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Contents

[1] 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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/113

of 16 January 2023

authorising the placing on the market of 3′-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283 Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) Commission Implementing Regulation (EU) 2021/96 ([3]) authorised the placing on the Union market of 3′-Sialyllactose sodium salt obtained by microbial fermentation using the genetically modified strain K12 DH1 of *Escherichia coli ('E. coli')* as a novel food under Regulation (EU) 2015/2283.

(4) On 13 May 2020, the company Chr. Hansen A/S ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 3′-Sialyllactose ('3′-SL') sodium salt, obtained by microbial fermentation using two genetically modified strains (a production strain and an optional degradation strain) derived from the host strain *E. coli* BL21(DE3), on the Union market as a novel food. The applicant requested for 3′-SL sodium salt to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), processed cereal-based food for infants and young

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

([3]) Commission Implementing Regulation (EU) 2021/96 of 28 January 2021 authorising the placing on the market of 3'-sialyllactose sodium salt as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 31, 29.1.2021, p. 201).

([4]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

children and baby food for infants and young children as defined in Regulation (EU) No 609/2013, foods for infants and young children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([5]) intended for the general population. Subsequently, on 17 June 2022, the applicant modified the initial request in the application on the use of 3′-SL sodium salt in food supplements to exclude infants and young children. The applicant also proposed that food supplements containing 3′-SL sodium salt should not be used if other foods with added 3′-SL sodium salt are consumed the same day.

(5) On 13 May 2020, the applicant also made a request to the Commission for the protection of proprietary scientific studies and data submitted in support of the application, namely, mass spectrometry ('MS'), nuclear magnetic resonance ('NMR') and a high-performance anion-exchange chromatography with pulsed amperometric detection ('HPAEC-PAD') method validation and the results for the determination of the identity of 3′-SL and of the carbohydrate by-products present in the novel food ([6]); a description ([7]) and certificates of deposition ([8]) of the genetically modified 3′-SL sodium salt production and optional degradation strains; real time quantitative polymerase chain reaction ('qPCR') system and method validation reports for the genetically modified 3′-SL sodium salt production and optional degradation strains ([9]); a bacterial reverse mutation test with 3′-SL sodium salt ([10]); an *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt ([11]); a 7-day dose range finding oral toxicity study in rats with 3′-SL sodium salt ([12]); a 90-day oral toxicity study in rats with 3′-SL sodium salt ([13]); and, the clinical study with term infants to evaluate the nutritional suitability and tolerability of an infant formula containing a mixture of human identical milk oligosaccharides ([14]).

(6) On 18 December 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 3′-SL sodium salt obtained by microbial fermentation using two genetically modified strains (a production strain and an optional degradation strain) derived from the host strain *E. coli* BL21(DE3), as a novel food, in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 29 April 2022, the Authority adopted its scientific opinion on the 'Safety of 3′-sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21 (DE3) as a novel food pursuant to Regulation (EU) 2015/2283 ' ([15]) in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority concluded that 3′-SL sodium salt is safe under the proposed conditions of use and for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 3′-SL sodium salt, when used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council, processed cereal-based food for infants and young children and baby food for infants and young children as defined in Regulation (EU) No 609/2013, foods for infants and young

([5]) 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).
([6]) Chr. Hansen 2019 and 2021 (unpublished).
([7]) Chr. Hansen 2019 and 2021 (unpublished).
([8]) Chr. Hansen 2020 (unpublished).
([9]) Chr. Hansen 2021 (unpublished).
([10]) Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.
([11]) Chr. Hansen 2018 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.
([12]) Chr. Hansen 2018 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.
([13]) Chr. Hansen 2019 and 2021 (unpublished) and Parschat K., Oehme A., Leuschner J., Jennewein S., and Parkot J. 2020. A safety evaluation of mixed human milk oligosaccharides in rats. Food and Chemical Toxicology, 136, 111118.
([14]) Chr. Hansen 2020 and 2021 (unpublished).
([15]) EFSA Journal 2022;20(5):7331.

children for special medical purposes as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children, in milk-based drinks and similar products intended for young children, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council, complies with the authorisation requirements of Article 12(1) of Regulation (EU) 2015/2283.

(9) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 3′-SL sodium salt without the scientific studies and data on the MS, NMR, and HPAEC-PAD method validation and the results for the determination of the identity of 3′-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 3′-SL sodium salt production and optional degradation strains; the qPCR system and method validation reports for the genetically modified 3′-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 3′-SL sodium salt; the 90-day oral toxicity study in rats with 3′-SL sodium salt; and, the clinical study with term infants to evaluate the nutritional suitability and tolerability of an infant formula containing a mixture of human identical milk oligosaccharides.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those scientific studies and data, and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data on the MS, NMR, and HPAEC-PAD method validation and the results for the determination of the identity of 3′-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 3′-SL sodium salt production and optional degradation strains; the qPCR system and method validation reports for the genetically modified 3′-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 3′-SL sodium salt; the 90-day oral toxicity study in rats with 3′-SL sodium salt; and, the clinical study with term infants to evaluate the nutritional suitability and tolerability of an infant formula containing a mixture of human identical milk oligosaccharides, under national law at the time they submitted the application and that third parties cannot lawfully access, use or refer to those data and studies.

