.2903/j.efsa.2020.6262. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

- (17) Commission Implementing Regulation (EU) 2023/689 <sup>(7)</sup> extended the approval of *Bacillus thuringiensis* subsp. *kurstaki* SA-12 until 15 August 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (18) 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

**Renewal of the approval of the active substance**

The approval of the active substance *Bacillus thuringiensis* subsp. *kurstaki* SA-12, as specified in Annex I, is renewed, subject to the conditions laid down in that Annex.

Article 2

**Amendments to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

**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*.

It shall apply from 1 July 2023.

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

Done at Brussels, 23 May 2023.

For the Commission

The President

Ursula VON DER LEYEN

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<sup>(7)</sup> Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *Aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *Israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *Kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 91, 29.3.2023, p. 1).

## ANNEX I

| Common Name, Identification Numbers                        | IUPAC Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------|------------|------------------------|------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 | n.a.       | No relevant impurities | 1 July 2023      | 30 June 2038           | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— A minimum time period of 1 day shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 below 10<sup>5</sup> CFU/g at harvest.</li> </ul> <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <ul style="list-style-type: none"> <li>— data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.</li> </ul> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in part A, entry 195 is deleted,

(2) in Part B, the following entry is added:

| No.  | Common Name,<br>Identification Numbers                        | IUPAC<br>Name | Purity <sup>(1)</sup>  | Date of approval | Expiration of<br>approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------|---------------------------------------------------------------|---------------|------------------------|------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| '166 | <i>Bacillus thuringiensis</i><br>subsp. <i>kurstaki</i> SA-12 | n.a.          | No relevant impurities | 1 July 2023      | 30 June 2038              | <p>The implementation of the uniform principles, as provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and in particular Appendices I and II thereto, are taken into account.</p> <p>In this overall assessment, the Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;</li> <li>— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 <sup>(2)</sup>.</li> </ul> <p>Conditions of use shall include the following risk mitigation measures:</p> <ul style="list-style-type: none"> <li>— A minimum time period of 1 day shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 below 10<sup>5</sup> CFU/g as recommended by EFSA.</li> </ul> |

| No. | Common Name,<br>Identification Numbers | IUPAC<br>Name | Purity <sup>(1)</sup> | Date of approval | Expiration of<br>approval | Specific provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----|----------------------------------------|---------------|-----------------------|------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                        |               |                       |                  |                           | <p>The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards:</p> <p>— data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10<sup>5</sup> CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.</p> |

<sup>(1)</sup> Further details on the identity and the specification of the active substance are provided in the renewal report.

<sup>(2)</sup> pesticides\_ppp\_app-proc\_guide\_phys-chem-ana\_microbial-contaminant-limits.pdf (europa.eu).'

# DECISIONS

## COUNCIL DECISION (EU) 2023/1006

of 25 April 2023

**on the position to be taken on behalf of the European Union at the eleventh meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants as regards the proposals for amendment of Annex A to that Convention**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Stockholm Convention on Persistent Organic Pollutants <sup>(1)</sup> (the 'Convention') entered into force on 17 May 2004 and was concluded on behalf of the Union by Council Decision 2006/507/EC <sup>(2)</sup>.
- (2) Pursuant to Article 8 of the Convention, the Conference of the Parties may list chemicals in Annexes A, B and/or C to the Convention and may specify control measures related to such chemicals.
- (3) The recommendations of the Persistent Organic Pollutants Review Committee (the 'POPRC'), set up in accordance with the Convention should be duly taken into account.
- (4) At its eleventh meeting, the Conference of the Parties is expected to adopt decisions to list additional chemicals in Annex A to the Convention.
- (5) In order to protect human health and the environment from further releases of dechlorane plus, methoxychlor and UV-328, it is necessary to reduce or to eliminate the production and use of those chemicals at global level and to support their listing in the relevant annexes to the Convention.
- (6) It is appropriate to establish the position to be taken on the Union's behalf in the Conference of the Parties, as the decisions will be binding on the Union or capable of decisively influencing the content of Union law, namely Regulation (EU) 2019/1021 of the European Parliament and of the Council <sup>(3)</sup>,

HAS ADOPTED THIS DECISION:

### Article 1

The position to be taken on the Union's behalf at the eleventh meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants, taking due account of the relevant recommendations of the Persistent Organic Pollutants Review Committee (the 'POPRC'), shall be the following:

- (a) to support the listing of dechlorane plus in Annex A, with the specific exemptions recommended by the POPRC;

<sup>(1)</sup> OJ L 209, 31.7.2006, p. 3.

<sup>(2)</sup> Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 1).

<sup>(3)</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

- (b) to support the listing of methoxychlor in Annex A, without any specific exemptions;
- (c) to support the listing of UV-328 in Annex A, with the specific exemptions recommended by the POPRC.

*Article 2*

Refinements of the position referred to in Article 1, in light of the developments at the eleventh meeting of the Conference of the Parties may be agreed upon by representatives of the Union, in consultation with the Member States, during on-the-spot coordination meetings without further decision of the Council.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 25 April 2023.

*For the Council*  
*The President*  
P. KULLGREN

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**COUNCIL DECISION (EU) 2023/1007****of 25 April 2023****on the position to be taken on behalf of the European Union at the sixteenth meeting of the Conference of the Parties to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal with regard to certain amendments of Articles and Annexes in that Convention**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal <sup>(1)</sup> (‘the Convention’) entered into force in 1992 and was concluded on behalf of the Union by Council Decision 93/98/EEC <sup>(2)</sup>.
- (2) In accordance with the Convention, the Conference of the Parties is to consider and adopt, as required, amendments to the Convention and its Annexes.
- (3) The Conference of the Parties, during its fifteenth meeting in June 2022, considered a proposal for amendments of Article 6(2) of the Convention submitted by the Russian Federation. That proposal aims to establish a 30 day time limit for State of import to respond to the notifier of a shipment of waste and includes one other change which is presented as being editorial. The Conference of the Parties decided to defer consideration of this proposal to the next meeting of the Conference of the Parties.
- (4) A proposal to amend Annex IV and certain entries in Annexes II and IX to the Convention was also submitted on the Union’s behalf and discussed by the Conference of the Parties, during its fifteenth meeting. The proposal aims, inter alia, to amend and to clarify the descriptions of disposal operations listed in Annex IV to the Convention and, in particular, to: include a general introduction clearly distinguishing the terms ‘non-recovery’ and ‘recovery’; include captions and introductory texts that explain the meaning of ‘non-recovery operations’ (Annex IV, Section A) and ‘recovery operations’ (Annex IV, Section B); clarify that all disposal operations that occur or might occur in practice are covered regardless of their legal status and regardless of whether they are considered to be environmentally sound, and that operations that occur prior to the submission to other operations are also covered; update and clarify the descriptions of operations in line with scientific, technical and other developments which have occurred since the Convention was adopted in 1989; and ensure, through the introduction of catch-all provisions, that all operations not specifically mentioned are covered by the Convention’s requirements. The Conference of the Parties decided to further consider this proposal at the next meeting of the Conference of the Parties.
- (5) With regard to the proposal for amendments of Article 6(2) of the Convention submitted by the Russian Federation, the Union should not support it, since the amendments would not help to address the problems that the Union considers as priorities for the functioning of the procedure of ‘prior informed consent’ of the Convention. In addition, amendments to the body of the Convention text require a long and arduous process in order to enter into force and it seems disproportionate to launch such a procedure for an amendment that offers little to no added value.

<sup>(1)</sup> OJ L 39, 16.2.1993, p. 3.

<sup>(2)</sup> Council Decision 93/98/EEC of 1 February 1993 on the conclusion, on behalf of the Community, of the Convention on the control of transboundary movements of hazardous wastes and their disposal (Basel Convention) (OJ L 39, 16.2.1993, p. 1).

- (6) With regard to the proposal to amend Annex IV and certain entries in Annexes II and IX, the Union should continue to support its adoption. With a view to gathering consensus on this proposal, the Union could display flexibility, in particular with regard to the proposed measures that are unlikely to gather sufficient support for their adoption at the sixteenth meeting of the Conference of Parties. This includes, for example, deferring the discussion on contentious topics (such as preparing for reuse and catch-all operations), seeking an agreement on the remaining aspects of the proposal and supporting possible amendments by other Parties, provided that they could achieve the same objectives as those behind the Union's proposals concerning Annex IV to the Convention.
- (7) It is appropriate to establish the position to be taken on the Union's behalf at the sixteenth meeting of the Conference of the Parties with regard to those proposals, as the envisaged acts, if adopted, would be amendments to both the text and the Annexes to the Convention and would, thus, be binding on the Union and affect the content of Union law, namely Directive 2008/98/EC of the European Parliament and of the Council <sup>(3)</sup>, and Regulation (EC) No 1013/2006 of the European Parliament and of the Council <sup>(4)</sup>,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The position to be taken on the Union's behalf at the sixteenth meetings of the Conference of the Parties to the Basel Convention shall be the following:

- (a) the Union shall not support the proposal for amendments to Article 6(2) of the Convention, as submitted by the Russian Federation;
- (b) the Union shall continue to support the adoption of amendments to Annex IV and certain entries in Annexes II and IX of the Convention. If needed in order to ensure that a consensus is found on an amendment of Annex IV to the Convention, the Union may show flexibility and agree to depart from the proposal that it submitted for consideration at the fifteenth meeting of the Conference of the Parties, and support other possible changes that could achieve the same objectives as those that underpin the Union's proposals concerning Annex IV to the Convention, and that do not undermine the Union's legal regime on the management and shipment of waste.

#### *Article 2*

Refinement of the position referred to in Article 1 point (b), in light of developments at the sixteenth meeting of the Conference of the Parties, may be agreed upon by representatives of the Union, in consultation with the Member States, during on-the-spot coordination meetings, without further decision of the Council.

#### *Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 25 April 2023.

*For the Council*  
*The President*  
P. KULLGREN

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<sup>(3)</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

<sup>(4)</sup> Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

**COUNCIL DECISION (EU) 2023/1008****of 15 May 2023**

**authorising the opening of negotiations with the Republic of Ecuador for an agreement between the European Union and the Republic of Ecuador on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Ecuadorian authorities competent for fighting serious crime and terrorism**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16(2) and 88, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Regulation (EU) 2016/794 of the European Parliament and of the Council <sup>(1)</sup> was adopted on 11 May 2016, is applicable as of 1 May 2017, and was amended by Regulation (EU) 2022/991 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) The provisions of Regulation (EU) 2016/794, in particular those concerning the transfer of personal data from the European Union Agency for Law Enforcement Cooperation (Europol) to third countries and international organisations, provide that Europol may transfer personal data to an authority of a third country on the basis of an international agreement concluded between the Union and that third country pursuant to Article 218 of the Treaty on the Functioning of the European Union (TFEU) adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.
- (3) Negotiations should be opened with a view to concluding an agreement between the European Union and the Republic of Ecuador on the exchange of personal data between Europol and the Ecuadorian authorities competent for fighting serious crime and terrorism (the 'Agreement').
- (4) As stated in Recital 35 of Regulation (EU) 2016/794, the Commission should be able to consult the European Data Protection Supervisor (EDPS) during the negotiations of the Agreement and, in any event, before the Agreement is concluded.
- (5) The Agreement should respect the fundamental rights and observe the principles recognised by the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular the right to private and family life, recognised in Article 7 of the Charter, the right to the protection of personal data, recognised in Article 8 of the Charter, and the right to an effective remedy and to a fair trial recognised by Article 47 of the Charter. The Agreement should be applied in accordance with those rights and principles.
- (6) The Agreement should not affect, and should be without prejudice to, the transfer of personal data or other forms of cooperation between the authorities responsible for safeguarding national security.

<sup>(1)</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

<sup>(2)</sup> Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation (OJ L 169, 27.6.2022, p. 1).

