

Official Journal of the European Union

L 158



English edition

Legislation

Volume 64

6 May 2021

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2021/731 of 26 January 2021 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to rules of procedure for penalties imposed on third-country central counterparties or related third parties by the European Securities and Markets Authority ⁽¹⁾.....** 1
- ★ **Commission Delegated Regulation (EU) 2021/732 of 26 January 2021 amending Delegated Regulation (EU) No 667/2014 with regard to the content of the file to be submitted by the investigation officer to the European Securities and Markets Authority, the right to be heard with regard to interim decisions and the lodging of fines and periodic penalty payments ⁽¹⁾** 8
- ★ **Commission Implementing Regulation (EU) 2021/733 of 5 May 2021 amending Implementing Regulation (EU) No 887/2011 and Implementing Regulation (EU) 2017/961 as regards the name of the holder of the authorisation of *Enterococcus faecium* CECT 4515 as a feed additive and amending Implementing Regulation (EU) 2020/1395 as regards the name of the holder of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive ⁽¹⁾** 11
- ★ **Commission Implementing Regulation (EU) 2021/734 of 5 May 2021 amending Implementing Regulation (EU) 2021/521 making specific arrangements to the mechanism making certain products subject to the production of an export authorisation** 13

DECISIONS

- ★ **Commission Implementing Decision (EU) 2021/735 of 4 May 2021 concerning the extension of the action taken by the Irish Department of Agriculture, Food and the Marine permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council (notified under document C(2021) 3026).....** 15

⁽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.

RULES OF PROCEDURE

- ★ **Management Board Decision No 5/2020 of 21 October 2020 on internal rules concerning restrictions of certain data-subject rights in relation to the processing of personal data in the framework of activities carried out by the European Union Aviation Safety Agency 17**

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/731**of 26 January 2021****supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to rules of procedure for penalties imposed on third-country central counterparties or related third parties by the European Securities and Markets Authority****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories ⁽¹⁾, and in particular Article 25i(7) thereof,

Whereas:

- (1) Regulation (EU) No 648/2012 has been amended by Regulation (EU) 2019/2099 of the European Parliament and of the Council ⁽²⁾. Those amendments have introduced into Regulation (EU) No 648/2012, inter alia, an empowerment for the Commission to specify further the rules of procedure for the exercise by the European Securities and Markets Authority ('ESMA') of the power to impose fines or periodic penalty payments on third-country central counterparties ('third-country CCPs') and related third parties to whom third-country CCPs have outsourced operational functions or activities ('related third parties'). In particular, those rules of procedures should include provisions on the rights of the defence, temporal provisions, and the collection of fines or periodic penalty payments and the limitation periods for the imposition and enforcement of penalties.
- (2) Article 41(2) of the Charter of Fundamental Rights of the European Union recognises the right of every person to be heard before any individual measure is taken which would affect him or her adversely, and the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy.
- (3) To ensure that the rights of defence of third-country CCPs and related third parties subject to actions by ESMA are respected and to ensure that ESMA takes all relevant facts into account when adopting enforcement decisions, ESMA should hear the third-country CCP or related third parties or any other persons concerned. Third-country CCPs and related third parties should therefore have the right to make written submissions in response to statements of findings issued by the investigation officer and ESMA, including in case of material changes in the

⁽¹⁾ OJ L 201, 27.7.2012, p. 1.

⁽²⁾ Regulation (EU) 2019/2099 of the European Parliament and of the Council of 23 October 2019 amending Regulation (EU) No 648/2012 as regards the procedures and authorities involved for the authorisation of CCPs and requirements for the recognition of third-country CCPs (OJ L 322, 12.12.2019, p. 1).

initial statement of findings. The investigation officer and ESMA should also have the possibility to invite third-country CCPs and related third parties to provide further explanations at an oral hearing where the investigation officer or ESMA consider that some elements of the written submissions made to the investigation officer or to ESMA are not sufficiently clear or detailed, and that further explanation is needed.

- (4) It is important that transparency is ensured between the investigation officer appointed by ESMA in accordance with Article 25i of Regulation (EU) No 648/2012 and ESMA itself. Such transparency requires that the investigation officer's file, in addition to the statement of findings, contains any submissions made by the third-country CCPs or related third parties, the statement of findings on the basis on which those third-country CCPs or related third parties provided their submissions, and the minutes of any oral hearing.
- (5) According to the second subparagraph of Article 25l(1) of Regulation (EU) No 648/2012, ESMA has the possibility to adopt, where urgent action is needed, interim decisions imposing fines or periodic penalty payments without first hearing the persons subject to an investigation or proceedings. To ensure the effectiveness of ESMA's power to adopt interim decisions, the third-country CCPs and related third parties subject to an investigation should not have the right to access the file or to be heard before the investigation officer has submitted the file with his or her findings to ESMA or before ESMA has adopted its interim decision. However, to respect the rights of defence, the third-country CCPs and related third parties should have the right to access the file as soon as the investigation officer has submitted the file with his or her statement of findings to ESMA, and the right to be heard as soon as possible after ESMA has adopted its interim decision.
- (6) For reasons of consistency, limitation periods for the imposition and enforcement of fines or periodic penalty payments should take into account existing Union legislation applicable to the imposition and enforcement of penalties on supervised entities, ESMA's experience in applying such legislation in relation to trade repositories under Regulation (EU) No 648/2012, the fact that third-country CCPs are located outside the Union and the need for ESMA to coordinate with authorities in such third-country jurisdictions in relation to enforcement actions. Limitation periods should be calculated in accordance with existing Union legislation for acts of the Council and the Commission, and in particular with Regulation (EEC, Euratom) No 1182/71 of the Council ⁽³⁾.
- (7) According to Article 25m(5) of Regulation (EU) No 648/2012, the amounts corresponding to the fines and periodic penalty payments collected by ESMA are to be allocated to the general budget of the Union. Fines and periodic penalty payments collected by ESMA should be lodged to interest bearing accounts until they become final. For each decision imposing fines or periodic penalty payments, the amounts collected by ESMA should be lodged to a separate account or subaccount to ensure traceability until that decision becomes final.
- (8) In the interest of the immediate exercise by ESMA of effective supervisory and enforcement powers, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation specifies further the rules of procedure regarding fines and periodic penalty payments to be imposed by the European Securities and Markets Authority (ESMA) on third-country central counterparties (CCPs) or related third parties to whom those CCPs have outsourced operational functions or activities subject to ESMA's investigation and enforcement proceedings, including rules on the right of defence and limitation periods.