(12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data on the MS, NMR, and HPAEC-PAD method validation and the results for the determination of the identity of 3′-SL and of the carbohydrate by-products present in the novel food; the description and certificates of deposition of the genetically modified 3′-SL sodium salt production and optional degradation strains; the qPCR system and method validation reports for the genetically modified 3′-SL sodium salt production and optional degradation strains; the bacterial reverse mutation test with 3′-SL sodium salt; the *in vitro* mammalian cell micronucleus test with 3′-SL sodium salt; the 7-day dose range finding oral toxicity study in rats with 3′-SL sodium salt; the 90-day oral toxicity study in rats with 3′-SL sodium salt; and, the clinical study with term infants to evaluate the nutritional suitability and tolerability of an infant formula containing a mixture of human identical milk oligosaccharides, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place 3′-SL sodium salt produced with derivative strains of *E. coli* BL21(DE3) on the market within the Union during a period of 5 years from the entry into force of this Regulation.

(13) However, restricting the authorisation of 3′-SL sodium salt produced with derivative strains of *E. coli* BL21(DE3) and the reference to the scientific studies and data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(14) In line with the conditions of use of food supplements containing 3′-SL sodium salt as proposed by the applicant, it is necessary to inform consumers by appropriate labelling that food supplements containing 3′-SL sodium salt should not be consumed by infants and children under 3 years of age and should not be used if other foods with added 3′-SL sodium salt are consumed the same day.

(15) It is appropriate that the inclusion of 3′-SL sodium salt produced with derivative strains of *E. coli* BL21(DE3) as a novel food in the Union list of novel foods contains also the required specifications and other information related to its authorisation, as referred to in Article 9(3) of Regulation (EU) 2015/2283.

(16) 3′-SL sodium salt produced with derivative strains of *E. coli* BL21(DE3) should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(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

1. 3′-Sialyllactose sodium salt produced with derivative strains of *E. coli* BL21(DE3) is authorised to be placed on the market within the Union.

3′-Sialyllactose sodium salt produced with derivative strains of *E. coli* BL21(DE3) shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Chr. Hansen A/S ([16]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 6 February 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Chr. Hansen A/S.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of Chr. Hansen A/S.

Article 4

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

([16]) Address: Boege Allé 10-12, 2970 Hoersholm, Denmark.

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

Done at Brussels, 16 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'3′-Sialyllactose ('3′-SL') sodium salt (produced by derivative strains of *E. coli* BL21(DE3))	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '3′-Sialyllactose sodium salt'. The labelling of food supplements containing 3′-Sialyllactose (3′-SL) sodium salt shall bear a statement that (a) they should not be consumed by children under 3 years of age; (b) they should not be used if other foods containing added 3′-sialyllactose sodium salt are consumed the same day.		Authorised on 6 February 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "Chr. Hansen A/S", Boege Allé 10-12, 2970 Hoersholm, Denmark. During the period of data protection, the novel food 3′-Sialyllactose sodium salt is authorised for placing on the market within the Union only by Chr. Hansen A/S unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "Chr. Hansen A/S". End date of the data protection: 6 February 2028.'
	Infant formula as defined under Regulation (EU) No 609/2013	0,23 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,28 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based foods for infants and young children and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	0,28 g/L or 0,28 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk based drinks and similar products intended for young children	0,28 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

	Foods for special medical purposes for infants and young children as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher 0,23 g/L or 0,28 g/kg in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.			
	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants and young children	0,7 g/day			

(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised novel food	Specification
'3′-Sialyllactose ('3′-SL') sodium salt (produced by derivative strains of *E. coli* BL21(DE3))	**Description:** 3'-Sialyllactose (3′-SL) sodium salt is a purified, white to off-white powder or agglomerate produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid. **Definition:** Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Chemical formula: $C_{23}H_{38}NO_{19}Na$ Molecular mass: 655,53 Da CAS No: 128596-80-5

	Source: Two genetically modified strains (a production strain and an optional degradation strain) of *Escherichia coli* BL21(DE3) **Characteristics/Composition:** 3′-Sialyllactose sodium salt (% of dry matter): ≥ 88,0 % (w/w) 3′-Sialyl-lactulose (% of dry matter): ≤ 5,0 % (w/w) D-Lactose (% of dry matter): ≤ 5,0 % (w/w) Sialic acid (% of dry matter): ≤ 1,5 % (w/w) N-acetyl-D-glucosamine (% of dry matter): ≤ 1,0 % (w/w) Sum of other carbohydrates (% of dry matter)[a]: ≤ 5,0 % (w/w) Moisture: ≤ 9,0 % (w/w) Ash: ≤ 8,5 % (w/w) Residual protein: ≤ 0,01 % (w/w) Sodium: ≤ 4,2 % (w/w) **Microbiological criteria:** Standard plate count: ≤ 1 000 *CFU/g Enterobacteriaceae: ≤ 10 CFU/g *Salmonella* spp.: Absence in 25 g Yeast and mould: ≤ 100 CFU/g *Cronobacter* (*Enterobacter*) *sakazakii*: Absence in 10 g Residual endotoxins: ≤ 10 **EU/mg [a] Sum of other carbohydrates = 100 (% (w/w) of dry matter) – 3'-Sialyllactose sodium salt (% (w/w) of dry matter) – quantified carbohydrates (% (w/w) of dry matter) – Ash (% (w/w) of dry matter); * CFU: Colony Forming Units; ** EU: Endotoxin Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/114