- (7) Ireland is bound by Regulation (EU) 2016/794 and is therefore taking part in the adoption of this Decision.
- (8) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (9) The EDPS has been consulted on this Decision and the addendum thereto, and issued an opinion on 19 April 2023,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Commission is hereby authorized to open negotiations with the Republic of Ecuador for an agreement between the European Union and the Republic of Ecuador on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Ecuadorian authorities competent for fighting serious crime and terrorism.
2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision.

*Article 2*

The Commission is hereby nominated as the Union negotiator.

*Article 3*

1. The negotiations referred to in Article 1 shall be conducted in consultation with the Law Enforcement Working Party – Police (LEWP-Police), subject to any guidance which the Council may subsequently issue to the Commission.
2. The Commission shall report to the Council on both the conduct and the outcome of the negotiations on a regular basis and whenever requested by the Council, and shall forward the relevant documents to it as early as possible in order to allow the members of the Council reasonable time to prepare themselves properly for the forthcoming negotiations.

Where appropriate, or where requested by the Council, the Commission shall produce a written report.

*Article 4*

This Decision is addressed to the Commission.

Done at Brussels, 15 May 2023.

*For the Council*  
*The President*  
J. FORSSMED

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**COUNCIL DECISION (EU) 2023/1009****of 15 May 2023**

**authorising the opening of negotiations with the Plurinational State of Bolivia for an agreement between the European Union and the Plurinational State of Bolivia on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Bolivian authorities competent for fighting serious crime and terrorism**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16(2) and 88, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Regulation (EU) 2016/794 of the European Parliament and of the Council <sup>(1)</sup> was adopted on 11 May 2016, is applicable as of 1 May 2017, and was amended by Regulation (EU) 2022/991 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) The provisions of Regulation (EU) 2016/794, in particular those concerning the transfer of personal data from the European Union Agency for Law Enforcement Cooperation (Europol) to third countries and international organisations, provide that Europol may transfer personal data to an authority of a third country on the basis of an international agreement concluded between the Union and that third country pursuant to Article 218 of the Treaty on the Functioning of the European Union (TFEU) adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.
- (3) Negotiations should be opened with a view to concluding an agreement between the European Union and the Plurinational State of Bolivia on the exchange of personal data between Europol and the Bolivian authorities competent for fighting serious crime and terrorism (the 'Agreement').
- (4) As stated in recital 35 of Regulation (EU) 2016/794, the Commission should be able to consult the European Data Protection Supervisor (EDPS) during the negotiations of the Agreement and, in any event, before the Agreement is concluded.
- (5) The Agreement should respect the fundamental rights and observe the principles recognised by the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular the right to private and family life, recognised in Article 7 of the Charter, the right to the protection of personal data, recognised in Article 8 of the Charter and the right to an effective remedy and to a fair trial recognised by Article 47 of the Charter. The Agreement should be applied in accordance with those rights and principles.
- (6) The Agreement should not affect, and should be without prejudice to, the transfer of personal data or other forms of cooperation between the authorities responsible for safeguarding national security.
- (7) Ireland is bound by Regulation (EU) 2016/794 and is therefore taking part in the adoption of this Decision.

<sup>(1)</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

<sup>(2)</sup> Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation (OJ L 169, 27.6.2022, p. 1).

- (8) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (9) The EDPS has been consulted on this Decision and the addendum thereto, and issued an opinion on 3 May 2023,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Commission is hereby authorized to open negotiations with the Plurinational State of Bolivia for an agreement between the European Union and the Plurinational State of Bolivia on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Bolivian authorities competent for fighting serious crime and terrorism.
2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision.

*Article 2*

The Commission is hereby nominated as the Union negotiator.

*Article 3*

1. The negotiations referred to in Article 1 shall be conducted in consultation with the Law Enforcement Working Party – Police (LEWP-Police), subject to any guidance which the Council may subsequently issue to the Commission.
2. The Commission shall report to the Council on both the conduct and the outcome of the negotiations on a regular basis and whenever requested by the Council, and shall forward the relevant documents to it as early as possible in order to allow the members of the Council reasonable time to prepare themselves properly for the forthcoming negotiations.

Where appropriate, or where requested by the Council, the Commission shall produce a written report.

*Article 4*

This Decision is addressed to the Commission.

Done at Brussels, 15 May 2023.

*For the Council*  
*The President*  
J. FORSSMED

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**COUNCIL DECISION (EU) 2023/1010****of 15 May 2023**

**authorising the opening of negotiations with the Federative Republic of Brazil for an agreement between the European Union and the Federative Republic of Brazil on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Brazilian authorities competent for fighting serious crime and terrorism**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16(2) and 88, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Regulation (EU) 2016/794 of the European Parliament and of the Council <sup>(1)</sup> was adopted on 11 May 2016, is applicable as of 1 May 2017, and was amended by Regulation (EU) 2022/991 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) The provisions of Regulation (EU) 2016/794, in particular those concerning the transfer of personal data from the European Union Agency for Law Enforcement Cooperation (Europol) to third countries and international organisations, provide that Europol may transfer personal data to an authority of a third country on the basis of an international agreement concluded between the Union and that third country pursuant to Article 218 of the Treaty on the Functioning of the European Union (TFEU) adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.
- (3) Negotiations should be opened with a view to concluding an agreement between the European Union and the Federative Republic of Brazil on the exchange of personal data between Europol and the Brazilian authorities competent for fighting serious crime and terrorism (the 'Agreement').
- (4) As stated in Recital 35 of Regulation (EU) 2016/794, the Commission should be able to consult the European Data Protection Supervisor (EDPS) during the negotiations of the Agreement and, in any event, before the Agreement is concluded.
- (5) The Agreement should respect the fundamental rights and observe the principles recognised by the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular the right to private and family life, recognised in Article 7 of the Charter, the right to the protection of personal data, recognised in Article 8 of the Charter and the right to an effective remedy and to a fair trial recognised by Article 47 of the Charter. The Agreement should be applied in accordance with those rights and principles.
- (6) The Agreement should not affect, and should be without prejudice to, the transfer of personal data or other forms of cooperation between the authorities responsible for safeguarding national security.
- (7) Ireland is bound by Regulation (EU) 2016/794 and is therefore taking part in the adoption of this Decision.

<sup>(1)</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

<sup>(2)</sup> Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation (OJ L 169, 27.6.2022, p. 1).

- (8) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (9) The EDPS has been consulted on this Decision and the addendum thereto, and issued an opinion on 3 May 2023,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Commission is hereby authorized to open negotiations with the Federative Republic of Brazil for an agreement between the European Union and the Federative Republic of Brazil on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Brazilian authorities competent for fighting serious crime and terrorism.
2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision.

*Article 2*

The Commission is hereby nominated as the Union negotiator.

*Article 3*

1. The negotiations referred to in Article 1 shall be conducted in consultation with the Law Enforcement Working Party – Police (LEWP-Police), subject to any guidance which the Council may subsequently issue to the Commission.
2. The Commission shall report to the Council on both the conduct and the outcome of the negotiations on a regular basis and whenever requested by the Council, and shall forward the relevant documents to it as early as possible in order to allow the members of the Council reasonable time to prepare themselves properly for the forthcoming negotiations.

Where appropriate, or where requested by the Council, the Commission shall produce a written report.

*Article 4*

This Decision is addressed to the Commission.

Done at Brussels, 15 May 2023.

*For the Council*  
*The President*  
J. FORSSMED

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**COUNCIL DECISION (EU) 2023/1011****of 15 May 2023**

**authorising the opening of negotiations with the United Mexican States for an agreement between the European Union and the United Mexican States on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Mexican authorities competent for fighting serious crime and terrorism**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16(2) and 88, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Regulation (EU) 2016/794 of the European Parliament and of the Council <sup>(1)</sup> was adopted on 11 May 2016, is applicable as of 1 May 2017, and was amended by Regulation (EU) 2022/991 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) The provisions of Regulation (EU) 2016/794, in particular those concerning the transfer of personal data from the European Union Agency for Law Enforcement Cooperation (Europol) to third countries and international organisations, provide that Europol may transfer personal data to an authority of a third country on the basis of an international agreement concluded between the Union and that third country pursuant to Article 218 to the Treaty on the Functioning of the European Union (TFEU) adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.
- (3) Negotiations should be opened with a view to concluding an agreement between the European Union and the United Mexican States on the exchange of personal data between Europol and the Mexican authorities competent for fighting serious crime and terrorism (the 'Agreement').
- (4) As stated in Recital 35 of Regulation (EU) 2016/794, the Commission should be able to consult the European Data Protection Supervisor (EDPS) during the negotiations of the Agreement and, in any event, before the Agreement is concluded.
- (5) The Agreement should respect the fundamental rights and observe the principles recognised by the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular the right to private and family life, recognised in Article 7 of the Charter, the right to the protection of personal data, recognised in Article 8 of the Charter and the right to an effective remedy and to a fair trial recognised by Article 47 of the Charter. The Agreement should be applied in accordance with those rights and principles.
- (6) The Agreement should not affect, and should be without prejudice to, the transfer of personal data or other forms of cooperation between the authorities responsible for safeguarding national security.
- (7) Ireland is bound by Regulation (EU) 2016/794 and is therefore taking part in the adoption of this Decision.

<sup>(1)</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

<sup>(2)</sup> Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation (OJ L 169, 27.6.2022, p. 1).

- (8) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (9) The EDPS has been consulted on this Decision and the addendum thereto, and issued an opinion on 3 May 2023,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Commission is hereby authorized to open negotiations with the United Mexican States for an agreement between the European Union and the United Mexican States on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Mexican authorities competent for fighting serious crime and terrorism.
2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision.

*Article 2*

The Commission is hereby nominated as the Union negotiator.

*Article 3*

1. The negotiations referred to in Article 1 shall be conducted in consultation with the Law Enforcement Working Party – Police (LEWP-Police), subject to any guidance which the Council may subsequently issue to the Commission.
2. The Commission shall report to the Council on both the conduct and the outcome of the negotiations on a regular basis and whenever requested by the Council, and shall forward the relevant documents to it as early as possible in order to allow the members of the Council reasonable time to prepare themselves properly for the forthcoming negotiations.

Where appropriate, or where requested by the Council, the Commission shall produce a written report.

*Article 4*

This Decision is addressed to the Commission.

Done at Brussels, 15 May 2023.

*For the Council*  
*The President*  
J. FORSSMED

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**COUNCIL DECISION (EU) 2023/1012****of 15 May 2023****authorising the opening of negotiations with the Republic of Peru for an agreement between the European Union and the Republic of Peru on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Peruvian authorities competent for fighting serious crime and terrorism**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16(2) and 88, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) Regulation (EU) 2016/794 of the European Parliament and of the Council <sup>(1)</sup> was adopted on 11 May 2016, is applicable as of 1 May 2017, and was amended by Regulation (EU) 2022/991 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) The provisions of Regulation (EU) 2016/794, in particular those concerning the transfer of personal data from the European Union Agency for Law Enforcement Cooperation (Europol) to third countries and international organisations, provide that Europol may transfer personal data to an authority of a third country on the basis of an international agreement concluded between the Union and that third country pursuant to Article 218 of the Treaty on the Functioning of the European Union (TFEU) adducing adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals.
- (3) Negotiations should be opened with a view to concluding an agreement between the European Union and the Republic of Peru on the exchange of personal data between Europol and the Peruvian authorities competent for fighting serious crime and terrorism (the 'Agreement').
- (4) As stated in Recital 35 of Regulation (EU) 2016/794, the Commission should be able to consult the European Data Protection Supervisor (EDPS) during the negotiations of the Agreement and, in any event, before the Agreement is concluded.
- (5) The Agreement should respect the fundamental rights and observe the principles recognised by the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular the right to private and family life, recognised in Article 7 of the Charter, the right to the protection of personal data, recognised in Article 8 of the Charter and the right to an effective remedy and to a fair trial recognised by Article 47 of the Charter. The Agreement should be applied in accordance with those rights and principles.
- (6) The Agreement should not affect, and should be without prejudice to, the transfer of personal data or other forms of cooperation between the authorities responsible for safeguarding national security.
- (7) Ireland is bound by Regulation (EU) 2016/794 and is therefore taking part in the adoption of this Decision.