⁽³⁾ Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits (OJ L 124, 8.6.1971, p. 1).

*Article 2***Right to be heard by the investigation officer**

1. Upon completion of the investigation and before submitting the file to ESMA pursuant to Article 3(1), the investigation officer shall inform the person subject to investigation in writing stating his or her findings and shall provide that person with the opportunity to make written submissions pursuant to paragraph 3. That statement of findings shall set out the facts liable to constitute one or more of the infringements listed in Annex III to Regulation (EU) No 648/2012, including any aggravating or mitigating factors of those infringements.
2. The statement of findings shall set a reasonable time limit within which the person subject to investigation may make its written submissions. The investigation officer shall not be obliged to take into account written submissions received after that time limit has expired.
3. In its written submissions, the person subject to investigation may set out all the facts known to it which are relevant to its defence. It shall attach any relevant documents as proof of the facts set out. It may propose that the investigation officer hear other persons who may corroborate the facts set out in the submissions of the person subject to investigation.
4. The investigation officer may also invite a person subject to investigation to which a statement of findings has been addressed to attend an oral hearing. The persons subject to investigation may be assisted by their lawyers, or by other qualified persons admitted by the investigation officer. Oral hearings shall not be held in public.

*Article 3***Right to be heard by ESMA with regard to fines and supervisory measures**

1. The complete file to be submitted by the investigation officer to ESMA shall include the following documents:
 - (a) the statement of findings and a copy of the statement of findings addressed to the person subject to the investigation;
 - (b) copy of the written submissions by the person subject to the investigation;
 - (c) the minutes of any oral hearing.
2. Where ESMA considers that the file submitted by the investigation officer is not complete, it shall send back the file to the investigation officer with reasoned request for additional documents.
3. Where ESMA considers, on the basis of a complete file, that the facts described in the statement of findings appear not to constitute an infringement listed in Annex III to Regulation (EU) No 648/2012, it shall decide to close the investigation and notify that decision to the persons subject to investigation.
4. Where ESMA does not agree with the findings of the investigation officer it shall submit a new statement of findings to the persons subject to investigation.

The statement of findings shall set a reasonable time limit within which the persons subject to investigation may make written submissions. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit.

ESMA may also invite the persons subject to investigation to which a statement of findings has been addressed to attend an oral hearing. The persons subject to investigation may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

5. Where ESMA agrees with all or some of the findings of the investigation officer it shall inform the persons subject to investigation accordingly. Such communication shall set a reasonable time limit within which the person subject to investigation may make written submissions. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit.

ESMA may also invite the persons subject to investigation to which a statement of findings has been addressed to attend an oral hearing. The persons subject to investigation may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

6. Where ESMA decides that one or more of the infringements listed in Annex III to Regulation (EU) No 648/2012 has been committed by a person subject to investigation and adopts a decision imposing a fine in accordance with Article 25j) of that Regulation, it shall immediately notify that decision to the person subject to investigation.

Article 4

Right to be heard by ESMA with regard to periodic penalty payments

Before making a decision imposing a periodic penalty payment in accordance with Article 25k of Regulation (EU) No 648/2012, ESMA shall submit a statement of findings to the person subject to the proceedings setting out the reasons justifying the imposition of a periodic penalty payment and the amount of the periodic penalty payment per day of non-compliance. The statement of findings shall set a time limit within which the person subject to proceedings may make written submissions. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit for deciding on the periodic penalty payment.

Once the person subject to proceedings has complied with the relevant decision referred to in Article 25k(1) of Regulation (EU) No 648/2012, a periodic penalty payment can no longer be imposed.

The decision imposing a periodic penalty payment shall indicate the legal basis and the reasons for the decision, the amount and the starting date of the periodic penalty payment.

ESMA may also invite the person subject to proceedings to attend an oral hearing. The persons subject to proceedings may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

Article 5

Right to be heard by ESMA with regard to interim decisions imposing fines

1. By way of derogation from Articles 2 and 3 of this Regulation, the procedure set out in this Article shall apply where ESMA adopts interim decisions imposing fines pursuant to the second subparagraph of Article 25l(1) of Regulation (EU) No 648/2012 without first hearing the persons subject to investigations.

2. The investigation officer shall submit the file with his or her findings to ESMA and immediately inform the person subject to investigation of his or her findings but shall not provide that person with the opportunity to make submissions. The statement of findings of the investigation officer shall set out the facts liable to constitute one or more of the infringements listed in Annex III to Regulation (EU) No 648/2012, including any aggravating or mitigating factors of those infringements.

Where so requested, the investigation officer shall grant access to the file to the person subject to investigation.

3. Where ESMA considers that the facts described in the statement of findings of the investigation officer appear not to constitute an infringement listed in Annex III to Regulation (EU) No 648/2012, it shall decide to close the investigation and notify that decision to the person subject to investigation.

4. Where ESMA decides that one or more of the infringements listed in Annex III to Regulation (EU) No 648/2012 has been committed by a person subject to investigation and adopts an interim decision imposing fines in accordance with the second subparagraph of Article 25l(1) of that Regulation, ESMA shall immediately notify that interim decision to that person.

ESMA shall set a reasonable time limit within which a person subject to investigation may make written submissions on the interim decision. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit.

Where so requested, ESMA shall grant access to the file to the persons subject to the investigation.

ESMA may invite the persons subject to investigation to attend an oral hearing. The persons subject to investigation may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

5. ESMA shall hear the person subject to the investigation and take a final decision as soon as possible after the adoption of the interim decision.

Where ESMA considers, based on the complete file and after having heard the persons subject to investigation, that one or more of the infringements listed in Annex III to Regulation (EU) No 648/2012 has been committed by the person subject to investigation it shall adopt a confirmatory decision imposing fines in accordance with Article 25j of that Regulation. ESMA shall immediately notify that decision to the persons subject to investigation.