of 16 January 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, buprofezin, cyflufenamid, fluazinam, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metiram, metsulfuron-methyl, phosphane and pyraclostrobin

(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 ([1]), and in particular Article 17, first paragraph, thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009 whereas Part B of that Annex sets out the active substances approved under Regulation (EC) No 1107/2009 and Part E sets out the active substances approved under Regulation (EC) No 1107/2009 as candidates for substitution.

(2) Commission Implementing Regulation (EU) 2021/2068 ([3]) extended the approval period of the active substances mecoprop-P, metiram and pyraclostrobin until 31 January 2023 and of the active substances fluazinam, flutolanil and mepiquat until 28 February 2023. Commission Implementing Regulation (EU) 2018/670 ([4]) extended the approval period of the active substance buprofezin until 31 January 2023. Commission Implementing Regulation (EU) 2017/1527 ([5]) extended the approval period of the active substance cyflufenamid until 31 March 2023.

(3) The approval of the active substance benzovindiflupyr is set to expire on 2 March 2023 in accordance with Commission Implementing Regulation (EU) 2016/177 ([6]).

(4) The approval of the active substance lambda-cyhalothrin is set to expire on 31 March 2023 in accordance with Commission Implementing Regulation (EU) 2016/146 ([7]).

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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).

([3]) Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 421, 26.11.2021, p. 25).

([4]) Commission Implementing Regulation (EU) 2018/670 of 30 April 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bromuconazole, buprofezin, haloxyfop-P and napropamide (OJ L 113, 3.5.2018, p. 1).

([5]) Commission Implementing Regulation (EU) 2017/1527 of 6 September 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances cyflufenamid, fluopicolide, heptamaloxyloglucan and malathion (OJ L 231, 7.9.2017, p. 3).

([6]) Commission Implementing Regulation (EU) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (OJ L 35, 11.2.2016, p. 1).

([7]) Commission Implementing Regulation (EU) 2016/146 of 4 February 2016 renewing the approval of the active substance lambda-cyhalothrin, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (OJ L 30, 5.2.2016, p. 7).

(5) The approval of the active substance metsulfuron-methyl is set to expire on 31 March 2023 in accordance with Commission Implementing Regulation (EU) 2016/139 ([8]).

(6) The approval of the active substance phosphane is set to expire on 31 March 2023 in accordance with Commission Implementing Regulation (EU) No 1043/2012 ([9]).

(7) Applications for the renewal of the approval of those active substances were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([10]).

(8) The approvals of those active substances are likely to expire before a decision has been taken on their renewal because the decision-making procedure as regards the renewal has been delayed. Therefore, and as this delay is for reasons beyond the control of the applicants, it is necessary to extend their approval periods to enable the completion of the assessment required in order to take a decision on the applications for renewal of approval.

(9) In particular, an extension of the approval period is required for the active substances fluazinam, flutolanil, mecoprop-P, mepiquat, metiram and pyraclostrobin to provide the time necessary to carry out an assessment relating to endocrine disrupting properties of those active substances in accordance with the procedure set out in Articles 13 and 14 of Implementing Regulation (EU) No 844/2012.

(10) In case the Commission is to adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission is to set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission is to adopt a Regulation providing for the renewal of the approval of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(11) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(12) Taking into account that the current approval of buprofezin, mecoprop-P, metiram and pyraclostrobin expires on 31 January 2023, this Regulation should enter into force as soon as possible.

(13) 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

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

([8]) Commission Implementing Regulation (EU) 2016/139 of 2 February 2016 renewing the approval of the active substance metsulfuron-methyl, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (OJ L 27, 3.2.2016, p. 7).

([9]) Commission Implementing Regulation (EU) No 1043/2012 of 8 November 2012 approving the active substance phosphane, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 310, 9.11.2012, p. 24).

([10]) 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).
Although Implementing Regulation (EU) No 844/2012 was repealed by Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), the provisions concerning the renewal of the approval of active substances laid down in Implementing Regulation (EU) No 844/2012 continue to apply in accordance with Article 17 of Implementing Regulation (EU) 2020/1740.