<sup>(1)</sup> Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

<sup>(2)</sup> Regulation (EU) 2022/991 of the European Parliament and of the Council of 8 June 2022 amending Regulation (EU) 2016/794, as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role in research and innovation (OJ L 169, 27.6.2022, p. 1).

- (8) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (9) The EDPS has been consulted on this Decision and the addendum thereto, and issued an opinion on 3 May 2023,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The Commission is hereby authorized to open negotiations with the Republic of Peru for an agreement between the European Union and the Republic of Peru on the exchange of personal data between the European Union Agency for Law Enforcement Cooperation (Europol) and the Peruvian authorities competent for fighting serious crime and terrorism.
2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision.

*Article 2*

The Commission is hereby nominated as the Union negotiator.

*Article 3*

1. The negotiations referred to in Article 1 shall be conducted in consultation with the Law Enforcement Working Party – Police (LEWP-Police), subject to any guidance which the Council may subsequently issue to the Commission.
2. The Commission shall report to the Council on both the conduct and the outcome of the negotiations on a regular basis and whenever requested by the Council, and shall forward the relevant documents to it as early as possible in order to allow the members of the Council reasonable time to prepare themselves properly for the forthcoming negotiations.

Where appropriate, or where requested by the Council, the Commission shall produce a written report.

*Article 4*

This Decision is addressed to the Commission.

Done at Brussels, 15 May 2023.

*For the Council*  
*The President*  
J. FORSSMED

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**COUNCIL DECISION (EU) 2023/1013****of 16 May 2023****on a derogation from Decision 2013/471/EU on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates, and repealing Decision (EU) 2021/1072**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 301, third paragraph, thereof,

Whereas:

- (1) Council Decision (EU) 2021/1072 <sup>(1)</sup> introduced a temporary derogation from Articles 2, 3 and 4 of Council Decision 2013/471/EU <sup>(2)</sup> as regards the payment of daily allowances and the reimbursement of travelling expenses to members of the European Economic and Social Committee (the 'Committee') and their alternates (together referred to as the 'beneficiaries'), entitling beneficiaries who attend meetings remotely by electronic means to a daily allowance.
- (2) The temporary derogation was deemed necessary in order to guarantee that the Committee's activities could take place in an appropriate and sustainable manner at all times in order to ensure institutional continuity for the period of continued travel difficulties or sanitary restrictions to physical meetings caused by the COVID-19 pandemic in the Union.
- (3) The reports submitted by the Committee on the application of the temporary derogation have shown the budgetary and environmental benefits of having a daily allowance for beneficiaries who attend meetings remotely by electronic means as well as the advantages and efficiency gains in relation to the Committee's institutional and business continuity. Those benefits remain relevant irrespective of cases of travel difficulties caused by the COVID-19 pandemic in the Union, as shown by the Committee's request to the Council for a structural solution allowing for the possibility to grant a daily allowance to beneficiaries who attend certain types of meetings of the Committee remotely by electronic means.
- (4) It is therefore appropriate to replace the temporary derogation introduced by Decision (EU) 2021/1072 with a structural solution allowing for the possibility to grant a daily allowance to beneficiaries who attend remotely by electronic means those meetings that have been duly authorised in accordance with the internal rules of the Committee, except for Bureau meetings, plenary sessions of the Assembly, meetings of sections and meetings of the Consultative Commission on Industrial Change. It is also appropriate that, in case of duly justified and exceptional circumstances, where it is impossible to organise meetings of the Committee fully in person, the daily allowance for beneficiaries for remote attendance by electronic means be granted in relation to any other duly authorised meeting of the Committee which is essential in guaranteeing the Committee's institutional and business continuity.
- (5) Actual administrative costs incurred by a beneficiary who attends a meeting remotely by electronic means are lower than the rate of the daily allowance currently applicable for the attendance of in-person meetings, while the time spent by a beneficiary remains the same. It is therefore appropriate that the daily allowance granted to beneficiaries who attend meetings remotely by electronic means is adapted accordingly.

<sup>(1)</sup> Council Decision (EU) 2021/1072 of 28 June 2021 on a temporary derogation from Decision 2013/471/EU on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 230, 30.6.2021, p. 30).

<sup>(2)</sup> Council Decision 2013/471/EU of 23 September 2013 on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates (OJ L 253, 25.9.2013, p. 22).

- (6) Detailed rules related to the granting of the daily allowance to beneficiaries who attend meetings remotely by electronic means should be established by the Committee with the aim to maximise the benefits resulting from remote attendance while at the same time ensuring there is no unjustified increase in the number of meetings organised by the Committee.
- (7) The Committee should submit to the Council regular reports on the application of the daily allowance to beneficiaries who attend meetings remotely by electronic means so as to allow the Council to evaluate its impact, in line with the reporting requirements set out in Decision 2013/471/EU. The reports should in particular indicate the evolution in the number of meetings of the Committee attended remotely by electronic means and their duration, as well as any budgetary and environmental savings associated with such meetings.
- (8) This Decision should be part of a future comprehensive revision of Decision 2013/471/EU, to be undertaken before the end of the current term of office of the Committee.
- (9) Decision (EU) 2021/1072 should be repealed,

HAS ADOPTED THIS DECISION:

#### *Article 1*

1. By way of derogation from Articles 2, 3 and 4 of Decision 2013/471/EU, beneficiaries who attend meetings of the Committee remotely by electronic means shall be entitled only to a daily allowance set at EUR 145.
2. The granting of the daily allowance referred to in paragraph 1 shall only be applicable to meetings that have been authorised in accordance with the internal rules of the Committee, except for Bureau meetings, plenary sessions of the Assembly, meetings of sections and meetings of the Consultative Commission on Industrial Change.
3. In duly justified and exceptional circumstances, the daily allowance referred to in paragraph 1 shall also be granted for any other duly authorised meeting other than for those for which the daily allowance is granted in accordance with paragraph 2, provided that such a meeting cannot be organised fully in person and that it is essential in guaranteeing the Committee's institutional and business continuity.

#### *Article 2*

The Committee shall adopt detailed provisions implementing Article 1 by 26 July 2023.

#### *Article 3*

Reporting on the application of the daily allowance referred to in Article 1 shall be included in the reporting requirements under Article 9 of Decision 2013/471/EU.

#### *Article 4*

Decision (EU) 2021/1072 is repealed.

#### *Article 5*

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

Done at Brussels, 16 May 2023.

*For the Council*  
*The President*  
E. SVANTESSON

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**COUNCIL DECISION (EU) 2023/1014****of 16 May 2023****appointing an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions <sup>(1)</sup>,

Having regard to the proposal of the Spanish Government,

Whereas:

- (1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.
- (2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 <sup>(2)</sup>, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the resignation of Mr Javier VILA FERRERO.
- (4) The Spanish Government has proposed Ms Ana Isabel CÁRCABA GARCÍA, representative of a regional body who holds a regional authority electoral mandate, *Consejera de Hacienda, Gobierno del Principado de Asturias* (Regional Minister for Finance of the Government of the Principality of Asturias), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

*Article 1*

Ms Ana Isabel CÁRCABA GARCÍA, representative of a regional body who holds an electoral mandate, *Consejera de Hacienda, Gobierno del Principado de Asturias* (Regional Minister for Finance of the Government of the Principality of Asturias), is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

*Article 2*

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 16 May 2023.

*For the Council*  
*The President*  
E. SVANTESSON

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<sup>(1)</sup> OJ L 139, 27.5.2019, p. 13.

<sup>(2)</sup> Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

**COUNCIL DECISION (CFSP) 2023/1015****of 23 May 2023****confirming the participation of Denmark in PESCO, and amending Decision (CFSP) 2017/2315 establishing permanent structured cooperation (PESCO) and determining the list of participating Member States**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 46(3) thereof,

Having regard to Protocol No 10 on permanent structured cooperation established by Article 42 of the Treaty on European Union attached to the Treaty on European Union and to the Treaty on the Functioning of European Union,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Having regard to the opinion of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) Article 46(3) of the Treaty on European Union (TEU) provides that any Member State which wishes to participate in permanent structured cooperation (PESCO) is to notify its intention to the Council and to the High Representative of the Union for Foreign Affairs and Security Policy ('the High Representative').
- (2) On 1 June 2022, a referendum was held in Denmark on revoking the exemption from participation in decisions and actions of the Union which have defence implications laid down in Article 5 of Protocol No 22 to the Treaties on the position of Denmark. That referendum resulted in a vote in favour of revocation.
- (3) In accordance with Article 7 of Protocol No 22, Denmark informed the other Member States that it no longer wished to avail itself of Article 5 of that Protocol as from 1 July 2022, by a letter from its Minister for Foreign Affairs of 20 June 2022.
- (4) On 23 March 2023, the Council and the High Representative received a notification in accordance with Article 46(3) of the TEU from Denmark that Denmark has the intention to participate in PESCO.
- (5) Denmark has set out in its National Implementation Plan its ability to meet the more binding commitments, contained in the Annex to Council Decision (CFSP) 2017/2315 <sup>(1)</sup>, that the participating Member States have made to one another.
- (6) The necessary conditions having been met, it is therefore appropriate for the Council to adopt a decision confirming the participation of Denmark in PESCO.
- (7) Decision (CFSP) 2017/2315 should be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1*

The participation of Denmark in PESCO is hereby confirmed.

<sup>(1)</sup> Council Decision (CFSP) 2017/2315 of 11 December 2017 establishing permanent structured cooperation (PESCO) and determining the list of participating Member States (OJ L 331, 14.12.2017, p. 57).

*Article 2*

In Article 2 of Decision (CFSP) 2017/2315, the following indent is inserted after the third indent:

‘— Denmark,’.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 23 May 2023.

*For the Council*

*The President*

J. BORRELL FONTELLES

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**COMMISSION IMPLEMENTING DECISION (EU) 2023/1016****of 22 May 2023****amending Decision 2002/994/EC concerning certain protective measures with regard to the products of animal origin imported from China****(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 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 <sup>(1)</sup>(Official Controls Regulation), and in particular Article 128(1) thereof,

Whereas:

- (1) Commission Decision 2002/994/EC <sup>(2)</sup> applies to all products of animal origin imported from China and intended for human consumption or animal feed use.
- (2) Pursuant to Article 2(1) of that Decision, Member States are to prohibit imports of those products. Article 2(2) provides for two derogations from that prohibition.
- (3) In accordance with the first derogation, Member States are to authorise imports of products listed in Part I of the Annex to Decision 2002/994/EC in accordance with the specific animal and public health conditions applicable to the products concerned.
- (4) In accordance with the second derogation, Member States are to authorise imports of products listed in Part II of the Annex to Decision 2002/994/EC that are accompanied by a declaration of the Chinese competent authority stating that each consignment has been subjected to a chemical test, in order to ensure that the products concerned do not present a danger to human health.
- (5) Regulation (EC) No 853/2004 of the European Parliament and of the Council <sup>(3)</sup>, as amended by Commission Delegated Regulation (EU) 2022/2258 <sup>(4)</sup>, introduced certain fat derivatives, such as vitamin D3 and precursors used for the production of vitamin D3, as highly refined products. That amendment was introduced because any animal and public health risk is eliminated by the specific treatment of those products of animal origin laid down in Regulation (EC) No 853/2004.

<sup>(1)</sup> OJ L 95, 7.4.2017, p. 1.

<sup>(2)</sup> Commission Decision 2002/994/EC of 20 December 2002 concerning certain protective measures with regard to the products of animal origin imported from China (OJ L 348, 21.12.2002, p. 154).

<sup>(3)</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

<sup>(4)</sup> Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022 amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs (OJ L 299, 18.11.2022, p. 5).