Where ESMA adopts a final decision that does not confirm the interim decision, the interim decision shall be deemed to be repealed.

Article 6

Right to be heard by ESMA with regard to interim decisions imposing periodic penalty payments

1. By way of derogation from Article 4, the procedure set out in this Article shall apply where ESMA adopts interim decisions imposing periodic penalty payments pursuant to the second subparagraph of Article 25l(1) of Regulation (EU) No 648/2012 without first hearing the person subject to proceedings.

2. The interim decision imposing a periodic penalty payment shall indicate the legal basis and the reasons for the decision, the amount and the starting date of the periodic penalty payment.

Once the person subject to proceedings has complied with the relevant decision referred to in the second subparagraph of Article 25k(1) of Regulation (EU) No 648/2012, an interim decision imposing periodic penalty payment can no longer be adopted.

ESMA shall immediately notify the interim decision to the person subject to proceedings and shall set a time limit within which that person may make written submissions. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit.

Where so requested, ESMA shall grant access to the file to the person subject to proceedings.

ESMA may also invite the person subject to proceedings to attend an oral hearing. The person subject to proceedings may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

3. Where ESMA considers, on the basis of the complete file and after having heard the person subject to proceedings, that the grounds for imposing periodic penalty payments were present at the time of the adoption of the interim decision, ESMA shall adopt a confirmatory decision imposing periodic penalty payments in accordance with Article 25k of Regulation (EU) No 648/2012. ESMA shall immediately notify that decision to the person subject to proceedings.

Where ESMA adopts a decision that does not confirm the interim decision, the interim decision shall be deemed to be repealed.

*Article 7***Access to the file and use of documents**

1. Where so requested, ESMA shall grant access to the file to the parties to whom the investigation officer or ESMA has sent a statement of findings. Access shall be granted following the notification of any statement of findings.
2. File documents accessed pursuant to paragraph 1 of this Article shall be used only for the purposes of judicial or administrative proceedings concerning the application of Regulation (EU) No 648/2012.

*Article 8***Limitation periods for the imposition of penalties**

1. The powers conferred on ESMA to impose fines and periodic penalty payments on third-country CCPs and related third parties to which the third-country CCPs has outsourced operational functions or activities shall be subject to a limitation period of 5 years.
2. The limitation period referred to in paragraph 1 shall start on the day following that on which the infringement is committed. However, in the case of continuing or repeated infringements, that limitation period shall start on the day on which the infringement ceases.
3. Any action taken by ESMA for the purpose of the investigation or proceedings in respect of an infringement listed in Annex III to Regulation (EU) No 648/2012 shall interrupt the limitation period for the imposition of fines and periodic penalty payments. That limitation period shall be interrupted with effect from the date on which the action is notified to the person subject to investigation or proceedings in respect of an infringement listed in Annex III to Regulation (EU) No 648/2012.
4. Each interruption shall cause the limitation period to recommence. However, the limitation period shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without ESMA having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which limitation is suspended pursuant to paragraph 5.
5. The limitation period for imposing fines and periodic penalty payments shall be suspended for as long as the decision of ESMA is the subject of proceedings pending before the Board of Appeal, in accordance with Article 60 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council ⁽⁴⁾, and before the Court of Justice of the European Union, in accordance with Article 25n of Regulation (EU) No 648/2012.

*Article 9***Limitation periods for the enforcement of penalties**

1. The power of ESMA to enforce decisions taken pursuant to Articles 25j and 25k of Regulation (EU) No 648/2012 shall be subject to a limitation period of 8 years.
2. The 8-year period referred to in paragraph 1 shall start on the day following that on which the decision becomes final.
3. The limitation period for the enforcement of penalties shall be interrupted by:
 - (a) a notification by ESMA to the person subject to proceedings of a decision varying the original amount of the fine or periodic penalty payment;
 - (b) any action of ESMA or an authority of third country acting at the request of ESMA, designed to enforce payment or payment terms and conditions of the fine or periodic penalty payment.

⁽⁴⁾ Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

4. Each interruption shall cause the limitation period to recommence.
5. The limitation period for the enforcement of penalties shall be suspended for so long as:
 - (a) time to pay is allowed;
 - (b) enforcement of payment is suspended pursuant to a pending decision of ESMA Board of Appeal, in accordance with Article 60 of Regulation (EU) No 1095/2010, and the Court of Justice of the European Union, in accordance with Article 25n of Regulation (EU) No 648/2012.

Article 10

Collection of fines and periodic penalty payments

The amounts of fines and periodic penalty payments collected by ESMA shall be lodged to an interest-bearing account opened by the accounting officer of ESMA until they become final. In case multiple fines or periodic penalty payments are collected by ESMA in parallel, the accounting officer of ESMA shall ensure that they are lodged to different accounts or subaccounts. Amounts paid shall not be entered in ESMA's budget or recorded as budgetary amounts.

Once ESMA's Accounting Officer has established that the fines or periodic penalty payments have become final following the outcome of all possible legal challenges he or she shall transfer those amounts plus any interest accruing to the European Commission. These amounts shall be entered in the Union budget under general revenue.

ESMA's Accounting Officer shall report on a regular basis to the Authorising Officer of Directorate-General for Financial Stability, Financial Services and Capital Markets Union of the European Commission on the amounts of fines and periodic penalty payments imposed and their status.

Article 11

Calculation of periods, dates and time limits

Regulation (EEC, Euratom) No 1182/71 shall apply to periods of time, dates and time limits set out in this Regulation.