Article 2

This Regulation shall enter into force on the third 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, 16 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(a) Part A is amended as follows:

(1) in the sixth column, expiration of approval, of row 57, Mecoprop-P, the date is replaced by '31 January 2024';

(2) in the sixth column, expiration of approval, of row 81, Pyraclostrobin, the date is replaced by '31 January 2024';

(3) in the sixth column, expiration of approval, of row 115, Metiram, the date is replaced by '31 January 2024';

(4) in the sixth column, expiration of approval, of row 187, Flutolanil, the date is replaced by '29 February 2024';

(5) in the sixth column, expiration of approval, of row 189, Fluazinam, the date is replaced by '29 February 2024';

(6) in the sixth column, expiration of approval, of row 191, Mepiquat, the date is replaced by '29 February 2024';

(7) in the sixth column, expiration of approval, of row 296, Cyflufenamid, the date is replaced by '31 March 2024';

(8) in the sixth column, expiration of approval, of row 320, Buprofezin, the date is replaced by '31 January 2024';

(b) Part B is amended as follows: in the sixth column, expiration of approval, of row 28, Phosphane, the date is replaced by '31 March 2024';

(c) Part E is amended as follows:

(1) in the sixth column, expiration of approval, of row 3, Metsulfuron-methyl, the date is replaced by '31 March 2024';

(2) in the sixth column, expiration of approval, of row 4, Benzovindiflupyr, the date is replaced by '2 March 2024';

(3) in the sixth column, expiration of approval, of row 5, Lambda-Cyhalothrin, the date is replaced by '31 March 2024'.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/115

of 16 January 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance dimoxystrobin

(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 ([1]), and in particular Article 17, first paragraph, thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) Commission Implementing Regulation (EU) 2021/2068 ([3]) extended the approval period of the active substance dimoxystrobin until 31 January 2023.

(3) An application for the renewal of the approval of the active substance dimoxystrobin was submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([4]).

(4) Although a European Food Safety Authority (EFSA) statement ([5]) on the evaluation of the active substance dimoxystrobin is available and the Commission has already initiated discussions at the Standing Committee on Plants, Animals, Food and Feed, it still appears that the approval is likely to expire before a decision has been taken on renewal. Therefore, and as this delay is for reasons beyond the control of the applicant, it is necessary to extend its approval for a limited period of time to enable the completion of the assessment required in order to take a decision on the application for a renewal of its approval.

(5) In case the Commission is to adopt a Regulation providing that the approval of dimoxystrobin is not renewed because the approval criteria are not satisfied, the Commission is to set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards the case where the Commission is to adopt a Regulation providing for the renewal of the approval of dimoxystrobin, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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).

([3]) Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 421, 26.11.2021, p. 25).

([4]) 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).
Although Implementing Regulation (EU) No 844/2012 was repealed by Commission Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), the provisions concerning the renewal of the approval of active substances laid down in Implementing Regulation (EU) No 844/2012 continue to apply in accordance with Article 17 of Implementing Regulation (EU) 2020/1740.

([5]) EFSA (European Food Safety Authority), 2022. Statement concerning the assessment of environmental fate and behaviour and ecotoxicology in the context of the pesticides peer review of the active substance dimoxystrobin. EFSA Journal 2022;20(11):7634. https://doi.org/10.2903/j.efsa.2022.7634.

(6) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(7) Taking into account that the current approval of dimoxystrobin expires on 31 January 2023, this Regulation should enter into force as soon as possible.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column, 'Expiration of approval', of entry 128, Dimoxystrobin, the date is replaced by '31 January 2024'.

Article 2

This Regulation shall enter into force on the third 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, 16 January 2023

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/116

of 16 January 2023

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance oxamyl

(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 ([1]), and in particular Article 17, first paragraph, thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) Commission Implementing Regulation (EU) 2021/2068 ([3]) extended the approval period of the active substance oxamyl until 31 January 2023.

(3) An application for the renewal of the approval of the active substance oxamyl was submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([4]).

(4) Although the European Food Safety Authority's conclusion ([5]) on the evaluation of the active substance oxamyl is available and the Commission has initiated discussions at the Standing Committee on Plants, Animals, Food and Feed, it still appears that the approval is likely to expire before a decision has been taken on renewal. Therefore, and as this delay is for reasons beyond the control of the applicant, it is necessary to extend its approval for a limited period of time to enable the completion of the assessment required in order to take a decision on the application for a renewal of its approval.

(5) In case the Commission is to adopt a Regulation providing that the approval of oxamyl is not renewed because the approval criteria are not satisfied, the Commission is to set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards the case where the Commission is to adopt a Regulation providing for the renewal of the approval of oxamyl, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(6) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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).

([3]) Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 421, 26.11.2021, p. 25).

([4]) 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).
Although Implementing Regulation (EU) No 844/2012 was repealed by Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20), the provisions concerning the renewal of the approval of active substances laid down in Implementing Regulation (EU) No 844/2012 continue to apply in accordance with Article 17 of Implementing Regulation (EU) 2020/1740.

([5]) EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance oxamyl. EFSA Journal 2022;20(5):7296. https://doi.org/10.2903/j.efsa.2022.7296.

(7) Taking into account that the current approval of oxamyl expires on 31 January 2023, this Regulation should enter into force as soon as possible.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, in the sixth column, 'Expiration of approval', of entry 116, Oxamyl, the date is replaced by '31 October 2023'.