- (6) Commission Implementing Regulation (EU) 2021/405 <sup>(5)</sup> provides that highly refined products derived from ungulates may enter into the Union from third countries listed in Annex XII to that Regulation. China is among the third countries listed in Annex XII to that Regulation. Consequently, vitamin D3 and precursors used for the production thereof should be allowed to enter into the Union from China in accordance with Article 22, point (a), of that Regulation.
- (7) Vitamin D3 is a highly purified product and it is used also in feed to satisfy nutritional requirements for animals. Vitamin D3 plays an essential role to regulate the physiological processes of calcium and phosphorus. Different additives specifically adapted to the use in feed have been authorised to prevent deficiencies in this vitamin. Vitamin D3 is also necessary for the health and welfare of animals. The relevant imports should comply with feed, public and animal health requirements. Consequently, vitamin D3 and precursors used for the production thereof should be allowed to enter into the Union from China in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council <sup>(6)</sup> and Regulation (EC) No 1831/2003 of the European Parliament and of the Council <sup>(7)</sup>.
- (8) It is therefore appropriate to extend the derogation from the prohibition of entry into the Union from China pursuant to Article 2(2) of Decision 2002/994/EC to vitamin D3 and precursors used for the production thereof.
- (9) Decision 2002/994/EC should therefore be amended accordingly.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The Annex to Decision 2002/994/EC is amended in accordance with the Annex to this Decision.

#### *Article 2*

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

Done at Brussels, 22 May 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(5)</sup> Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 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 (OJ L 114, 31.3.2021, p. 118).

<sup>(6)</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

<sup>(7)</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

## ANNEX

In the Annex to Decision 2002/994/EC, Part I is replaced by the following:

## PART I

List of products of animal origin intended for human consumption or animal feed use authorised to be imported into the Union without the attestation provided by Article 3:

- fishery products, except:
  - those obtained from aquaculture,
  - peeled and/or processed shrimps,
  - crayfish of the species *Procambrus clarkii* caught in natural fresh waters by fishing operations;
- gelatine;
- food additives as regulated under Regulation (EC) No 1333/2008 of the European Parliament and of the Council (\*);
- substances to be used as or in food supplements as regulated under Directive 2002/46/EC of the European Parliament and of the Council (\*\*);
- vitamin D3 intended for human consumption, and precursors used for the production thereof, when complying with the specific treatments for these highly refined products (fat derivatives) set in Section XVI of Annex III to Regulation (EC) No 853/2004 (\*\*\*);
- petfood as regulated under Regulation (EC) No 1069/2009 of the European Parliament and of the Council (\*\*\*\*);
- chondroitin sulphate and glucosamine considered as feed material, as regulated under Commission Regulation (EU) No 68/2013 (\*\*\*\*\*);
- vitamin D3 to be used as feed additive in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council (\*\*\*\*\*) and precursors used for the production thereof, for feed for farmed animals and petfood as regulated under Regulation (EC) No 1069/2009;
- L-cysteine and L-cystine to be used as feed additives in accordance with Regulation (EC) No 1831/2003.

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(\*) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

(\*\*) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(\*\*\*) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(\*\*\*\*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

(\*\*\*\*\* ) Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

(\*\*\*\*\*) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).'

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**COMMISSION IMPLEMENTING DECISION (EU) 2023/1017****of 23 May 2023****amending Implementing Decision (EU) 2020/1729 as regards the monitoring of methicillin-resistant *Staphylococcus aureus* (MRSA) in fattening pigs***(notified under document C(2023)3251)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC <sup>(1)</sup>, and in particular Articles 4(5), 7(3) and Article 9(1), fourth subparagraph, thereof,

Whereas:

- (1) Directive 2003/99/EC requires the Member States to ensure that monitoring provides comparable data on the occurrence of antimicrobial resistance (AMR) in zoonotic agents and, in so far as they present a threat to public health, other agents.
- (2) Directive 2003/99/EC also provides that Member States are to assess the trends and sources of AMR in their territory and transmit to the Commission a report every year covering data collected in accordance with that Directive.
- (3) Commission Implementing Decision (EU) 2020/1729 <sup>(2)</sup> lays down detailed rules for the harmonised monitoring and reporting of AMR in zoonotic and commensal bacteria. The rules laid down in that Implementing Decision cover the period 2021 to 2027 and provide for a yearly rotational sampling system of animal species. In accordance with that rotational system, fattening pigs have to be sampled in 2025.
- (4) Methicillin-resistant *Staphylococcus aureus* (MRSA) is a pathogen that causes many healthcare- and community-associated infections that are difficult to treat in humans as they are resistant to multiple antibiotics. In recent decades, the emergence and increasing prevalence of livestock-associated MRSA (LA-MRSA), particularly sequence type 398 belonging to clonal complex 398, in pigs have become a global concern as its spread can compromise the effective treatment of infectious diseases in humans. Rearing and slaughtering pigs infected with LA-MRSA are also potential risk factors for infection in certain human populations such as farmers and slaughterhouse workers. Monitoring the prevalence of LA-MRSA in fattening pigs would therefore be very valuable for obtaining comprehensive, comparable and reliable information on the development and spread of MRSA at Union level in view to develop, if deemed necessary, appropriate interventions to prevent and control MRSA infections.
- (5) On 17 October 2022, the European Food Safety Authority (EFSA) published a scientific report on “Technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs” <sup>(3)</sup> (the EFSA technical specifications). This report highlights the appropriateness to conduct a one-year EU-wide survey in batches of fattening pigs at slaughter to estimate the MRSA prevalence in the European population of fattening pigs, and defines a protocol for this survey including the target population, sample requirements, analytical methods and data reporting requirements.
- (6) The EFSA technical specifications should be considered when laying down rules for harmonised monitoring and reporting of MRSA in fattening pigs in the Union.

<sup>(1)</sup> OJ L 325, 12.12.2003, p. 31.

<sup>(2)</sup> Commission Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU (OJ L 387, 19.11.2020, p. 8)

<sup>(3)</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/7620>

- (7) In order to take advantage of the sampling of fattening pigs scheduled in 2025 for other bacteria in accordance with the yearly rotational system already in place, the requirements for MRSA monitoring in fattening pigs should be laid down in Implementing Decision (EU) 2020/1729 and apply from 1 January 2025.
- (8) Implementing Decision (EU) 2020/1729 should therefore be amended accordingly.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

#### *Article 1*

#### **Amendments to Implementing Decision (EU) 2020/1729**

Implementing Decision (EU) 2020/1729 is amended as follows:

- (1) in Article 1(2), the following point (f) is added:  
'(f) methicillin-resistant *Staphylococcus aureus* (MRSA).';
- (2) in Article 3, paragraph 2 is replaced by the following:  
'(2) National reference laboratories for AMR, or other laboratories designated by the competent authority in accordance with Article 37 of Regulation (EU) 2017/625, shall be responsible for carrying out:
  - (a) the antimicrobial susceptibility testing of bacterial isolates, referred to in paragraph 1 of this Article, in accordance with the technical requirements set out in Part A, point 4, of the Annex;
  - (b) the specific monitoring of ESBL-, AmpC- or CP-producing *E. coli* in accordance with the technical requirements set out in Part A, point 5, of the Annex;
  - (c) the specific monitoring of MRSA in accordance with the technical requirements set out in Part A, point 5a, of the Annex;
  - (d) the alternative method referred to in Part A, point 6, of the Annex.';
- (3) The Annex is amended in accordance with the Annex to this Decision.

#### *Article 2*

#### **Application**

This Decision shall apply from 1 January 2025.

#### *Article 3*

#### **Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 23 May 2023.

*For the Commission*  
Stella KYRIAKIDES  
*Member of the Commission*

## ANNEX

In the Annex to Commission Implementing Decision (EU) 2020/1729, Part A is amended as follows:

1. in point 1, the following paragraph (f) is added:

‘(f) MRSA isolates obtained from nasal samples taken at slaughter from fattening pigs.’;

2. in point 2, paragraph (a) is replaced by the following:

‘(a) In the years 2021, 2023, 2025 and 2027: AMR monitoring shall be carried out in fattening pigs, bovine animals under one year of age, pig meat and bovine meat except for the monitoring of MRSA in fattening pigs which shall not be carried out in the years 2023 and 2027.’

3. point 3.1 is replaced by the following:

‘3.1 *At slaughterhouse level*

- (a) *Sampling design:*

When designing their sampling plan at slaughterhouse level for caecal content, Member States shall take into account EFSA technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria <sup>(1)</sup>.

When designing their sampling plan at slaughterhouse level for nasal samples in fattening pigs, Member States shall take into account EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs <sup>(2)</sup>.

Member States shall ensure a proportionate stratified sampling of samples in slaughterhouses processing at least 60 % of the specific domestic animal population in the Member States with an even distribution over the monitoring period of the samples taken, and, to the extent possible, a randomisation of the sampling days of each month. The samples shall be taken from healthy animals sampled from randomly selected epidemiological units. The epidemiological unit for broilers and fattening turkeys shall be the flock. The epidemiological unit for fattening pigs and bovine animals under one year of age shall be the slaughter batch.

Only one caecal sample from the same epidemiological unit shall be taken per year. Each caecal sample shall be taken from one carcass randomly selected from the epidemiological unit. However, for broilers, each caecal sample shall be derived from ten carcasses randomly selected from the epidemiological unit.

Twenty nasal samples from twenty different pigs randomly selected from the same epidemiological unit shall be taken per year. These samples shall be pooled into four composite groups of five samples. If the epidemiological unit comprises less than twenty pigs, all the pigs of this epidemiological unit shall be sampled, and the resulting samples shall be pooled as evenly as possible to form the four composite groups of samples. The samples shall be taken after stunning of the pigs but before scalding of the carcasses.

The number of samples collected per slaughterhouse shall be proportional to the annual throughput of each slaughterhouse covered by the sampling plan.

- (b) *Sampling size:*

In order to test for antimicrobial susceptibility the required minimum number of bacterial isolates referred to in point 4.1, Member States shall take annually a sufficient number of samples referred to in point 1(a)(ii) and (iii), point 1(b), and point 1(c)(i) to (iv) by accounting for the estimated prevalence of the bacterial species monitored in the animal population considered.

<sup>(1)</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/6364>

<sup>(2)</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/7620>

By way of derogation from the first paragraph of this point, when the prevalence of the bacterial species monitored is known to be inferior or equal to 30 % in the animal population considered or when this prevalence is unknown in the first year of the monitoring or when the number of epidemiological units available for sampling is insufficient to prevent the repeated sampling of the same units, Member States may decide to limit to 300 the annual number of samples to be taken. This annual number can be further reduced to 150 for each specific combination of bacterial isolates/animal populations where Member States have an annual national production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat, less than 100 000 tonnes of pig meat or less than 50 000 tonnes of bovine meat. Member States making use of the possibility of limitation of the annual number of samples shall base their decision on documented evidence, such as results of surveys, and shall submit this evidence to the Commission before implementing the reduced sampling for the first time.

Member States shall take annually at least 300 samples from each animal population referred to in points 1(d)(i) to (iv). By way of derogation from that requirement, where Member States have an annual national production of less than 100 000 tonnes of broiler meat, less than 100 000 tonnes of turkey meat, less than 100 000 tonnes of pig meat or less than 50 000 tonnes of bovine meat, they may decide to take a minimum of 150 samples instead of 300 samples for each specific animal population considered.