Article 12

Entry into force

This Regulation shall enter into force on the 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, 26 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2021/732**of 26 January 2021****amending Delegated Regulation (EU) No 667/2014 with regard to the content of the file to be submitted by the investigation officer to the European Securities and Markets Authority, the right to be heard with regard to interim decisions and the lodging of fines and periodic penalty payments****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories ⁽¹⁾, and in particular Article 64(7) thereof,

Whereas:

- (1) Regulation (EU) No 648/2012 has been amended by Regulation (EU) 2019/834 of the European Parliament and of the Council ⁽²⁾. Those amendments concerned, inter alia, the definition of financial counterparties, the right of access to the investigation file by persons subject an investigation, the fines to be paid by a trade repository that has, intentionally or negligently, committed one of the infringements listed in Annex I to Regulation (EU) No 648/2012, and the right of persons that may be subject to a periodic penalty payment to be heard.
- (2) Commission Delegated Regulation (EU) No 667/2014 ⁽³⁾ was adopted on the basis of Article 64(7) of Regulation (EU) No 648/2012 and deals with the rules of procedure for penalties imposed on trade repositories by the European Securities and Markets Authority ('ESMA'), including rules on the right of defence. Since the amendments introduced by Regulation (EU) 2019/834 into Regulation (EU) No 648/2012 concern those rules of procedure, it is necessary to ensure that those amendments are also reflected in Delegated Regulation (EU) No 667/2014.
- (3) It is important that transparency is ensured between the investigation officer appointed by ESMA in accordance with Article 64 of Regulation (EU) No 648/2012 and ESMA itself. Such transparency requires that the investigation officer's file contains the submissions made by persons subject to the investigation and the statement of findings on the basis on which those persons provided their submissions.
- (4) According to the second subparagraph of Article 67(1) of Regulation (EU) No 648/2012, ESMA has the possibility to adopt, where urgent action is needed, interim decisions without first hearing the persons subject to an investigation or proceedings. To ensure the effectiveness of ESMA's power to adopt interim decisions, persons subject to an investigation should not have the right to access the file or to be heard before the investigation officer submits the file with his or her findings to ESMA or before ESMA adopts its interim decision. However, to respect the rights of defence, persons subject to an investigation should have the right to access the file as soon as the investigation officer has submitted the file with his or her statement of findings to ESMA and the right to be heard as soon as possible after ESMA has adopted its interim decision.

⁽¹⁾ OJ L 201, 27.7.2012, p. 1.

⁽²⁾ Regulation (EU) 2019/834 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EU) No 648/2012 as regards the clearing obligation, the suspension of the clearing obligation, the reporting requirements, the risk-mitigation techniques for OTC derivative contracts not cleared by a central counterparty, the registration and supervision of trade repositories and the requirements for trade repositories (OJ L 141, 28.5.2019, p. 42).

⁽³⁾ Commission Delegated Regulation (EU) No 667/2014 of 13 March 2014 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to rules of procedure for penalties imposed on trade repositories by the European Securities and Markets Authority including rules on the right of defence and temporal provisions (OJ L 179, 19.6.2014, p. 31).

- (5) According to Article 68(5) of Regulation (EU) No 648/2012, the amounts corresponding to the fines and periodic penalty payments collected by ESMA are to be allocated to the general budget of the Union. Fines and periodic penalty payments collected by ESMA should be lodged to interest bearing accounts until they become final. For each decision imposing fines or periodic penalty payments, the amounts collected by ESMA should be lodged to a separate account or subaccount to ensure traceability until that decision becomes final.
- (6) Delegated Regulation (EU) No 667/2014 should be amended accordingly.
- (7) In the interest of the immediate exercise by ESMA of effective supervisory and enforcement powers, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) No 667/2014 is amended as follows:

- (1) in Article 3, paragraph 1 is replaced by the following:

‘1. The complete file to be submitted by the investigation officer to ESMA shall include the following documents:

- (a) the statement of findings and a copy of the statement of findings addressed to the person subject to the investigation;
- (b) a copy of the written submissions by the person subject to the investigation;
- (c) the minutes of any oral hearing.’;

- (2) the following Article 3a is inserted:

‘Article 3a

Right to be heard by ESMA with regard to interim decisions on supervisory measures

1. By way of derogation from Articles 2 and 3, the procedure set out in this Article shall apply where ESMA adopts interim decisions pursuant to the second subparagraph of Article 67(1) of Regulation (EU) No 648/2012.

2. The investigation officer shall submit the file with his or her findings to ESMA and immediately inform the person subject to investigation of his or her findings but shall not provide that person with the opportunity to make submissions. The statement of findings of the investigation officer shall set out the facts liable to constitute one or more of the infringements listed in Annex I to Regulation (EU) No 648/2012, including any aggravating or mitigating factors of those infringements.

Where so requested, the investigation officer shall grant access to the file to the person subject to investigation.

3. Where ESMA considers that the facts described in the statement of findings of the investigation officer appear not to constitute an infringement listed in Annex I to Regulation (EU) No 648/2012, it shall decide to close the investigation and notify that decision to the person subject to investigation.

4. Where ESMA decides that one or more of the infringements listed in Annex I to Regulation (EU) No 648/2012 has been committed by a person subject to investigation and adopts an interim decision imposing supervisory measures as laid down in Article 73(1), points (a), (c) and (d), of Regulation (EU) No 648/2012, ESMA shall immediately notify that interim decision to that person.

ESMA shall set a reasonable time limit within which the persons subject to investigation may make written submissions on the interim decision. ESMA shall not be obliged to take into account written submissions received after the expiry of that time limit.

Where so requested, ESMA shall grant access to the file to the persons subject to the investigation.

ESMA may invite the persons subject to investigation to attend an oral hearing. The persons subject to investigation may be assisted by their lawyers, or by other qualified persons admitted by ESMA. Oral hearings shall not be held in public.

5. ESMA shall hear the person subject to the investigation and take a final decision as soon as possible after the adoption of the interim decision.

Where ESMA considers, based on the complete file and after having heard the persons subject to investigation, that one or more of the infringements listed in Annex I to Regulation (EU) No 648/2012 has been committed by the person subject to investigation, it shall adopt a confirmatory decision imposing one or more of the supervisory measures laid down in Article 73(1), points (a), (c) and (d), of Regulation (EU) No 648/2012. ESMA shall immediately notify the person concerned of that decision.