Article 2

This Regulation shall enter into force on the third 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, 16 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2023/117

of 13 January 2023

on the service level requirements for the activities to be carried out by eu-LISA concerning the e-CODEX system

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2022/850 of the European Parliament and of the Council of 30 May 2022 on a computerised system for the cross-border electronic exchange of data in the area of judicial cooperation in civil and criminal matters (e-CODEX system), and amending Regulation (EU) 2018/1726 [1], and in particular Article 6(1), point (b), thereof,

Whereas:

(1) It is necessary to define the service level requirements for the activities to be carried out by eu-LISA with regard to the e-CODEX system and other necessary technical specifications for those activities, including the number of e-CODEX correspondents.

(2) The service level requirements for the activities to be carried out by eu-LISA with regard to the e-CODEX system should cover the tasks set out in Regulation (EU) 2022/850.

(3) An e-CODEX correspondent is a natural person, designated by a Member State or the Commission, who can request and receive technical support from eu-LISA concerning all the components of the e-CODEX system.

(4) The number of e-CODEX correspondents in Member States and in the Commission should be determined in proportion to the number of authorised e-CODEX access points and to the number of digital procedural standards which they apply.

(5) 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 Treaty on the Functioning of the European Union, Denmark did not take part in the adoption of Regulation (EU) 2022/850 and is therefore not bound by or subject to the application of this Decision.

(6) In accordance with Articles 1 and 2 and Article 4a(1) of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, and without prejudice to Article 4 of that Protocol, Ireland did not take part in the adoption of Regulation (EU) 2022/850 and is therefore not bound by or subject to the application of this Decision.

(7) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council [2] and delivered an opinion on 24 November 2022.

(8) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 19(1) of Regulation (EU) 2022/850,

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[1] OJ L 150, 1.6.2022, p. 1.

[2] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAS ADOPTED THIS DECISION:

Article 1

The service level requirements for the activities to be carried out by eu-LISA referred to in Article 7 of Regulation (EU) 2022/850 and other necessary technical specifications for those activities shall be as set out in the Annex to this Decision.

Article 2

The number of e-CODEX correspondents referred to in Article 6(1), point (b), of Regulation (EU) 2022/850 shall be as set out in the Annex to this Decision.

Article 3

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, 13 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Service level requirements for the activities to be carried out by eu-LISA concerning the e-CODEX system

1. INTRODUCTION

This Annex establishes the service level requirements for the activities to be carried out by eu-LISA referred to in Article 7 of Regulation (EU) 2022/850 ([1]) and other necessary technical specifications for those activities, including the number of e-CODEX correspondents.

In this regard, all activities have the objective of guaranteeing the provision of cost-effective high quality services necessary to ensure the long-term sustainability of the e-CODEX system and its governance.

For that purpose, this Annex defines the indicators that shall be used to measure the quality of the services provided and the minimum target levels to be achieved.

This Annex also specifies the number of e-CODEX correspondents that are entitled to request and receive technical support from eu-LISA.

2. DEFINITIONS

2.1. The definitions and composition of the e-CODEX system laid down in Articles 3 and 5 of Regulation (EU) 2022/850 and in the Annex thereto apply.

2.2. For the purpose of this Annex, the following definitions also apply:

(a) 'supported e-CODEX package set-up' means the combination between versions of the connector and gateway that were tested and recommended by eu-LISA for the correct functioning of an access point;

(b) 'working days' means normal working days for the European Institutions, agencies and bodies, excluding public holidays, as established for each calendar year pursuant to Article 61 of the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ([2]);

(c) 'business hours' means working hours on working days between 09:00 – 17:00 (EET/EEST);

(d) ITSM' or 'IT Service Management' means the activities that are performed by eu-LISA to design, build, deliver, operate and control information technology (IT) services;

(e) 'Business Continuity Plan' means the process of creating systems of prevention of and recovery from potential threats to e-CODEX. In addition to prevention, the goal of a Business Continuity Plan is to enable ongoing operations before and during execution of disaster;

(f) 'demand management process' means a process aimed at ensuring that the requests for change are recorded, assessed and, if approved, converted into requirements to be further handled with a controlled product, program or project management process at eu-LISA;

(g) 'operational change management process' means a process aimed at facilitating the realisation of the operational technical changes, in a controlled way and with limited and acceptable risks, maximizing the added-value, and reducing or avoiding disruption and re-work;

([1]) Regulation (EU) 2022/850 of the European Parliament and of the Council of 30 May 2022 on a computerised system for the cross-border electronic exchange of data in the area of judicial cooperation in civil and criminal matters (e-CODEX system), and amending Regulation (EU) 2018/1726 (OJ L 150, 1.6.2022, p. 1).

([2]) OJ L 56, 4.3.1968, p. 1.

(h) 'release' means a cluster of new and/or updated changes, which have been first tested and approved;

(i) 'Release management process' means a process aimed at providing a structured way of delivering new releases, covering the definition and agreement on release and deployment plans and ensuring that each release package consists of a set of related assets and service components that are compatible with each other.