Member States shall sample annually enough epidemiological units from the animal population referred to in point 1(f) to achieve an accurate estimation of the prevalence of MRSA in their domestic population of fattening pigs. To this end, they shall use the calculation formulae for the number of slaughter batches to be sampled as referred to in EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs <sup>(3)</sup>;

4. in point 4.1, the following paragraph is added:

‘For MRSA:

— Up to 208 isolates obtained from samples referred to in point 1(f) and confirmed in accordance with point 5a.’;

5. point 4.2 is amended as follows:

- a) the first paragraph is replaced by the following:

‘Member States shall use the epidemiological cut-off values and the concentration ranges set out in Tables 2, 3, 4 and 4a to determine the antimicrobial susceptibility of *Salmonella* spp., *C. coli*, *C. jejuni*, indicator commensal *E. coli*, *E. faecalis*, *E. faecium* and MRSA.’;

- b) the following paragraph is inserted after the third paragraph:

‘For the specific monitoring of MRSA, Member States shall use the methods referred to in point 5a.’;

- c) the following Table 4a is inserted after Table 4:

‘Table 4a

**Panel of antimicrobial substances to be included in AMR monitoring, EUCAST thresholds for resistance and concentration ranges to be tested in *Staphylococcus aureus***

| Antimicrobial   | Class of antimicrobial | Interpretative thresholds of AMR (mg/L) |                          | Range of concentrations (mg/L)<br>(No of wells in brackets) |
|-----------------|------------------------|-----------------------------------------|--------------------------|-------------------------------------------------------------|
|                 |                        | ECOFF 2022                              | Clinical breakpoint 2022 |                                                             |
| Cefoxitin       | Cephamycin             | >4                                      | >4*                      | 0,5-16 (6)                                                  |
| Chloramphenicol | Phenicol               | >16                                     | >8                       | 4-64 (5)                                                    |

<sup>(3)</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/7620>

|                               |                              |       |       |                 |
|-------------------------------|------------------------------|-------|-------|-----------------|
| Ciprofloxacin                 | Fluoroquinolone              | >2    | >1    | 0,25-8 (6)      |
| Clindamycin                   | Lincosamide                  | >0,25 | >0,25 | 0,125-4 (6)     |
| Erythromycin                  | Macrolide                    | >1    | >1    | 0,25-8 (6)      |
| Gentamicin                    | Aminoglycoside               | >2    | >2    | 0,5-16 (6)      |
| Linezolid                     | Oxazolidinone                | >4    | >4    | 1-8 (4)         |
| Mupirocin                     | Carboxylic acid              | >1    | NA    | 0,5-2 + 256 (4) |
| Quinupristin/<br>Dalfopristin | Streptogramin                | >1    | >2    | 0,5-4 (4)       |
| Sulfamethoxazole              | Folate pathway<br>antagonist | >128  | NA    | 64-512 (4)      |
| Tetracycline                  | Tetracycline                 | >1    | >2    | 0,5-16 (6)      |
| Tiamulin                      | Pleuromutilin                | >2    | NA    | 0,5-4 (4)       |
| Trimethoprim                  | Folate pathway<br>antagonist | >2    | >4    | 1-16 (5)        |
| Vancomycin                    | Glycopeptide                 | >2    | >2    | 1-8 (4)         |

NA : not available, \*: Not given as a clinical breakpoint by EUCAST

6. the following point 5a is inserted after point 5:

**‘5a. Specific monitoring of MRSA**

In order to detect MRSA in nasal samples collected in accordance with point 1(f), the laboratories referred to in Article 3(2) shall use isolation and PCR-based <sup>(4)</sup> confirmatory methods as referred to in EFSA technical specifications for a baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in pigs <sup>(5)</sup> and detailed in the protocols of the EURL for AMR <sup>(6)</sup>.

For confirming presumptive MRSA isolates, the laboratories may decide to replace the PCR-based confirmatory method by a WGS method implemented in accordance with the protocols of the EURL for AMR <sup>(7)</sup>.

All confirmed MRSA isolates, with a maximum of 208 isolates, identified through the PCR-based or WGS methods shall be tested with the panel of antimicrobial substances in accordance with Table 4a. No more than one isolate per epidemiological unit shall be tested. MRSA isolates which have been confirmed by the PCR-based method and do not belong to the clonal complex 398 shall be tested by the WGS method implemented in accordance with the protocols of the EURL for AMR <sup>(8)</sup>. Twenty percent of MRSA isolates confirmed by the PCR-based method and belonging to the clonal complex 398 shall be tested by the WGS method, with a maximum of twenty isolates tested.’

<sup>(4)</sup> Method based on Polymerase Chain Reaction (PCR) assays

<sup>(5)</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/7620>

<sup>(6)</sup> <https://www.eurl-ar.eu/protocols.aspx>

<sup>(7)</sup> <https://www.eurl-ar.eu/protocols.aspx>

<sup>(8)</sup> <https://www.eurl-ar.eu/protocols.aspx>

# RECOMMENDATIONS

## COMMISSION RECOMMENDATION (EU) 2023/1018

of 4 May 2023

### on combating online piracy of sports and other live events

THE EUROPEAN COMMISSION,

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

Whereas:

- (1) Sports and other live events such as concerts contribute to fostering a diverse European cultural scene. They also play an important role in bringing citizens together and in providing a sense of community. The organisation of such events as well as their live transmission and retransmission require substantial investments and contribute to economic growth and job creation in the Union.
- (2) As stated in the European Parliament resolution of 19 May 2021 on the challenges of sports event organisers in the digital environment <sup>(1)</sup> and as evidenced by recent studies <sup>(2)</sup>, the main value of most live sports events lies in the exploitation during the live transmission and ends when the event ends. Therefore, unauthorised retransmissions of live sports events can cause significant loss in revenue for both sports event organisers and broadcasters and thus undermine the viability of the services they offer. The need for efficient remedies for live sports events was highlighted by the European Parliament, which also noted that at the same time sports events organisers should contribute to a European sports model that contributes to the development of sport and is in line with social and educational objectives. This Recommendation is a follow-up to that resolution and recommends measures that Member States and market players are encouraged to take.
- (3) Similar considerations apply to live transmissions of other events which, due to their specificity, trigger the most interest from the audience and generate most of their value during their live transmission. This concerns for instance live transmissions of cultural events such as concerts, opera, musicals, theatre performances, or game shows. Economic harm caused by live event piracy includes the loss of users' subscription fees, entrance ticket sales and advertising revenues, thereby affecting all the stakeholders contributing to the live event value chain.
- (4) Piracy takes place through increasingly sophisticated means to make unauthorised retransmissions of live events available to online users through different services, such as illegal IPTV, apps or websites. Revenues deriving from online piracy of sports events have been estimated to amount to EUR 522 million in 2019, considering only illegal business models relying on users' subscription fees <sup>(3)</sup>. It is a global phenomenon, with pirate services streaming live events increasingly using 'offshore' hosting companies to reach users in the Union while minimising the exposure to copyright or criminal law <sup>(4)</sup>. In recent years, a new type of service supporting piracy has been developed, referred to as 'Piracy-as-a-Service' which provides a suite of off-the-shelf services that make it easy to create, operate, and

<sup>(1)</sup> P9\_TA(2021)0236.

<sup>(2)</sup> Challenges facing sports event organisers in the digital environment. European added value assessment, European Parliamentary Research Service, December 2020. Illegal IPTV in the European Union. Economic, Legal and Technical analysis Report, EUIPO, July 2019. Live event piracy. Challenges and best practices from online intermediaries to prevent the use of their services for live event piracy, EUIPO, March 2023.

<sup>(3)</sup> Challenges facing sports event organisers in the digital environment. European added value assessment, European Parliamentary Research Service, December 2020.

<sup>(4)</sup> Live event piracy. Challenges and best practices from online intermediaries to prevent the use of their services for live event piracy, EUIPO, March 2023.

monetise a fully functioning pirate operation. In some cases, those infringing services mirror legitimate streaming services. Furthermore, operators making unauthorised retransmissions available have developed resilience strategies to circumvent enforcement measures. It is therefore necessary to carefully monitor the development of new forms of piracy and resilience strategies, which may also impact other types of content and affect the ability of holders of rights to enforce their rights effectively, taking into account in particular the technological changes and new business models.

- (5) Unauthorised online retransmissions of live events begin with the illicit interception and capture of the pre-broadcast or the broadcast signal which is then passed through various providers of intermediary services to be delivered to end users via different interfaces (websites, apps, IPTV). Services of providers offering high-performance solutions can be used for unauthorised retransmissions, like for example dedicated server providers. In addition, services upstream in the transmission chain such as content delivery networks or reverse proxies may be misused by operators of unauthorised retransmission to deliver such retransmissions or obfuscate the source of unauthorised retransmissions. Furthermore, downstream, internet access providers provide internet connectivity to end users and serve as a gateway to all content available online.
- (6) Considering the structure of the internet, the respective roles of different types of intermediary services, as well as the technological means available to them, providers of such services can have a crucial role in assisting holders of rights and national authorities to remove or disable access to unauthorised retransmissions of live events. It is therefore necessary to identify effective solutions adapted to the respective functions of the different types of intermediary service providers, in accordance with Union law, in particular with the different obligations applicable to providers of intermediary services under Regulation (EU) 2022/2065 of the European Parliament and of the Council <sup>(5)</sup>, in order to allow them to expeditiously remove or disable access to unauthorised retransmissions of live events.
- (7) Various tools to combat the unauthorised retransmissions of content protected by copyright and related rights are already provided for in Union law. In particular, pursuant to Article 8(3) of Directive 2001/29/EC of the European Parliament and of the Council <sup>(6)</sup> and Articles 9 and 11 of Directive 2004/48/EC of the European Parliament and of the Council <sup>(7)</sup>, holders of rights can request injunctions against infringers or against intermediaries whose services are used by a third party to infringe a copyright or related right. In addition, Regulation (EU) 2022/2065 provides a general framework to ensure a safe, predictable and trusted online environment, addressing the dissemination of illegal content online. It harmonises the rules on notice and action mechanisms and streamlines the processing of notices sent to providers of hosting services. In practice, the implementation of available remedies depends on the nature of the providers of intermediary services. Certain intermediary services, such as providers of hosting services, are able to take action to remove or disable access to the illegal content hosted by them upon the receipt of a notice, while others, such as internet access providers, without prejudice to any further voluntary action, are only obliged to act on the basis of an injunction granted by a judicial or administrative authority to prevent access of end users to infringing content.
- (8) Sports events are not, as such, protected by copyright and related rights. Sports event organisers are not recognised as holders of rights under Union copyright law and accordingly, in principle, they could not avail themselves of the rights and remedies existing under the Union intellectual property law, in particular under Directive 2004/48/EC, unless they hold the rights on a contractual basis from other holders of rights or they benefit from an intellectual property right granted under national law.

<sup>(5)</sup> Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

<sup>(6)</sup> Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

<sup>(7)</sup> Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

- (9) Sports event organisers may benefit from specific protection granted under national law in certain Member States. The possibility for Member States to protect sports events at national level, where appropriate by virtue of protection of intellectual property has been recognised in the case-law of the Court of Justice of the European Union. In certain Member States, sports event organisers, alongside broadcasting organisations, have access to remedies which allow them to take action in relation to unauthorised retransmissions of live sports events.
- (10) In addition, broadcasting organisations enjoy different rights under Union law which may allow them to take action against unauthorised retransmission of live sports events.
- (11) In the absence of specific rights and remedies at Union level which apply to sports events, it is often difficult for sports event organisers to act in a timely manner against unauthorised retransmissions of live sports events. In order to prevent the loss of value from the live transmission of sports events, Member States should be encouraged to ensure that sports event organisers have access to remedies allowing them to request disabling access to the unauthorised retransmissions in a very fast manner. However, in some cases sport event organisers also benefit from the rights and remedies laid down in Directive 2004/48/EC as they have been granted intellectual property rights under national law. In such cases Member States are encouraged to consider whether and to what extent the recommendations concerning unauthorised retransmissions of live sports events should also apply to those sports event organisers.
- (12) Live transmission of events other than sports is generally protected by copyright and related rights granted under Union law to authors, performers, phonogram producers, film producers and broadcasting organisations. In the case of those rights, holders of rights can rely on the remedies provided in Directive 2001/29/EC, Directive 2004/48/EC and Regulation (EU) 2022/2065. This also applies to sports event organisers that are granted intellectual property rights under national law. It is important to ensure that remedies available to holders of rights allow prompt action, which takes into account the specific nature of the live transmission of an event, in particular its time sensitive element.
- (13) The purpose of this Recommendation is to combat online piracy of sports and other live events. Therefore, as regards sports live events, it is necessary to encourage Member States and all relevant stakeholders to take effective measures against unauthorised retransmission of live sports events, while guaranteeing the necessary safeguards to protect fundamental rights.
- (14) As regards other live events, Member States and stakeholders should be encouraged to apply the existing remedies against copyright infringements in a manner that takes account of the specificity of live transmissions.
- (15) It is necessary to foster collaboration between sports event organisers, holders of rights, providers of intermediary services and public authorities.
- (16) This Recommendation should not apply to any legitimate use of content. In particular, the unauthorised retransmission of live events should be distinguished from any use of content protected by copyright and related rights in accordance with any limitations or exceptions provided for under Directive 2001/29/EC or Directive (EU) 2019/790 of the European Parliament and of the Council <sup>(8)</sup>, such as audio clips or videos shared among and by persons in the audience of a live event or shared by journalists for the purpose of informing the general public, including in real time. In addition, this Recommendation does not apply to the short news reports prepared by broadcasting organisations in accordance with Article 15 of the Directive 2010/13/EU of the European Parliament and of the Council <sup>(9)</sup>, for instance by relying on short extracts chosen from the signal of a broadcasting organisation transmitting on an exclusive basis.