Where ESMA adopts a final decision that does not confirm the interim decision, the interim decision shall be deemed to be repealed.’;

(3) Article 8 is amended as follows:

(a) the first subparagraph is replaced by the following:

‘The amounts of fines and periodic penalty payments collected by ESMA shall be lodged to an interest-bearing account opened by the accounting officer of ESMA until such time as they become final. In case multiple fines or periodic penalty payments are collected by ESMA in parallel, the accounting officer of ESMA shall ensure that they are lodged to different accounts or subaccounts. Amounts paid shall not be entered into ESMA’s budget or recorded as budgetary amounts.’;

(b) the third subparagraph is replaced by the following:

‘ESMA’s Accounting Officer shall report on a regular basis to the Authorising Officer of Directorate-General for Financial Stability, Financial Services and Capital Markets Union of the European Commission on the amounts of fines and periodic penalty payments imposed and their status.’.

Article 2

This Regulation shall enter into force on the 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, 26 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/733**of 5 May 2021****amending Implementing Regulation (EU) No 887/2011 and Implementing Regulation (EU) 2017/961 as regards the name of the holder of the authorisation of *Enterococcus faecium* CECT 4515 as a feed additive and amending Implementing Regulation (EU) 2020/1395 as regards the name of the holder of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) Evonik Nutrition & Care GmbH has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Implementing Regulation (EU) No 887/2011 ⁽²⁾, Commission Implementing Regulation (EU) 2017/961 ⁽³⁾ and Commission Implementing Regulation (EU) 2020/1395 ⁽⁴⁾.
- (3) The applicant claims that Evonik Nutrition & Care GmbH has changed their name to Evonik Operations GmbH. The application was accompanied by the relevant supporting data.
- (4) That proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food and Safety Authority was informed of the application.
- (5) To allow the applicant to exploit its marketing rights under the name of Evonik Operations GmbH it is necessary to change the terms of the authorisation.
- (6) Implementing Regulation (EU) No 887/2011, Implementing Regulation (EU) 2017/961 and Implementing Regulation (EU) 2020/1395 should therefore be amended accordingly.
- (7) Since safety reasons do not require the immediate application of the amendment made by this Regulation to Implementing Regulation (EU) No 887/2011, Implementing Regulation (EU) 2017/961 and Implementing Regulation (EU) 2020/1395, it is appropriate to provide for a transitional period during which existing stocks may be used up.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 887/2011 of 5 September 2011 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as feed additive for chickens for fattening (holder of the authorisation Norel SA) (OJ L 229, 6.9.2011, p. 7).

⁽³⁾ Commission Implementing Regulation (EU) 2017/961 of 7 June 2017 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH) (OJ L 145, 8.6.2017, p. 7).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/1395 of 5 October 2020 concerning the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of authorisation Evonik Nutrition & Care GmbH) (OJ L 324, 6.10.2020, p. 3).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) No 887/2011

Implementing Regulation (EU) No 887/2011 is amended as follows:

- (1) in the title, the words 'holder of the authorisation Evonik Nutrition & Care GmbH.' are replaced by the words 'holder of the authorisation Evonik Operations GmbH';
- (2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Evonik Nutrition & Care GmbH' are replaced by 'Evonik Operations GmbH'.

Article 2

Amendments to Implementing Regulation (EU) 2017/961

Implementing Regulation (EU) 2017/961 is amended as follows:

- (1) in the title, the words 'holder of the authorisation Evonik Nutrition & Care GmbH.' are replaced by the words 'holder of the authorisation Evonik Operations GmbH';
- (2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Evonik Nutrition & Care GmbH' are replaced by 'Evonik Operations GmbH'.

Article 3

Amendments to Implementing Regulation (EU) 2020/1395

Implementing Regulation (EU) 2020/1395 is amended as follows:

- (1) in the title, the words 'holder of the authorisation Evonik Nutrition & Care GmbH.' are replaced by the words 'holder of the authorisation Evonik Operations GmbH';
- (2) in the second column of the Annex, 'Name of the holder of authorisation', the words 'Evonik Nutrition & Care GmbH' are replaced by 'Evonik Operations GmbH'.

Article 4

Transitional measures

Existing stocks of the additives which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

Article 5

Entry into force

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, 5 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/734**of 5 May 2021****amending Implementing Regulation (EU) 2021/521 making specific arrangements to the mechanism making certain products subject to the production of an export authorisation**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports ⁽¹⁾, and in particular Article 6 thereof,

Whereas:

- (1) On 30 January 2021, the Commission adopted Implementing Regulation (EU) 2021/111 ⁽²⁾ making the exportation of COVID-19 vaccines as well as active substances, including master and working cell banks, used to manufacture these vaccines, subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479. At the end of the six weeks period following the date of entry into force of those measures, the Commission adopted Implementing Regulation (EU) 2021/442 ⁽³⁾ making the exportation of the same products subject to an export authorisation until 30 June 2021, pursuant to Article 6 of Regulation (EU) 2015/479.
- (2) On 24 March 2021, the Commission adopted Implementing Regulation (EU) 2021/521 ⁽⁴⁾ introducing, as an additional factor to be taken into consideration when considering granting an export authorisation, the need to consider whether this authorisation does not pose a threat to the security of supply within the Union of the goods covered by Implementing Regulation (EU) 2021/442. By the same Implementing Regulation, the exemption of certain destination countries from the scope of Implementing Regulation (EU) 2021/442 was also temporarily suspended.
- (3) Implementing Regulation (EU) 2021/521 was adopted pursuant to Article 5 of Regulation (EU) 2015/479 and applies for a maximum period of six weeks.
- (4) Despite an acceleration of vaccination across the Union, the pandemic remains severe and the conditions described in the recitals of Implementing Regulation (EU) 2021/521 still persist.
- (5) The specific arrangements introduced by Implementing Regulation (EU) 2021/521 should therefore continue to apply until 30 June 2021.
- (6) Iceland, Liechtenstein and Norway (the EEA EFTA States) participate in the Union's internal market in accordance with the Agreement on the European Economic Area. Most exports to the EEA EFTA States consist of vaccine procured by a Member State pursuant to an Advance Purchasing Agreement concluded by the Union and resold to those countries. On the basis of the information gathered through the application of Implementing Regulation (EU) 2021/521 there is no indication that exports are being channelled through the EEA EFTA States to other countries not exempted from the export authorization mechanism pursuant to Article 1(9) of Implementing Regulation (EU) 2021/442. Therefore, it is not necessary to continue the suspension of the exemption from that mechanism with regard to exports to the EEA EFTA States.
- (7) Implementing Regulation (EU) 2021/521 should therefore be amended accordingly and the amendment apply immediately.