3. TASKS OF EU-LISA

3.1. Tasks of eu-LISA under Article 7(1) of Regulation (EU) 2022/850

3.1.1. With regard to Article 7(1), point (a) of Regulation (EU) 2022/850 (developing, maintaining, fixing bugs in and updating, including as regards security, software products and other assets and distributing them to the entities operating authorised e-CODEX access points), eu-LISA shall be responsible for all software development lifecycle aspects related to the development and maintenance of the e-CODEX components.

eu-LISA shall maintain a repository where e-CODEX components artefacts are stored and available to the entities operating authorised e-CODEX access points. The components of the e-CODEX system covered by a European Union Public Licence shall be made publicly available.

3.1.2. With regard to Article 7(1), point (b) of Regulation (EU) 2022/850 (preparing, maintaining and updating the documentation relating to the components of the e-CODEX system, its supporting software products and other assets, and distributing that documentation to the entities operating authorised e-CODEX access points), documentation outputs shall be made available to the entities operating authorised e-CODEX access points in a repository provided by eu-LISA. eu-LISA shall define an appropriate release management process.

3.1.3. With regard to Article 7(1), point (c) of Regulation (EU) 2022/850 (developing, maintaining and updating a configuration file containing an exhaustive list of authorised e-CODEX access points, including the digital procedural standards which each of those authorised e-CODEX access points applies, and distributing it to the entities operating authorised e-CODEX access points), due to the criticality of the Configuration File service, eu-LISA shall develop and maintain the Configuration Management Tool in-line with the availability requirements set out below. This tool is a software product used to assist in the performance of the task referred to in Article 7(1).

3.1.4. With regard to Article 7(1), point (d) of Regulation (EU) 2022/850 (making technical changes and adding new features, published as new software versions, to the e-CODEX system in order to respond to emerging requirements, such as those resulting from the implementing acts referred to in Article 6(2), or where requested by the e-CODEX Advisory Group), new software versions shall take the form of releases. In order to respond to emerging business and technical requirements, eu-LISA shall be responsible for the continuous evolution of the software components comprising the e-CODEX system.

The Management Board of eu-LISA, after taking into account the opinion of the e-CODEX Advisory Group, shall adopt the eu-LISA demand management process and operational change management process.

3.1.5. With regard to Article 7(1), point (e) of Regulation (EU) 2022/850 (supporting and coordinating testing activities, including connectivity, involving the authorised e-CODEX access points), eu-LISA shall provide support and coordinate testing activities involving the authorised e-CODEX access points. In this regard, eu-LISA shall define guidance, test plans, test scenarios and test cases, as well as produce testing/compliance reports.

3.1.6. With regard to Article 7(1), point (f) of Regulation (EU) 2022/850 (providing technical support for the e-CODEX correspondents in relation to the e-CODEX system), eu-LISA shall provide technical support to the e-CODEX correspondents in relation to the e-CODEX system. For that purpose, eu-LISA shall make resources continuously available during business hours to provide e-CODEX correspondents with a single-entry point of contact for technical support, including for the gateway ('helpdesk' service). eu-LISA shall follow up on gateway requests insofar as they concern its correct functioning with the connector, in a supported e-CODEX package set-up.

Technical support shall be provided in accordance with the e-CODEX Operator's Manual.

When dealing with requests for technical support and with incidents, eu-LISA shall provide support to the extent of its competence and to the best of its ability, unless the requests and incidents are exclusively related to circumstances specific to the infrastructure of the entities operating an authorised e-CODEX access point.

3.1.7. With regard to Article 7(1), point (g) of Regulation (EU) 2022/850 (developing, deploying, maintaining and updating the digital procedural standards and distributing them to the entities operating authorised e-CODEX access points), eu-LISA shall be responsible for the development, maintenance, updating and the deployment of digital procedural standards adopted under implementing acts either under Regulation (EU) 2022/850 (Article 6(2) thereof), under other Union legal acts in the area of judicial cooperation in civil and criminal matters, or those prepared by the e-CODEX Advisory Group (Article 12(2), point (b), of Regulation (EU) 2022/850).

eu-LISA shall be responsible for organising the deployment of new and/or updated digital procedural standards by distributing them to the relevant entities operating authorised e-CODEX access points.

3.1.8. With regard to Article 7(1), point (h) of Regulation (EU) 2022/850 (publishing on its website a list of the authorised e-CODEX access points which have been notified to it and the digital procedural standards which each of those authorised e-CODEX access points applies), the list of authorised access points shall indicate the name of the entities operating them and shall be published on the e-CODEX dedicated eu-LISA website.

3.1.9. With regard to Article 7(1), point (i) of Regulation (EU) 2022/850 (responding to requests for technical advice and support from the Commission services in the context of the preparation of the implementing acts referred to in Article 6(2)), eu-LISA shall provide technical assistance and expertise to the Commission in the elaboration of new digital procedural standards, including, in particular, preparation of technical background and evidence, as well as assistance throughout the procedure until the adoption of the implementing acts, including participation in meetings.