<sup>(8)</sup> Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market (OJ L 130, 17.5.2019, p. 92).

<sup>(9)</sup> Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

- (17) Regulation (EU) 2022/2065 includes rules applicable to intermediary services in the internal market which are relevant in the case of unauthorised retransmission of live events. In particular, Article 16 of Regulation (EU) 2022/2065 introduces harmonised rules on 'notice and action' for providers of hosting services to provide for timely and diligent processing of notices related to illegal content. Recital 52 of that Regulation states that providers of hosting services should act upon notices in a timely manner, in particular by taking into account the type of illegal content being notified and the urgency of taking action.
- (18) Given the specific nature of live events, urgent action from providers of hosting services upon receipt of a notice is essential in order to minimise the harm caused by unauthorised retransmissions of live events.
- (19) Regulation (EU) 2022/2065 also imposes additional obligations on online platforms to take the necessary technical and organisational measures to ensure that notices submitted by trusted flaggers are given priority and are processed and decided upon without undue delay. Other providers of hosting service are not covered by those obligations; however, this mechanism is useful to accelerate the processing of notices concerning live events. Therefore, it is appropriate to recommend that providers of hosting services, other than online platforms, give priority to notices submitted by trusted flaggers in order to take urgent action during the transmission of a live event. The specific situation of micro or small enterprises should be taken into account in this context.
- (20) Additionally, certain providers of hosting services have been developing technical solutions which allow holders of rights, through a dedicated application programming interface, to notify, including in real-time, unauthorised uses of their content and further speed up the processing of those notices. Regulation (EU) 2022/2065 calls upon the Commission to support and promote the development and implementation of voluntary standards in respect of the electronic submission of notices by trusted flaggers, including through application programming interfaces. The development and use of such technical solutions by intermediaries other than online platforms should also be encouraged, provided that a redress mechanism is incorporated therein.
- (21) There are different ways to encrypt or mark the broadcast signal, including forensic watermarking, in order to protect it from unauthorised uses. Holders of rights should make the best use of these solutions which can help identify the source of unauthorised retransmissions rapidly and precisely.
- (22) Providers of intermediary services upstream in the internet infrastructure such as content delivery networks or reverse proxies can often be the only services identified by holders of rights when they detect unauthorised retransmission of live events. To the extent that they do not provide hosting services, rules on notices are not applicable to them. However, some providers do allow for notices and contribute to the identification of the IP addresses used by rogue operators, thereby playing an important role in combating unauthorised retransmissions of live events. They should therefore be encouraged to support and share information with holders of rights and hosting service providers on the identification of the sources of the unauthorised retransmissions, including, when appropriate, the origin IP address of the servers. They should also put in place a robust policy against misuse of their services, for example by providing in their terms and conditions the possibility to suspend their services to rogue operators that frequently make unauthorised retransmission available. These practices should also apply to services offering high-performance solutions, in particular dedicated server providers which are typically misused to deliver unauthorised retransmissions.
- (23) Directive 2001/29/EC and Directive 2004/48/EC grant the holders of rights the possibility to seek an injunction against a provider of intermediary service whose services are being used by a third party to infringe their intellectual property rights. In 2017, the Commission issued the Communication 'Guidance on certain aspects of Directive 2004/48/EC' <sup>(10)</sup> stating that in certain cases it may be appropriate for such injunction to require the provider of intermediary service to take down or disable access to illegal content. In cases of large-scale infringements or infringements occurring in a structural manner, the guidance indicates that it could be

<sup>(10)</sup> COM (2017) 708 final (the 'Guidance').

proportionate, based on a case-by-case analysis, to require that access to an entire website is blocked. In line with the case law of the Court of Justice of the European Union, the guidance underlines that, subject to certain safeguards, the injunction does not have to explicitly describe the measures that the providers need to take to achieve the result sought. However, Union law does not provide for rules on the specific features of an injunction nor are there explicit rules pertaining to live transmissions.

- (24) Different technical measures may be used to implement blocking injunctions and prevent access of end users to the unauthorised retransmission, for example through Domain Name System (DNS) or IP blocking.
- (25) In addition, in line with the Guidance, dynamic injunctions which cover new internet locations where the unauthorised retransmission becomes available immediately after issuing the injunction, can be an effective means to prevent the continuation of unauthorised retransmission under the condition that necessary safeguards are provided. Such injunctions are a useful remedy to tackle the resilience strategies developed by pirate services, for example setting up mirror sites under different domain names or switching to different IP addresses to circumvent blocking measures.
- (26) Dynamic injunctions have so far been available only in a few Member States <sup>(11)</sup>. They are granted either by the courts or by certain administrative authorities empowered to order blocking or removal measures ex officio or following complaints. This type of injunctions is particularly adapted to address unauthorised retransmissions of live events.
- (27) It is essential that sports event organisers, even if they are not recognised as rightholders under Union law, are able to seek injunctions to prevent unauthorised retransmission of a live sports event and to prohibit the continuation of such unauthorised retransmission, in accordance with national law. It is also important that injunctions addressing live sports events are dynamic, in order to cover, with sufficient rapidity, the additional pirate services, unidentified at the time of the proceedings, which give access to the unauthorised retransmission of the same live sports event, provided the necessary safeguards are applied.
- (28) Since the loss of value for other types of live events is often higher during the live transmission, it is equally important to encourage a wider availability of dynamic injunctions to prevent unauthorised retransmission of such events.
- (29) In order to prevent over blocking, the additional internet locations to which dynamic injunctions apply should be correctly identified. Several possibilities could be envisaged to update the list of internet locations covered by an injunction, such as agreeing on a methodology as part of the injunction, including for the cooperation between holders of rights and addressees of the injunctions, subject to control by a judicial authority.
- (30) An injunction is usually addressed to internet access providers, as those are well placed to prevent the access of end users to a specific service which offers unauthorised retransmissions of live events. However, other providers of intermediary services may be misused to facilitate unauthorised retransmissions or to circumvent blocking injunctions. For instance, content delivery networks and reverse proxies may be used to obfuscate the origin of the unauthorised retransmission, while alternative DNS resolvers and proxy services such as Virtual Private Networks (VPNs) may be used to facilitate access to services that have been blocked. Providers of intermediary services should consider whether they could take further voluntary measures to prevent their services from being misused. Such own initiative measures could be discussed in particular in the context of the monitoring of this Recommendation that the Commission will undertake with the support of the European Observatory on Infringements of Intellectual Property Rights hosted by the European Union Intellectual Property Office ('EUIPO Observatory').

<sup>(11)</sup> Study on dynamic blocking injunctions in the European Union, EUIPO, March 2021; Mapping report on national remedies against online piracy of sports content, European Audiovisual Observatory, December 2021; Live event piracy. Challenges and best practices from online intermediaries to prevent the use of their services for live event piracy, EUIPO, March 2023.

- (31) Other market players such as providers of advertising, as well as payment services providers, through their obligations under the EU anti-money laundering framework and voluntary actions, can also contribute to the fight against online piracy. To demonetise piracy services, the Commission is facilitating a memorandum of understanding on online advertising and intellectual property rights. Signatories of that memorandum voluntarily commit to minimise the placement of advertising on websites and mobile applications that infringe intellectual property rights, including copyright. Such cooperation should be further encouraged to make sure that such services do not facilitate the promotion and functioning of operators giving access to unauthorised retransmission of live events.
- (32) In order to address piracy in a holistic manner, it is important to increase the availability, affordability, and attractiveness of commercial offers for end users to access transmission or retransmissions of live events. As concerns events of major importance for society such as Olympic Games, the Football World Cup or the European Football Championship, Member States may ensure wide access by the public to television coverage in line with Article 14 of the Directive 2010/13/EU.
- (33) Furthermore, according to a recent study, the accessibility and availability of competitively priced legal offers has resulted in a slight decrease in the number of users consuming pirated content <sup>(12)</sup>. It is therefore important to raise end users' awareness about the availability of legal offer. For example, certain Member States ensure that when a website is blocked pursuant to an injunction, users that try to access it are informed about the blocking and are given information on the sources where the content can be accessed legally. This can be done for instance by referring to the European online content portal, Agorateka, developed by the EUIPO Observatory, which links to existing national portals.
- (34) Cross-border cooperation between Member States is important to better tackle the phenomenon of unauthorised retransmissions of live events, which by nature take place across borders. The exchange of information on services that are subject to an injunction in one Member State can be helpful to inform the enforcement authorities in other Member States where the same services are available.
- (35) The EUIPO Observatory is entrusted by Regulation (EU) No 386/2012 of the European Parliament and of the Council <sup>(13)</sup> to provide mechanisms which help to improve the exchange of information on enforcement of intellectual property rights between Member States authorities and to foster cooperation with and between those authorities. The existing cooperation facilitated by the EUIPO Observatory on these matters should develop into a dedicated network for Member States to structurally exchange information on measures, procedures and remedies applied to unauthorised retransmissions of sports and other live events, including on the impact and efficiency of those enforcement tools, and on the challenges and good practices in that field. The network should allow the dialogue across all Member States and include the administrative authorities with specific powers in relation to enforcement of intellectual property rights that exist in certain Member States. The information gathered under the network should contribute to the monitoring of the effects of the recommendation.
- (36) Enhancing the expertise of persons involved in the enforcement of rights against unauthorised retransmissions of live events by appropriate training measures constitutes another way to achieve more efficient enforcement. The EUIPO Observatory should be encouraged to develop and organise knowledge building activities for national judges and national authorities in this specific area.
- (37) The Commission will closely monitor the actions taken in light of this Recommendation, with the support of the EUIPO Observatory, which should provide technical expertise and organisational support as well as monitor the evolution of unauthorised retransmission of live events in Member States. In order to carry out this task, it is essential that Member States and stakeholders share relevant information about the follow-up given to this

<sup>(12)</sup> Intellectual Property Crime Threat Assessment, EUIPO and Europol, March 2022.

<sup>(13)</sup> Regulation (EU) No 386/2012 of the European Parliament and of the Council of 19 April 2012 on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights (OJ L 129, 16.5.2012, p. 1).

Recommendation and the volume of unauthorised retransmissions of live events. Stakeholders should also provide information on the evolution of legal offers of the content covered by this Recommendation. On this basis, the Commission will assess the effects given to this Recommendation and determine whether additional steps are required, including to prevent the illegal dissemination of other types of copyright-protected content.

- (38) Recourse to remedies under this Recommendation requires the proper balancing of rights and interests of persons concerned by the measures taking into account the different fundamental rights and of the proportionality of such measures in any individual case. The application of such measures should be strictly targeted and not impose excessive obligations on intermediaries. Such measures should not lead to general monitoring.
- (39) In order to ensure respect for the fundamental right to the protection of natural persons in relation to the processing of personal data, as well as the free movement of personal data, the processing of personal data in the context of any measures taken to give effect to this Recommendation should be in full compliance with the rules on data protection, in particular with Regulation (EU) 2016/679 <sup>(14)</sup> and Directive (EU) 2016/680 of the European Parliament and of the Council <sup>(15)</sup>, and should be monitored by the competent supervisory authorities.
- (40) This Recommendation respects the fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union. In particular, this Recommendation seeks to ensure full respect for Articles 8, 11, 16, 17 and 47 of the Charter.
- (41) By reason of the complementarity between this Recommendation and Regulation (EU) 2022/2065, the effects of the Recommendation on unauthorised retransmissions of live sports and other live events, should be assessed, taking due account of the findings of the EUIPO Observatory, in conjunction with the effects of that Regulation, that is, by no later than 17 November 2025.

HAS ADOPTED THIS RECOMMENDATION:

## PURPOSE

- (1) This Recommendation encourages Member States, national authorities, holders of rights and providers of intermediary services to take effective, appropriate, and proportionate measures to combat unauthorised retransmissions of live sports events and other live events in accordance with the principles set out in this Recommendation and in full compliance with Union law, including the Charter of Fundamental Rights of the European Union.
- (2) This Recommendation recalls the obligations of Member States, holders of rights, providers of intermediary services and recipients of their services in accordance with the binding provisions of Union law, in particular Directive 2000/31/EC of the European Parliament and of the Council <sup>(16)</sup>, Directive 2001/29/EC, Directive 2002/58/EC of the European Parliament and of the Council <sup>(17)</sup>, Regulation (EU) 2022/2065, Directive

<sup>(14)</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

<sup>(15)</sup> Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

<sup>(16)</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

<sup>(17)</sup> Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (OJ L 201, 31.7.2002, p. 37).

(EU) 2019/790 and Directive 2004/48/EC. The Recommendation does not apply to any legitimate use of content, such as use of copyright-protected content under limitations and exceptions and the use of short extracts in line with Article 15 of Directive 2010/13/EU.

## DEFINITIONS

(3) For the purposes of this Recommendation the following definitions apply:

- (a) 'sports event organiser' means any natural or legal person undertaking the responsibility for the organisation of a sports event which is accessible to the public;
- (b) 'live transmission of an event' means a transmission in real time, by any means, including by wire or wireless means, of an event to a public which is not present at the place where the event takes place in real time;
- (c) 'live transmission of a sports event' means a transmission in real time, by any means, including by wire or wireless means, of a sports event to a public which is not present at the place where the event takes place in real time;
- (d) 'holder of rights in live transmission of sports events' means any natural or legal person that holds rights in the live transmission of a sports event, irrespective of whether these are intellectual property rights, and who is legally entitled to enforce those rights;
- (e) 'holder of rights in the live transmission of an event' means any natural or legal person that holds copyright or related rights in the live transmission of works and other subject matter;
- (f) 'unauthorised retransmission' means a simultaneous transmission or retransmission intended for reception by the public of an initial live transmission of an event or of a live transmission of a sports event, and which has not been authorised by the holder of the rights.

## UNAUTHORISED RETRANSMISSION OF LIVE SPORTS EVENTS

### Ensuring the prompt treatment of notices related to unauthorised retransmissions of live sports events

#### *Prompt treatment of notices*

- (4) When processing the notices related to unauthorised retransmissions of live sports events, providers of hosting services should take into consideration the specific nature of live transmissions of sports event in order to aim at minimising the harm caused during the unauthorised retransmission of such an event.
- (5) In order to ensure that the notice is processed and a decision is taken during the live transmission of a sports event, providers of hosting services, other than online platforms, are encouraged to cooperate with holders of rights in live transmission of sports events, in particular by:
  - (a) effectively engaging with trusted flaggers for the purposes of this Recommendation;
  - (b) developing and using technical solutions aimed at facilitating the processing of notices, such as application programming interfaces.

#### *Cooperation between holders of rights and providers of intermediary services*

- (6) In order to protect the live transmission of sports events, holders of rights in live transmission of sports events should be encouraged to use the best available technical solutions to facilitate identification of the source of unauthorised retransmission.

- (7) Providers of intermediary services, in particular those which are able to identify and locate the source of unauthorised retransmissions of live sports events, are encouraged to:
- (a) cooperate, including with providers of hosting services and holders of rights in live transmission of sports events, to facilitate the identification of the source of unauthorised retransmissions and;
  - (b) put in place specific measures against repeated misuse of their services.

### **Injunctions addressing unauthorised retransmission of live sports events**

- (8) Member States are encouraged to assess whether, in their jurisdiction, sports event organisers are entitled to take legal action to prevent, or to prohibit the unauthorised retransmission of a live sports event. Where this is not the case, Member States are encouraged to grant legal standing to sports event organisers to seek an injunction in order to prevent imminent unauthorised retransmission of live sports events or to prohibit the continuation of the unauthorised retransmission.

#### *Addressees of the injunctions*

- (9) Member States are encouraged to provide for injunctions against operators of unauthorised retransmissions of live sports events, as well as against providers of intermediary services whose services are misused by a third party for unauthorised retransmissions of live sports events, regardless of the intermediary's lack of liability, in order to terminate or prevent such unauthorised retransmission of live sports events. Such injunction may consist in blocking access to unauthorised retransmissions of live sports events.
- (10) Member States are encouraged to provide for the possibility to apply those injunctions to providers of intermediary services which target their activities to recipients of the services in Member States.
- (11) Member States are encouraged to enable holders of rights in live transmission of sports events to apply for an injunction before the start of the sports event, including by submitting evidence before the competent authority showing that the operator in question has already provided access to unauthorised retransmission of similar sports events for which they hold the rights.

#### *Dynamic nature of the injunctions*

- (12) Member States are encouraged to provide for the possibility to seek injunctions imposed on a given intermediary service provider, that can be extended to enable the blocking of pirate services which carry out unauthorised retransmissions of live sports event even if they were unidentified at the time of the application for an injunction, but where they concern the same sports event, in line with their national procedural rules.
- (13) In order to identify those pirate services in an appropriate manner after the issuance of an injunction, Member States should encourage the use of a case-by-case methodology for updating the list of internet locations covered by the injunction (identified for instance via a domain name, IP address or URL), including through the cooperation between the holders of rights and the addressees of the injunction, subject to control by a judicial authority. Member States may consider whether an independent national authority should certify the list of internet locations covered by an injunction.
- (14) Where Member States empower an independent administrative authority to issue injunctions or update the list of internet locations covered by the injunction, such decisions should be subject to the right of appeal to the courts.

#### *Safeguards*

- (15) When introducing or applying rules on injunctions related to unauthorised retransmission of live sports events, Member States are encouraged to take into consideration that the measures set out in the injunction should not be unreasonably burdensome for the addressees. They should be strictly targeted and should not unnecessarily deprive users of the possibility of lawfully accessing the information available.

- (16) Where the injunction takes the form of a blocking measure, care should be taken to ensure that it targets pirate services identified by internet locations which are mainly dedicated to providing access to unauthorised retransmissions or other types of unauthorised content.
- (17) The technical measures applied for the implementation of such injunctions should be adequate to prevent or, at least, make difficult, the access to the unauthorised retransmission of live sports events, and seriously discourage end users from accessing those unauthorised retransmissions.
- (18) Member States are encouraged to ensure that holders of rights in live transmission of sports events regularly update the information on the internet locations which are no longer used for unauthorised retransmission of sports events, so that the restrictions on these internet locations may be removed.
- (19) Member States are encouraged to provide that the duration of the injunction should not go beyond what is necessary to ensure the effective protection of the holders of rights in the live transmission of sports events. Member States are encouraged to provide that the blocking measures applied in this context take effect only when the live transmission of the sports event occurs.

#### *Voluntary cooperation*

- (20) Providers of intermediary services should be encouraged to consider appropriate and proportionate voluntary initiatives to prevent their services from being misused for unauthorised retransmission of live sports events.
- (21) Other market players such as advertising and payment services should be encouraged to ensure that their services do not facilitate the promotion and functioning of operators giving access to unauthorised retransmission of live sports events.

### **UNAUTHORISED RETRANSMISSIONS OF OTHER LIVE EVENTS**

#### **Ensuring the prompt treatment of notices related to unauthorised retransmissions of other live events**

##### *Prompt treatment of notices*

- (22) When processing the notices related to unauthorised retransmissions of other live events, providers of hosting services should take into consideration the specific nature of live transmissions in order to aim at minimising the harm caused during the unauthorised retransmission of such an event.
- (23) In order to ensure that the notice is processed and a decision is taken during the live transmission of an event, providers of hosting services, other than online platforms, are encouraged to cooperate with holders of rights, in particular by:
  - (a) effectively engaging with trusted flaggers for the purposes of this Recommendation;
  - (b) developing and using technical solutions aimed at facilitating the processing of notices, such as application programming interfaces.

##### *Cooperation between holders of rights and providers of intermediary services*

- (24) In order to protect the live transmission of an event, holders of rights in live transmission of an event should be encouraged to use the best available technical solutions to facilitate identification of the source of unauthorised retransmission.
- (25) Providers of intermediary services, in particular those which are able to identify and locate the source of unauthorised retransmission of live events, are encouraged to:
  - (a) cooperate, including with holders of rights to facilitate the identification of the source of unauthorised retransmission of live events;
  - (b) put in place specific measures against repeated misuse of their services.

## **Injunctions addressing unauthorised retransmissions of other live events**

### *Dynamic nature of injunctions*

- (26) Member States are encouraged to provide for the possibility to seek injunctions imposed on a given intermediary service provider, that can be extended to enable the blocking of pirate services which carry out unauthorised retransmission, even if they were unidentified at the time of the application for an injunction, but where they concern the same live event, in line with their national procedural rules and in compliance with the applicable provisions of Union law, including the Charter, in particular, the right to freedom of expression and information and the right to protection of personal data.
- (27) In order to identify those pirate services in an appropriate manner after the issuance of an injunction Member States should encourage the use of a case-by-case methodology for updating the list of internet locations covered by the injunction (identified for instance via a domain name, IP address or URL), including through the cooperation between the holders of rights and the addressees of an injunction, subject to control by a judicial authority.
- (28) Where Member States empower an independent administrative authority to issue injunctions or update the list of internet locations covered by the injunction, such decisions should be subject to the right of appeal to the courts.

### *Safeguards*

- (29) When introducing or applying rules on injunctions related to unauthorised retransmission of live events, Member States are encouraged to take into consideration that the measures set out in the injunction should not be unreasonably burdensome for the addressees. They should be strictly targeted and should not unnecessarily deprive users of the possibility of lawfully accessing the information available.
- (30) Member States are encouraged to ensure that holders of rights in live transmission of an event regularly update the information on the internet locations which are no longer used for unauthorised retransmission of live events, so that the restrictions on these internet locations may be removed.

### *Voluntary cooperation*

- (31) Providers of intermediary services should be encouraged to consider appropriate and proportionate voluntary initiatives to prevent their services from being misused for unauthorised retransmission of live events.
- (32) Other market players such as advertising and payment services should be encouraged to ensure that their services do not facilitate the promotion and functioning of operators giving access to unauthorised retransmission of live event.

## **RAISING AWARENESS AND VOLUNTARY COOPERATION BETWEEN PUBLIC AUTHORITIES**

### *Commercial offers and awareness*

- (33) Holders of rights in live transmissions of sports and other events should be encouraged to increase the availability, affordability, and attractiveness of their commercial offers to end users across the Union.
- (34) Member States are encouraged to raise users' awareness on legal offers of live sports and other events. Member States are also invited to inform users who try to access services offering unauthorised retransmission of live sports and other live events, which had been blocked pursuant to an injunction, about the reasons for the blocking and provide them with information about the legal offers available for watching such events.

- (35) Member States are encouraged to raise awareness of the issues covered by this Recommendation with national law enforcement authorities and build capacity to facilitate investigation and to take appropriate action against operators of unauthorised retransmission of live sports and other live events on a commercial scale, including through participation in existing cross-border law enforcement operations.

*Cooperation between public authorities*

- (36) Member States are encouraged to proactively exchange information on the services access to which access has been blocked on their territory on the basis of an injunction granted by a national authority.
- (37) The Commission invites the EUIPO Observatory to establish a dedicated network of administrative authorities to regularly exchange information on the measures applied, the challenges and good practices in addressing the issues covered in this Recommendation. Member States that do not have specialised administrative authorities, including those which have developed other relevant initiatives in relation to piracy, are also encouraged to take part in these exchanges. The network should, in particular, aim at assessing opportunities for further cross-border cooperation.
- (38) The EUIPO Observatory is encouraged to make available knowledge building activities for national judges and authorities on existing rules and practices regarding the enforcement of rights against unauthorised retransmissions of live sports and other live events.

**FOLLOW-UP AND MONITORING**

- (39) The Commission invites the EUIPO Observatory to support it in the identification of indicators, in cooperation with stakeholders, in order to monitor the implementation and effects of this Recommendation.
- (40) Member States and stakeholders are encouraged to submit to the EUIPO Observatory and the Commission all relevant information regarding such measures and actions. Additionally, Member States and stakeholders are invited to submit available information and data on the volume of unauthorised retransmissions of live sports and other live events. Stakeholders are also encouraged to submit data on the availability and discoverability of legal offers of the content covered by this Recommendation.
- (41) On this basis and other relevant sources, the Commission invites the EUIPO Observatory to support it in monitoring the effects of this Recommendation on online piracy of sports and other live events.
- (42) The Commission will assess the effects of this Recommendation on unauthorised retransmissions of live sports and other live events, taking due account of the findings of the EUIPO Observatory, by not later than 17 November 2025. On this basis, the Commission will assess whether additional measures are needed at Union level, including to prevent the illegal dissemination of other types of copyright-protected content, taking account of technological developments, the evolution of distribution channels and consumption patterns, and any impact that the implementation of Regulation (EU) 2022/2065 may have had on the unauthorised retransmissions of live sports and other live events.

Done at Brussels, 4 May 2023.

*For the Commission*  
Thierry BRETON  
*Member of the Commission*

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# ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

## **DECISION No 4/2023 OF THE TRADE COMMITTEE of 26 April 2023 regarding its Rules of Procedure [2023/1019]**

THE TRADE COMMITTEE,

Having regard to the Free Trade Agreement between the European Union and the Republic of Singapore (the 'Agreement'), and in particular Article 16.1, paragraph 4 (f), thereof,

Whereas pursuant to Article 16.1, paragraph 4(f) of the Agreement, the Trade Committee may adopt its own Rules of Procedure,

HAS ADOPTED THIS DECISION:

1. The Rules of Procedure of the Trade Committee are established as set out in the Annex to this Decision.
2. This Decision shall enter into force on the date of its adoption.

Done on 26 April 2023,

*For the Trade Committee  
The Co-Chairs*

*Executive Vice-President and Commissioner for Trade of the  
European Commission*  
Valdis DOMBROVSKIS

*Minister-in-charge of Trade Relations of the Republic of  
Singapore*  
S ISWARAN

*ANNEX*

RULES OF PROCEDURE OF THE TRADE COMMITTEE ESTABLISHED BY ARTICLE 16.1 OF THE FREE  
TRADE AGREEMENT BETWEEN THE EUROPEAN UNION, OF THE ONE PART, AND THE REPUBLIC OF  
SINGAPORE, OF THE OTHER PART

*RULE 1***Role and Name of the Trade Committee**

1. The Trade Committee established pursuant to Article 16.1 of the Free Trade Agreement between the European Union and the Republic of Singapore, (the 'Agreement') is responsible for all matters referred to in Article 16.1 of the Agreement.
2. The Committee referred to in paragraph 1 shall be referred to in documents of the Committee, including decisions and recommendations, as the Trade Committee.

*RULE 2***Composition and Co-chairs**

1. Pursuant to Article 16.1 of the Agreement, the Trade Committee shall comprise representatives of the European Union and of the Republic of Singapore and shall be co-chaired by the Member of the European Commission responsible for Trade and the Minister for Trade and Industry of Singapore, or their respective delegates.
2. Each Party shall notify the other Party of the name, position and contact details of the delegated official who is in charge of co-chairing the Trade Committee for that Party. That delegated official is deemed to have the authorisation to represent the Party until the date the Party has notified the other Party that it has appointed a new Co-chair.

*RULE 3***Secretariat**

1. Officials from the department responsible for Trade for each Party shall act as the Secretariat of the Trade Committee.
2. Each Party shall notify the other Party of the name, position and contact details of the official who is to be the member of the Secretariat of the Trade Committee for that Party. That official is deemed to continue acting as member of the Secretariat for the Party until the date the Party has notified the other Party that it has appointed a new member.

*RULE 4***Meetings**

1. In accordance with Article 16.1 of the Agreement, the Trade Committee shall meet every two years or without undue delay at the request of either Party.
2. The meetings shall be held at an agreed date and time alternately in Brussels and in Singapore, unless agreed otherwise by the Co-chairs.
3. The meetings shall be convened by the Co-chair of the Party hosting the meeting.
4. A meeting may be held in person, by videoconference, or by any other means.

*RULE 5***Delegations**

Before each meeting, each member of the Secretariat of the Trade Committee for each Party shall inform the other member of the intended composition of the delegations of their respective party. The lists shall specify the name and function of each member of the delegation.

*RULE 6***Agenda for the meetings**

1. At least 15 days in advance of a meeting, a provisional agenda for each meeting shall be drawn up by the Secretariat of the Trade Committee on the basis of a proposal made by the Party hosting the meeting. The other Party shall have the opportunity to provide comments.
2. The agenda shall be adopted by the Trade Committee at the beginning of each meeting. Items not appearing on the provisional agenda may be placed on the agenda by mutual agreement.

*RULE 7***Invitation of experts**

The Co-chairs of the Trade Committee may, by mutual agreement, invite independent experts to attend the meetings of the Trade Committee in order to provide information on specific subjects and only for the parts of the meeting where such specific subjects are discussed.

*RULE 8***Minutes**

1. Draft minutes of each meeting shall be drawn up by the member of the Secretariat of the Party hosting the meeting within 21 days from the end of the meeting, unless otherwise decided by the Co-chairs. The draft minutes shall be transmitted for comments to the member of the Secretariat of the other Party.
2. Where these rules of procedure apply to the meetings of specialised committees, the minutes of the specialised committee meetings shall be made available for any subsequent meetings of the Trade Committee.
3. The minutes shall, as a general rule, summarise each item on the agenda, specifying where applicable:
  - (a) all documents submitted to the Trade Committee;
  - (b) any statement that one of the Co-chairs of the Trade Committee requested to be entered in the minutes; and
  - (c) the decisions taken, recommendations made, statements agreed upon and conclusions adopted on specific items.
4. The minutes shall include a list of all decisions of the Trade Committee, taken by written procedure pursuant to Rule 9.2, since the last meeting of the Committee.
5. An annex to the minutes shall also include a list of the names, titles and capacity of all individuals who attended the meeting of the Trade Committee.
6. The Secretariat shall adjust the draft minutes on the basis of comments received and the draft minutes, as revised, shall be approved by the Parties within 30 days of the date of the meeting, or by any other date agreed by the Co-chairs. Once approved, two original versions of the minutes shall be prepared by the Secretariat and the Parties shall each receive one original version of the minutes.

*RULE 9***Decisions and recommendations**

1. The Trade Committee may adopt decisions and recommendations in respect of all matters, where the Agreement so provides. The Trade Committee shall adopt decisions and recommendations by mutual agreement, as provided for in Article 16.4 of the Agreement.
2. In the period between meetings, the Trade Committee may adopt decisions or recommendations by written procedure.
3. For that purpose, the text of a draft decision or recommendation shall be presented in writing by a Co-chair to the other Co-chair in the working language of the Trade Committee. The other Party shall have one month, or any longer period of time specified by the proposing Party, to express its acceptance of the draft decision or recommendation. The draft decisions or recommendations shall be deemed to be adopted once the other Party expresses its acceptance within the period of time specified by the proposing Party and shall be recorded in the minutes of the Trade Committee meeting pursuant to Rule 8(4). If the other Party does not express its acceptance, the proposed decision or recommendation shall be discussed, and may be adopted, at the next meeting of the Trade Committee.
4. Where the Trade Committee is empowered under the Agreement to adopt decisions or recommendations, such acts shall be titled 'Decision' or 'Recommendation' respectively. The Secretariat of the Trade Committee shall give any decision or recommendation a progressive serial number, the date of adoption and a description of its subject-matter. Each decision and recommendation shall provide for the date of its entry into force or operation, as appropriate.
5. The decisions and recommendations adopted by the Trade Committee shall be done in duplicate, authenticated by the Co-chairs and shall be transmitted to each Party.

*RULE 10***Transparency**

1. Unless otherwise specified by the Agreement or decided by the Parties, the meetings of the Trade Committee shall not be open to the public.
2. Each Party may decide on the publication of the decisions and recommendations of the Trade Committee in its respective official publication or online.
3. Where a Party submits information to the Trade Committee which is considered as confidential under that Party's laws and regulations, the other Party shall treat that information as confidential, unless the submitting Party agrees otherwise.
4. Each Party may make public in any appropriate medium the agenda finalised between the Parties before the meeting of the Trade Committee, and the approved joint minutes drawn up in accordance with Rule 8.
5. Publication of documents mentioned under paragraphs 2 to 4 shall be made in compliance with each Party's applicable data protection rules.

*RULE 11***Languages**

1. The working language of the Trade Committee shall be English.
2. The Trade Committee shall adopt decisions concerning the amendment or interpretation of the Agreement. Article 16.21 of the Agreement applies mutatis mutandis to decisions of the Trade Committee amending or interpreting the Agreement. All other decisions of the Trade Committee, including the one through which these rules of procedure are adopted, shall be adopted in the working language referred to in paragraph 1.

3. Each Party shall be responsible for the translation of decisions and other documents into its own official language(s), if required pursuant to this Rule, and it shall bear the expenses associated with such translations.

#### *RULE 12*

##### **Expenses**

1. Each Party shall bear any expenses it incurs as a result of participating in the meetings of the Trade Committee, in particular with regard to staff, travel and subsistence expenditure, and with regard to video or teleconferences, postal and telecommunications expenditure.
2. Expenditure in connection with the organisation of meetings and reproduction of documents shall be borne by the Party hosting the meeting.

#### *RULE 13*

##### **Specialised Committees and other bodies**

1. Specialised Committees may be established in accordance with Article 16.1 of the Agreement for the purpose of dealing with all matters delegated to them by the Trade Committee.
2. Pursuant to Articles 16.1 and 16.2 of the Agreement, the Trade Committee shall supervise the work of all specialised committees and other bodies established under the Agreement.
3. The Trade Committee shall be informed in writing of the contact points designated by Specialised Committees or other bodies established under the Agreement. All relevant correspondence, documents and communication between the contact points of each Specialised Committee regarding the implementation of the Agreement shall be forwarded to the Secretariat of the Trade Committee simultaneously.
4. Pursuant to Article 16.2 of the Agreement, the Specialised Committees shall report to the Trade Committee the results and conclusions of each of their meetings.
5. Unless otherwise decided by each Specialised Committee, these Rules of Procedure shall apply *mutatis mutandis* to the specialised committees and other bodies established under the Agreement.

#### *RULE 14*

##### **Amendments of the Rules of Procedure**

These Rules of Procedure may be amended in writing by a decision of the Trade Committee in accordance with Rule 9.

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