⁽¹⁾ OJ L 83, 27.3.2015, p. 34.

⁽²⁾ Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation (OJ L 31 I, 30.1.2021, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) 2021/442 of 11 March 2021 making the exportation of certain products subject to the production of an export authorisation (OJ L 85, 12.3.2021, p. 190).

⁽⁴⁾ Commission Implementing Regulation (EU) 2021/521 of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorisation (OJ L 104, 25.3.2021, p. 52).

- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 3(1) of Regulation (EU) 2015/479,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2021/521 is amended as follows:

- (1) in Article 1, the second paragraph is replaced by the following:

‘However, the suspension shall not apply to the following countries and territories:

- Andorra,
- the Faroe Islands,
- Iceland
- Liechtenstein
- Norway
- San Marino,
- Vatican City,
- the overseas countries and territories listed in Annex II to the Treaty on the Functioning of the European Union,
- Büsingen,
- Helgoland,
- Livigno,
- Ceuta and Melilla.’;

- (2) in Article 3, the second paragraph is replaced by the following:

‘It shall apply until 30 June 2021.’.

Article 2

This Regulation shall enter into force on the 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, 5 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/735

of 4 May 2021

concerning the extension of the action taken by the Irish Department of Agriculture, Food and the Marine permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 3026)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof,

Whereas:

- (1) On 21 October 2020 the Irish Department of Agriculture, Food and the Marine ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems until 19 April 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. The microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The COVID-19 pandemic and the ensuing flight restrictions led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor of microbiological contamination.
- (3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8), active substances for use in biocidal products of product-type 6 as preservatives for products during storage as defined in Annex V to Regulation (EU) No 528/2012. As those active substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾, they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to them and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (4) On 5 February 2021, the Commission received a reasoned request from the competent authority to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems after 19 April 2021 and the claim that Biobor JF is essential in order to control such microbiological contamination.
- (5) According to the information provided by the competent authority, the only alternative biocidal product recommended by aircraft and engine manufacturers for the treatment of microbiological contamination (Kathon™ FP 1.5) was withdrawn from the market in March 2020 due to engine behaviour anomalies noticed after the treatment with that product.
- (6) The mechanical treatment of microbiological contamination of aircraft fuel tanks and fuel systems is not always possible. Moreover, mechanical treatment would expose workers to toxic gases and should therefore be avoided.
- (7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product and an application for approval of the active substances it contains is expected to be submitted in the near future. The approval of the active substances and subsequent authorisation of the biocidal product would constitute a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.
- (8) The lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the competent authority to extend the action.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Irish Department of Agriculture, Food and the Marine may extend until 22 October 2022 the action to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems.

Article 2

This Decision is addressed to the Irish Department of Agriculture, Food and the Marine.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

RULES OF PROCEDURE

MANAGEMENT BOARD DECISION No 5/2020

of 21 October 2020

on internal rules concerning restrictions of certain data-subject rights in relation to the processing of personal data in the framework of activities carried out by the European Union Aviation Safety Agency

THE MANAGEMENT BOARD OF THE EUROPEAN UNION AVIATION SAFETY AGENCY,

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

Having regard to 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 ⁽¹⁾, and in particular Article 25 thereof,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽²⁾, and in particular to Article 132 thereof,

Having regard to the rules of procedure of the Management Board of the European Union Aviation Safety Agency,

Having consulted the European Data Protection Supervisor,

Having informed the Staff Committee,

Whereas:

- (1) The European Union Aviation Safety Agency ('EASA') is empowered to conduct administrative inquiries, pre-disciplinary, disciplinary and suspension proceedings, in accordance with the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ('Staff Regulations') ⁽³⁾, and with Decision No 2011/216/E of EASA Executive Director of 16 December 2011 adopting implementing provisions regarding the conduct of administrative inquiries and disciplinary proceedings. If required, it also notifies cases to OLAF.
- (2) EASA staff members are under an obligation to report potentially illegal activities, including fraud and corruption, which are detrimental to the interests of the Union. Staff members are also obliged to report conduct relating to the discharge of professional duties which may constitute a serious failure to comply with the obligations of officials of the Union. This is regulated by EASA Management Board Decision 15-2018 of 14 December 2018.
- (3) EASA has put in place a policy to prevent and deal effectively with actual or potential cases of psychological or sexual harassment in the workplace, as provided for in EASA Decision No 2008/180/A of EASA Executive Director of 5 August 2009 adopting implementing measures pursuant to the Staff Regulations.

⁽¹⁾ OJ L 295, 21.11.2018, p. 39.

⁽²⁾ OJ L 212, 22.8.2018, p. 1.

⁽³⁾ Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1).