3.1.10. With regard to Article 7(1), point (j) of Regulation (EU) 2022/850 (evaluating the need for, and assessing, and preparing, new digital procedural standards, including by organising and facilitating workshops with the e-CODEX correspondents), eu-LISA shall evaluate the need for, assess and prepare, new digital procedural standards. This task is entrusted, in particular to the e-CODEX Advisory Group (Article 12(2), point (b), of the Regulation). Organising and facilitating workshops with the e-CODEX correspondents shall be used as one of the tools in the evaluation.

3.1.11. With regard to Article 7(1), point (k) of Regulation (EU) 2022/850 (developing, maintaining and updating the EU e-Justice Core Vocabulary on which the digital procedural standards are based), eu-LISA shall develop, maintain and update the EU e-Justice Core Vocabulary on which the digital procedural standards are based. In this regard, the EU e-Justice Core Vocabulary shall be maintained under demand management process and stored as part of a repository provided and hosted by eu-LISA.

3.1.12. With regard to Article 7(1), point (l) of Regulation (EU) 2022/850 eu-LISA is responsible for developing and distributing security operating standards, as provided for in Article 11 of Regulation (EU) 2022/850).

3.1.13. With regard to Article 7(1), point (m) of Regulation (EU) 2022/850 (providing training, including to all relevant stakeholders, on the technical use of the e-CODEX system in accordance with Regulation (EU) 2018/1726 ([3]), including providing online training materials), eu-LISA shall provide a training plan for the e-CODEX system based on the analysis of the stakeholders' needs.

([3]) Regulation (EU) 2018/1726 of the European Parliament and of the Council of 14 November 2018 on the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA), and amending Regulation (EC) No 1987/2006 and Council Decision 2007/533/JHA and repealing Regulation (EU) No 1077/2011 (OJ L 295, 21.11.2018, p. 99).

3.2. **Tasks of eu-LISA under Article 7(2) of Regulation (EU) 2022/850**

3.2.1. With regard to Article 7(2), point (a) of Regulation (EU) 2022/850 (providing, operating and maintaining the hardware and software IT infrastructure in its technical sites necessary for carrying out its tasks), eu-LISA shall provide, operate and maintain all required hardware and software IT infrastructure in its technical sites necessary for carrying out eu-LISA's tasks with regard to the e-CODEX system. eu-LISA shall update its relevant procedures, including the Business Continuity Plan, to contain all components of the e-CODEX system.

3.2.2. With regard to Article 7(2), point (b) of Regulation (EU) 2022/850 (providing, operating and maintaining a central testing platform, while ensuring the integrity and availability of the rest of the e-CODEX system), eu-LISA shall provide, operate and maintain the e-CODEX Central Testing Platform (CTP) in-line with the availability requirements set out below. Any maintenance regarding testing activities carried out on the CTP shall not adversely affect the integrity and availability of the rest of the e-CODEX system.

3.2.3. With regard to Article 7(2), point (c) of Regulation (EU) 2022/850 (informing the general public about the e-CODEX system by means of a set of large-scale communication channels, including websites or social media platforms), eu-LISA shall be responsible for informing the general public about the e-CODEX system and any major developments. This shall be done by means of a set of large-scale communication channels, including websites and/or social media platforms. Pursuant to Article 12(2), point (c), of Regulation (EU) 2022/850, in defining and carrying out its activities in this regard, eu-LISA shall take into account input from the e-CODEX Advisory Group.

3.2.4. With regard to Article 7(2), point (d) of Regulation (EU) 2022/850 eu-LISA is responsible for preparing, updating and distributing online non-technical information relating to the e-CODEX system and the activities it carries out)

4. **ROLE OF EU-LISA WITH REGARD TO THE GATEWAY**

According to Article 7(3) of Regulation (EU) 2022/850, eu-LISA is to make resources available on an on-call basis during business hours to provide e-CODEX correspondents with a single point of contact for technical support, including for the gateway.

According to Article 7(1) of Regulation (EU) 2022/850, eu-LISA is responsible for the components of the e-CODEX system, except for the gateway, since it is currently based on a building block known as 'eDelivery', which is maintained by the Commission and provided on a cross-sectoral basis. eu-LISA shall take over full responsibility for the management of the connector and the digital procedural standards from the entity managing the e-CODEX system. Given that the gateway and the connector are integral components of the e-CODEX system, eu-LISA should ensure that the connector is compatible with the latest version of the gateway.

eu-LISA shall follow up on gateway issues insofar as it concerns their correct functioning with the connector, in a supported e-CODEX package set-up.

For technical support issues in a supported e-CODEX package set-up, which concern the gateway, and for which the eu-LISA Service desk alone cannot provide a resolution, eu-LISA shall liaise with the entity responsible for the management of the gateway. This process shall be transparent for the e-CODEX correspondents.

While eu-LISA shall exercise a 'best effort' approach to their resolution, this may ultimately depend on assistance of the actors responsible for the gateway. Therefore, the service level requirement targets shall not apply in instances where eu-LISA may need assistance from the actors responsible for the gateway.