- (4) The Decision establishes an informal procedure whereby the alleged victim of the harassment can contact EASA's 'confidential' counsellors.
- (5) EASA can also conduct investigations into potential breaches of security rules for European Union classified information ('EUCI'), based on EASA Decision No 2020/010/ED of EASA Executive Director of 17 February 2020 on the EASA security rules on the protection of European Union Classified Information.
- (6) EASA is subject to both internal and external audits concerning its activities.
- (7) In the context of such administrative inquiries, audits and investigations, EASA cooperates with other Union institutions, bodies, offices and agencies.
- (8) EASA can cooperate with third countries' national authorities and international organisations, either at their request or on its own initiative.
- (9) EASA can also cooperate with EU Member States' public authorities, either at their request or on its own initiative.
- (10) EASA is involved in cases before the Court of Justice of the European Union when it either refers a matter to the Court, defends a decision it has taken and which has been challenged before the Court, or intervenes in cases relevant to its tasks. In this context, EASA might need to preserve the confidentiality of personal data contained in documents obtained by the parties or the interveners.
- (11) EASA is empowered to conduct inspections, other monitoring activities and investigations in compliance with Article 75(2)(e) of Regulation (EU) 2018/1139.
- (12) EASA is empowered to carry out IT security investigations handled internally or with external involvement (e.g. CERT-EU) in compliance with Article 75(2)(d) of Regulation (EU) 2018/1139.
- (13) The Data Protection Officer of EASA ('DPO') is empowered to process internal and external complaints and conduct internal audits and investigations in compliance with Article 45(2) of Regulation (EU) 2018/1725 ('the Regulation').
- (14) To fulfil its tasks, EASA collects and processes information and several categories of personal data, including identification data of natural persons, contact information, professional roles and tasks, information on private and professional conduct and performance, and financial data. EASA acts as data controller.
- (15) Under the Regulation, EASA is therefore obliged to provide information to data subjects on those processing activities and to respect their rights as data subjects.
- (16) EASA might be required to reconcile those rights with the objectives of administrative inquiries, audits, investigations and court proceedings. It might also be required to balance a data subject's rights against the fundamental rights and freedoms of other data subjects. To that end, Article 25 of the Regulation gives EASA the possibility to restrict, under strict conditions, the application of Articles 14 to 22, 35 and 36 of the Regulation, as well as its Article 4 in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20. Unless restrictions are provided for in a legal act adopted on the basis of the Treaties, it is necessary to adopt internal rules under which EASA is entitled to restrict those rights.
- (17) EASA might, for instance, need to restrict the information it provides to a data subject about the processing of his or her personal data during the preliminary assessment phase of an administrative inquiry or during the inquiry itself, prior to a possible dismissal of case or at the pre-disciplinary stage. In certain circumstances, providing such information might seriously affect EASA's capacity to conduct the inquiry in an effective way, whenever, for example, there is a risk that the person concerned might destroy evidence or interfere with potential witnesses before they are interviewed. EASA might also need to protect the rights and freedoms of witnesses as well as those of other persons involved.

- (18) It might be necessary to protect the anonymity of a witness or whistle-blower who has asked not to be identified. In such a case, EASA might decide to restrict access to the identity, statements and other personal data of such persons, in order to protect their rights and freedoms.
- (19) It might be necessary to protect confidential information concerning a staff member who has contacted EASA confidential counsellors in the context of a harassment procedure. In such cases, EASA might need to restrict access to the identity, statements and other personal data of the alleged victim, the alleged harasser and other persons involved, in order to protect the rights and freedoms of all concerned.
- (20) EASA should apply restrictions only when they respect the essence of fundamental rights and freedoms, are strictly necessary and are a proportionate measure in a democratic society. EASA should give reasons explaining the justification for those restrictions.
- (21) In application of the principle of accountability, EASA should keep a record of its application of restrictions.
- (22) When processing personal data exchanged with other organisations in the context of its tasks, EASA and those organisations should consult each other on potential grounds for imposing restrictions and the necessity and proportionality of those restrictions, unless this would jeopardise the activities of EASA.
- (23) Article 25(6) of the Regulation obliges the controller to inform data subjects of the principal reasons on which the application of the restriction is based and of their right to lodge a complaint with the EDPS.
- (24) Pursuant to Article 25(8) of the Regulation, EASA is entitled to defer, omit or deny the provision of information on the reasons for the application of a restriction to the data subject if this would in any way cancel the effect of the restriction. EASA should assess on a case-by-case basis whether the communication of the restriction would cancel its effect.
- (25) EASA should lift the restriction as soon as the conditions that justify the restriction no longer apply, and assess those conditions on a regular basis.
- (26) To guarantee utmost protection of the rights and freedoms of data subjects and in accordance with Article 44(1) of the Regulation, the DPO should be consulted in due time of any restrictions that may be applied and verify their compliance with this Decision.
- (27) Articles 16(5) and 17(4) of the Regulation provide for exceptions to data subjects' right to information and right of access. If these exceptions apply, EASA does not need to apply a restriction under this Decision,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

- 1. This Decision lays down rules relating to the conditions under which EASA may restrict the application of Articles 4, 14 to 22, 35 and 36, pursuant to Article 25 of the Regulation.
- 2. EASA, as the controller, is represented by its Executive Director.

Article 2

Restrictions

- 1. EASA may restrict the application of Articles 14 to 22, 35 and 36, and Article 4 thereof in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20:
 - (a) pursuant to Article 25(1) (b), (c), (f), (g) and (h) of the Regulation, when conducting administrative inquiries, pre-disciplinary, disciplinary or suspension proceedings under Article 86 and Annex IX of the Staff Regulations and the Decision No 2011/216/E of EASA Executive Director of 16th December 2011, and when notifying cases to OLAF;

- (b) pursuant to Article 25(1)(h) of the Regulation, when ensuring that EASA staff members may report facts confidentially where they believe there are serious irregularities, as set out in the EASA Management Board Decision 15-2018 of 14 December 2018;
- (c) pursuant to Article 25(1)(h) of the Regulation, when ensuring that EASA staff members are able to report to confidential counsellors in the context of a harassment procedure, as defined by Decision No 2008/180/A of EASA Executive Director of 5 August 2009;
- (d) pursuant to Article 25(1) (b), (c), (d) , (f), (g) and (h), when conducting investigations into potential breaches of security rules for European Union classified information ('EUCI'), based on EASA Decision No 2020/010/ED of EASA Executive Director of 17 February 2020 on the EASA security rules on the protection of European Union Classified Information;
- (e) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when conducting internal audits in relation to activities or departments of EASA;
- (f) pursuant to Article 25(1)(c), (d), (g) and (h) of the Regulation, when providing or receiving assistance to or from other Union institutions, bodies, offices and agencies or cooperating with them in the context of activities under points (a) to (d) of this paragraph and pursuant to relevant service level agreements, memoranda of understanding and cooperation agreements;
- (g) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when providing or receiving assistance to or from third countries national authorities and international organisations or cooperating with such authorities and organisations, either at their request or on its own initiative;
- (h) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when providing or receiving assistance and cooperation to and from EU Member States' public authorities, either at their request or on its own initiative;
- (i) pursuant to Article 25(1)(e) of the Regulation, when processing personal data in documents obtained by the parties or interveners in the context of proceedings before the Court of Justice of the European Union;
- (j) pursuant to Article 25(1)(c), (g) and (h) of the Regulation, when processing personal data while conducting inspections, other monitoring activities and investigations in compliance with Article 75(2)(e) of Regulation (EU) 2018/1139;
- (k) pursuant to Article 25(1) (b), (c), (d) , (f), (g) and (h) of the Regulation, when processing personal data while carrying out IT security investigations handled internally or with external involvement (e.g. CERT-EU) in compliance with Article 75(2)(d) of Regulation (EU) 2018/1139.