	Users of the Commission eDelivery implementation	Users of an implementation other than the eDelivery implementation
API Specifications	Included	Included
Deployment and configuration	Included	Not included
Certificates	Included	Included
Connectivity testing support	Included	Included
Integration testing support	Included	Included
Troubleshooting	Included	Not included

5. REPORTING TO THE ADVISORY GROUP

In order to allow the Advisory Group to monitor eu-LISA's compliance with the service level requirements as referred to in Article 12(2), point (d) of Regulation (EU) 2022/850, eu-LISA shall keep the e-CODEX Advisory Group regularly updated on all operational management activities carried out in relation to the e-CODEX system. In particular, eu-LISA shall maintain and regularly communicate to the e-CODEX Advisory Group:

(a) any information relevant for the assessment of the compliance with the service level requirements set out in this Implementing Decision;

(b) schedules and planning artefacts of change requests implementation and new software releases.

The e-CODEX Advisory Group shall establish the exact structure, contents and parameters of this reporting, as well as its exact modalities and frequency.

6. e-CODEX OPERATOR'S MANUAL

eu-LISA shall provide the e-CODEX Operator's Manual, which shall be the reference document for the operational management of the systems for the e-CODEX correspondents and eu-LISA's Service desk. It shall describe all possible interactions in relation of IT Service Management.

The e-CODEX Operator's Manual shall be a limited need-to-know basis document that eu-LISA's Service desk will provide to all correspondents in its latest approved version. The correspondents may only share the e-CODEX Operator's Manual if authorised to do so.

The e-CODEX Operator's Manual shall contain in particular:

(a) Communication approach and channels of communication;

(b) Operational Setup Requirements with defined Services and Service Level Targets;

(c) Incident Management/Escalation Procedure including Classification and Prioritisation;

(d) Request Fulfilment Management and Technical assistance procedures;

(e) Maintenance Management;

(f) Any applicable Annexes.

The e-CODEX Operator's Manual shall be adopted by the Management Board of eu-LISA, after taking into account the opinion of the e-CODEX Advisory Group.

7. e-CODEX CORRESPONDENTS

According to Article 6(5) and Article 8(2) of Regulation (EU) 2022/850, Member States and the Commission, respectively, are to designate a number of e-CODEX correspondents in proportion to the number of e-CODEX access points which it has authorised and to the number of digital procedural standards, which those authorised e-CODEX access points apply. They are to notify a list of the e-CODEX correspondents and any changes thereto to eu-LISA.

Each authorised e-CODEX access point shall have a minimum of two e-CODEX correspondents assigned. More than two correspondents could be assigned to an authorised e-CODEX access point, taking into account the number of digital procedural standards that it applies.

The total number of e-CODEX correspondents and the objective criteria allowing to assign more than two correspondents to an authorised e-CODEX access point shall be defined and reviewed annually, accordingly to the requirements of the authorised e-CODEX access points and taking into account the available resources of eu-LISA, by the Management Board of eu-LISA on a proposal made by the e-CODEX Programme Management Board.

The e-CODEX Advisory Group in the context of monitoring eu-LISA's compliance with the service level requirements pursuant to Article 12(2), point (d) of Regulation (EU) 2022/850 shall monitor the need of changing the total number of e-CODEX correspondents.

8. SERVICES AND TARGET LEVELS

8.1. Principles

The responsibility for setting up securely and operating securely an authorised e-CODEX access point lies with the entities operating authorised e-CODEX access points. In this context, e-CODEX correspondents shall provide initial user support with regard to the deployment of authorised e-CODEX access points under their responsibility.

eu-LISA shall provide technical support to the e-CODEX correspondents with regard to providing response and resolution as defined in the e-CODEX Operator's Manual.

eu-LISA shall set up a Service desk which shall constitute the single-entry point for technical support. e-CODEX correspondents shall open tickets in accordance with the e-CODEX Operator's Manual, which shall be analysed by eu-LISA as they are created. The e-CODEX correspondent shall initially identify and categorise the tickets following guidance from the Operator's Manual. With the agreement of the relevant e-CODEX correspondent, eu-LISA may reclassify a ticket.

Changes will be treated under the demand management process. In a complete and synthetic form eu-LISA shall share them regularly with the entities operating authorised e-CODEX access points and the e-CODEX Advisory Group.

The eu-LISA Service desk shall be available during business hours.

8.2. Components under IT Service Management:

(a) Connector software;

(b) Central Testing Platform;

(c) Configuration Management Tool;

(d) e-CODEX Repository;

(e) Digital Procedural Standards.

For those components, the Operator's Manual will specify related services and service level targets that should be met in the frame of incident resolution management and availability.

8.3. Availability

The availability of e-CODEX components is calculated over the reporting period that will be defined in the e-CODEX Operator's Manual. Planned unavailability periods will not be taken into account in the calculation of availability.

Component	Availability
Repository	95 %
CMT	98 %
CTP	90 %
ITSM tool	95 %

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