2. Pursuant to Article 25(1) (b), (c), (f), (g) and (h) of the Regulation, the DPO may restrict the application of Articles 14 to 22, 35 and 36, and Article 4 thereof in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20 while processing internal and external complaints and conducting internal audits and investigations in compliance with Article 45(2) of the Regulation.

3. Any restriction shall respect the essence of fundamental rights and freedoms and be necessary and proportionate in a democratic society.

4. A necessity and proportionality test shall be carried out on a case-by-case basis before restrictions are applied. Restrictions shall be limited to what is strictly necessary to achieve their objective.

5. For accountability purposes, EASA shall draw up a record describing the reasons for restrictions that are applied, which grounds among those listed in paragraph 1 apply and the outcome of the necessity and proportionality test. Those records shall be part of a register, which shall be made available on request to the EDPS. EASA shall prepare periodic reports on the application of Article 25 of the Regulation.

6. When processing personal data received from other organisations in the context of its tasks, EASA shall consult those organisations on potential grounds for imposing restrictions and the necessity and proportionality of the restrictions concerned, unless this would jeopardise the activities of EASA.

*Article 3***Risks to the rights and freedoms of data subjects**

1. Assessments of the risks to the rights and freedoms of data subjects of imposing restrictions and details of the period of application of those restrictions shall be registered in the record of processing activities maintained by EASA under Article 31 of the Regulation. They shall also be recorded in any data protection impact assessments regarding those restrictions conducted under Article 39 of the Regulation.
2. Whenever the EASA assesses the necessity and proportionality of a restriction it shall consider the potential risks to the rights and freedoms of the data subject.

*Article 4***Safeguards and storage periods**

1. EASA shall implement safeguards to prevent abuse and unlawful access or transfer of the personal data in respect of which restrictions apply or could be applied. Such safeguards shall include technical and organisational measures and be detailed as necessary in EASA internal decisions, procedures and implementing rules. The safeguards shall include:
 - (a) a clear definition of roles, responsibilities and procedural steps;
 - (b) if appropriate, a secure electronic environment which prevents unlawful and accidental access or transfer of electronic data to unauthorised persons;
 - (c) if appropriate, secure storage and processing of paper-based documents;
 - (d) due monitoring of restrictions and a periodic review of their application.

The reviews referred to in point (d) shall be conducted at least every six months.

2. Restrictions shall be lifted as soon as the circumstances that justify them no longer apply.
3. The personal data shall be retained in accordance with the applicable EASA retention rules, to be defined in the data protection records maintained under Article 31 of the Regulation. At the end of the retention period, the personal data shall be deleted, anonymised or transferred to archives in accordance with Article 13 of the Regulation.

*Article 5***Involvement of the Data Protection Officer**

1. The DPO shall be informed without undue delay whenever data subject rights are restricted in accordance with this Decision. He or she shall be given access to the associated records and any documents concerning the factual or legal context.
2. The DPO may request a review of the application of a restriction. EASA shall inform its DPO in writing of the outcome of the review.
3. EASA shall document the involvement of the DPO in the application of restrictions, including what information is shared with him or her.

*Article 6***Information to data subjects on restrictions of their rights**

1. EASA shall include a section in the data protection notices published on its website/intranet providing general information to data subjects on the potential for restriction of data subjects' rights pursuant to Article 2(1). The information shall cover which rights may be restricted, the grounds on which restrictions may be applied and their potential duration.

2. EASA shall inform data subjects individually, in writing and without undue delay of ongoing or future restrictions of their rights. EASA shall inform the data subject of the principal reasons on which the application of the restriction is based, of their right to consult the DPO with a view to challenging the restriction and of their rights to lodge a complaint with the EDPS.

3. EASA may defer, omit or deny the provision of information concerning the reasons for a restriction and the right to lodge a complaint with the EDPS for as long as it would cancel the effect of the restriction. Assessment of whether this would be justified shall take place on a case-by-case basis. As soon as it would no longer cancel the effect of the restriction, EASA shall provide the information to the data subject.

Article 7

Communication of a personal data breach to the data subject

1. Where EASA is under an obligation to communicate a data breach under Article 35(1) of the Regulation, it may, in exceptional circumstances, restrict such communication wholly or partly. It shall document in a note the reasons for the restriction, the legal ground for it under Article 2 and an assessment of its necessity and proportionality. The note shall be communicated to the EDPS at the time of the notification of the personal data breach.

2. Where the reasons for the restriction no longer apply, EASA shall communicate the personal data breach to the data subject concerned and inform him or her of the principal reasons for the restriction and of his or her right to lodge a complaint with the EDPS.

Article 8

Confidentiality of electronic communications

1. In exceptional circumstances, EASA may restrict the right to confidentiality of electronic communications under Article 36 of the Regulation. Such restrictions shall comply with Directive 2002/58/EC of the European Parliament and of the Council ⁽⁴⁾.

2. Where EASA restricts the right to confidentiality of electronic communications, it shall inform the data subject concerned, in its reply to any request from the data subject, of the principal reasons on which the application of the restriction is based and of his or her right to lodge a complaint with the EDPS.

3. EASA may defer, omit or deny the provision of information concerning the reasons for a restriction and the right to lodge a complaint with the EDPS for as long as it would cancel the effect of the restriction. Assessment of whether this would be justified shall take place on a case-by-case basis.

Article 9

Entry into force

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

Done in Warsaw, 21 October 2020.

Piotr SAMSON
Chair of the Management Board

⁽⁴⁾ 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 (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN