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EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1280

of 2 August 2021

as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ⁽¹⁾, and in particular Article 95(8) thereof,

Whereas:

- (1) Article 93(1)(j) of Regulation (EU) 2019/6 requires the holders of a manufacturing authorisation to use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practice for active substances.
- (2) Article 95(1) of Regulation (EU) 2019/6 requires importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products, that are established in the Union, to comply with good manufacturing practice or good distribution practice, as applicable.
- (3) Measures on good distribution practice should ensure the identity, integrity, traceability and quality of active substances used as starting materials in veterinary medicinal products during their movements from the premises where they are manufactured to the manufacturers of veterinary medicinal products by means of various modes of transport and by the use of various storage methods, as well as that those active substances remain within the legal supply chain during storage and transport.
- (4) Several international standards and guidelines on good distribution practice exist for active substances for medicinal products for human use ⁽²⁾; ⁽³⁾. At Union level, guidelines on good distribution practice have been adopted only in respect of active substances for medicinal products for human use ⁽⁴⁾. Corresponding measures in the veterinary

⁽¹⁾ OJ L 4, 7.1.2019, p. 43.

⁽²⁾ Good trade and distribution practices for pharmaceutical starting materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 6 (WHO Technical Report Series, No 996).

⁽³⁾ Guidelines on the principles of Good Distribution Practice of active substances for medicinal products for human use, PIC/S, PI 047-1 Annex, 1.7.2018.

⁽⁴⁾ Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) (OJ C 95, 21.3.2015, p. 1).

domain should take into account the experience gained with the application of the current system under Directive 2001/83/EC of the European Parliament and of the Council ⁽⁹⁾ in light of the similarities and potential differences between the requirements on good distribution practice for active substances used as starting materials in medicinal products for human use and in veterinary medicinal products.

- (5) A significant number of active substances are used as starting materials both in medicinal products for human use and in veterinary medicinal products. Importers, manufacturers and distributors often deal with such active substances. In addition, good distribution practice inspections for both types of medicinal products are often to be performed by the same competent authority experts. Therefore, in order to avoid unnecessary administrative burden on the industry and the competent authorities, it is practical to apply similar measures to the veterinary domain as in the human domain, unless specific needs dictate otherwise.
- (6) In order not to affect negatively the availability of veterinary medicinal products in the Union, the good distribution practice requirements for active substances used as starting materials in veterinary medicinal products should not be more stringent than the corresponding ones for those used as starting materials in medicinal products for human use.
- (7) The measures on good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation should ensure consistency with and complement the implementing measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials provided for in Article 93(2) of Regulation (EU) 2019/6 and good distribution practice for veterinary medicinal products provided for in Article 99(6) of that Regulation.
- (8) Relevant sections of good distribution practice for active substances used as starting materials in veterinary medicinal products should also be adhered to by third-party actors involved in the distribution of active substances used as starting materials in veterinary medicinal products and should be part of their contractual obligations. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified active substances used as starting materials in veterinary medicinal products.
- (9) A quality system is required to ensure that the objectives of good distribution practice are achieved and should clearly set out responsibilities, processes and risk management principles in relation to the activities of the persons involved throughout the distribution chain. That quality system should be the responsibility of the organisation's management, requires their leadership and active participation, and should be supported by personnel commitment.
- (10) The correct distribution of active substances used as starting materials in veterinary medicinal products relies significantly on an adequate number of competent personnel to carry out all the tasks for which the importers, manufacturers and distributors of active substances used as starting materials in veterinary medicinal products are responsible. Individual responsibilities should be clearly understood by personnel and be recorded.
- (11) The persons distributing active substances used as starting materials in veterinary medicinal products should have suitable and adequate premises, installations and equipment, in order to ensure proper storage and distribution of active substances used as starting materials in veterinary medicinal products.
- (12) Good documentation should be an essential part of any quality system. Written documentation should be required in order to prevent errors from oral communication and permit the tracking of relevant operations during the distribution of active substances used as starting materials in veterinary medicinal products. All types of documents should be defined and adhered to.
- (13) Procedures should describe all distribution activities that affect the identity, traceability and quality of the active substances used as starting materials in veterinary medicinal products.

⁽⁹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (14) Records of all significant activities or events should be made and kept to ensure the traceability of the origin and destination of active substances used as starting materials in veterinary medicinal products, as well as the identification of all suppliers of, or those supplied with, such active substances.
- (15) The quality system should fully describe all key operations in appropriate documentation.
- (16) Complaints, returns, and recalls should be recorded and handled carefully in accordance with established procedures. Records should be made available to the competent authorities. An assessment of returned active substances used as starting materials in veterinary medicinal products should be performed before any approval for resale.
- (17) Any activity covered by good distribution practice for active substances used as starting materials in veterinary medicinal products that is outsourced should be correctly defined and agreed in order to avoid misunderstandings that could affect the integrity of such substances. A written contract between the contract giver and the contract acceptor should clearly establish the duties of each party.
- (18) Regular self-inspections are necessary to monitor the implementation of and compliance with good distribution practice for active substances used as starting materials for veterinary medicinal products.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

- 1. This Regulation lays down the measures on good distribution practice for active substances used as starting materials in veterinary medicinal products.
- 2. This Regulation shall apply to importers and distributors of active substances used as starting materials in veterinary medicinal products, and to manufacturers who distribute active substances, which they manufactured, used as starting materials in veterinary medicinal products.
- 3. This Regulation shall not apply to intermediates of active substances used in veterinary medicinal products.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'good distribution practice for active substances used as starting materials in veterinary medicinal products' means the part of the quality assurance throughout the supply chain which ensures that the quality of active substances used as starting materials in veterinary medicinal products is maintained throughout all stages of the supply chain from the site of their manufacturer to the manufacturers of veterinary medicinal products;
- (b) 'quality system' means the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met;

- (c) 'quality risk management' means a systematic process, applied both proactively and retrospectively, for the assessment, control, communication and review of risks to the quality of an active substance used as a starting material in veterinary medicinal products across the substance's lifecycle;
- (d) 'procuring' means obtaining, acquiring or purchasing active substances used as starting materials in veterinary medicinal products from manufacturers, importers or other distributors;
- (e) 'holding' means storing active substances used as starting materials in veterinary medicinal products;
- (f) 'supplying' means all activities of providing, selling or donating active substances used as starting materials in veterinary medicinal products to distributors, pharmacists, manufacturers of veterinary medicinal products, or other persons in accordance with national law;
- (g) 'deviation' means departure from approved documentation or an established standard;
- (h) 'procedure' means a documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of active substances used as starting materials in veterinary medicinal products;
- (i) 'distribution of active substances used as starting materials in veterinary medicinal products' means all activities consisting of procuring, importing, holding, supplying or exporting of active substances used as starting materials in veterinary medicinal products;
- (j) 'documentation' means written procedures, instructions, contracts, records and data, in paper or in electronic form;
- (k) 'signed' means the record of the individual who performed a particular action or review. This record can be initials, a full handwritten signature, a personal seal, or an advanced electronic signature as defined in Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council ⁽⁶⁾;
- (l) 'expiry date' means the date placed on the container or labels of an active substance used as a starting material in veterinary medicinal products designating the time during which that active substance is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used;
- (m) 'batch' means a defined quantity of starting material, packaging material or product processed in a single process or series of processes, so that it is expected to be homogeneous;
- (n) 'retest date' means the date when an active substance used as a starting material in veterinary medicinal products should be re-examined to ensure that it is still suitable for use;
- (o) 'transport' means moving active substances used as starting materials in veterinary medicinal products between two locations without storing them for unjustified periods of time;
- (p) 'batch number' means a distinctive combination of numbers or letters that uniquely identifies a batch;
- (q) 'contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or active substance during production, sampling, packaging or repackaging, storage or transport;
- (r) 'calibration' means the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard;
- (s) 'quarantined' means the status of materials isolated physically or by other effective means pending a decision on approval or rejection;
- (t) 'qualification' means the action of proving that any equipment works correctly and actually leads to the expected results;

⁽⁶⁾ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

- (u) 'validation' means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria;
- (v) 'falsified active substance used as a starting material in veterinary medicinal products' means any active substance used as a starting material in veterinary medicinal products with a false representation of any of the following:
 - (i) its identity, including its packaging and labelling, its name or its components as regards any of the ingredients and the strength of those ingredients;
 - (ii) its source, including its manufacturer, its country of manufacturing, its country of origin; or
 - (iii) its history, including the records and documents relating to the distribution channels used.

CHAPTER II

QUALITY SYSTEM

Article 3

Development and maintenance of a quality system

1. The persons referred to in Article 1(2) shall develop and maintain a quality system.
2. The quality system shall take into account the size, structure and complexity of the activities of those persons and the changes foreseen for those activities.
3. The persons referred to in Article 1(2) shall ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

Article 4

Requirements for the quality system

1. The quality system shall set out responsibilities, processes and quality risk management principles.
2. It shall ensure that the following obligations are fulfilled:
 - (a) the procuring, import, holding, supplying, transport or export of active substances used as starting materials in veterinary medicinal products comply with the requirements of good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation;
 - (b) management responsibilities are clearly specified;
 - (c) active substances used as starting materials in veterinary medicinal products are delivered under the right conditions, to the correct consignees and within an appropriate time period;
 - (d) records are made contemporaneously;
 - (e) deviations are documented and investigated;
 - (f) appropriate corrective and preventive actions ('CAPA') are taken in line with the principles of quality risk management;
 - (g) changes that may affect the storage and distribution of active substances used as starting materials in veterinary medicinal products are evaluated.

CHAPTER III

PERSONNEL*Article 5***Persons responsible for the quality system**

1. The persons referred to in Article 1(2) shall designate a natural person as a person to be responsible for the quality system at each location where distribution activities are performed.
2. The persons responsible for the quality system shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained as well as be personally responsible for fulfilling their obligations.
3. The persons responsible for the quality system may delegate their tasks but not their responsibilities.

*Article 6***Personnel involved in the distribution of active substances used as starting materials in veterinary medicinal products**

1. The responsibilities of all personnel involved in the distribution of active substances used as starting materials in veterinary medicinal products shall be specified in writing.
2. Personnel shall be trained on the requirements of good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation. Furthermore, personnel shall have the appropriate competence and experience to ensure that active substances used as starting materials in veterinary medicinal products are properly handled, stored and distributed.

*Article 7***Training of personnel**

1. Personnel shall receive initial and continuing training relevant to their role, based on procedures and in accordance with a written training programme.
2. The persons referred to in Article 1(2) shall keep a record of all training and periodically assess and document its effectiveness.

*Article 8***Hygiene**

The persons referred to in Article 1(2) shall establish appropriate procedures relating to personnel hygiene, including personal health and appropriate clothing, relevant to the activities carried out. Personnel shall comply with those procedures.

CHAPTER IV

PREMISES AND EQUIPMENT*Article 9***Requirements for premises and equipment**

1. Premises and equipment shall be suitably located, designed, constructed and maintained to ensure:
 - (a) appropriate operations, such as receiving, proper storage, picking, packing and dispatch;
 - (b) protection from contamination, amongst other through narcotics, highly sensitising materials, materials of high pharmacological activity or toxicity;
 - (c) proper distribution of active substances used as starting materials in veterinary medicinal products.
2. There shall be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness.
3. Monitoring devices that are necessary to guarantee the quality attributes of the active substances used as starting materials in veterinary medicinal products shall be subject to calibration against certified traceable standards, according to an approved schedule.
4. Receiving and dispatch activities shall, if possible, be done in separate places. If that is not possible, those activities shall be conducted at separate times.
5. Areas for receiving active substances used as starting materials in veterinary medicinal products shall protect deliveries from prevailing weather conditions during unloading.
6. The reception area shall be separate from the storage area.
7. Appropriate cleaning equipment and cleaning agents shall be chosen and used so as not to constitute a source of contamination.
8. Premises shall be protected from the entry of birds, rodents, insects and other animals. A rodent and a pest control programme shall be implemented and maintained. Its effectiveness shall be monitored.
9. Defective equipment shall not be used and shall either be removed or labelled as defective. Equipment shall be disposed of in such a way as to prevent any misuse.
10. Segregated areas shall be provided for the storage of received, quarantined, rejected, recalled and returned active substances used as starting materials in veterinary medicinal products, including those with damaged packaging.
11. Any system replacing physical segregation, as applicable, such as electronic segregation based on a computerised system, shall provide equivalent security and shall be subject to appropriate validation.
12. Segregated areas and products shall be appropriately identified.

*Article 10***Access to premises**

Access shall be controlled and premises shall be suitably secured to prevent unauthorised access.

CHAPTER V

DOCUMENTATION, PROCEDURES AND RECORD KEEPING*Article 11***Documentation**

1. Documentation shall meet the following requirements:
 - (a) be readily available or retrievable;
 - (b) be sufficiently comprehensive with respect to the scope of the activities of the persons referred to in Article 1(2);
 - (c) be written in a language understood by personnel;
 - (d) be written in clear, unambiguous language.
2. When errors in the documentation are identified, they shall be corrected without delay, with clear traceability of who corrected them and when.
3. Any alteration made in the documentation shall be signed and dated. The alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.
4. Each employee shall have ready access to all necessary documentation for the tasks executed.
5. All documentation related to compliance of the persons referred to in Article 1(2) with good distribution practice for active substances used as starting materials in veterinary medicinal products as laid down in this Regulation shall be made available on request of competent authorities.
6. Relationships and control measures for original documents and official copies, data handling and records shall be stated for all paper-based, electronic and hybrid systems.

*Article 12***Procedures**

1. Procedures shall describe the distribution activities affecting the quality of the active substances used as starting materials in veterinary medicinal products. Those activities include:
 - (a) receipt and checking of deliveries;
 - (b) storage;
 - (c) cleaning and maintenance of the premises, including pest control;
 - (d) recording of the storage conditions;
 - (e) security of stocks on site and of consignments in transit;
 - (f) withdrawal from saleable stock;
 - (g) handling of returned active substances used as starting materials in veterinary medicinal products;
 - (h) recall plans.
2. Procedures shall be approved, signed and dated by the relevant person responsible for the quality system.

3. Valid and approved procedures shall be used. Documents shall be clear and appropriately detailed. The title, nature and purpose of documents shall be stated. Documents shall be reviewed regularly and kept up to date. Version control shall be applied to procedures. After revision of a document, a system shall exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures shall be removed from workstations and archived.

Article 13

Records

1. Records shall be clear, made at the time each operation is performed and in such a way that all significant activities or events are traceable.
2. Records shall be retained for at least 1 year after the expiry date of the active substance batch to which they relate. For active substances with retest dates, records shall be retained for at least 3 years after the batch is completely distributed.
3. Records shall ensure the traceability of the origin and destination of active substances used as starting materials in veterinary medicinal products, in order to identify all the suppliers of, or those supplied with those active substances. Records shall be kept of each purchase and sale. Records that shall be retained and be available include:
 - (a) the date of the transaction;
 - (b) name or designation of the active substances used as starting materials in veterinary medicinal products;
 - (c) original active substance manufacturer's batch number;
 - (d) quantity received or supplied;
 - (e) retest date or expiry date;
 - (f) name or company name and permanent address or registered place of business of the supplier and of the original active substance manufacturer, if not the same, or of the shipping agent or the consignee;
 - (g) purchase orders;
 - (h) bills of lading, transport and distribution records;
 - (i) receipt documents;
 - (j) certificates of analysis, including those of the original active substance manufacturer;
 - (k) any additional requirements specified by national law.

CHAPTER VI

OPERATIONS

Article 14

Verification of eligibility and approval of suppliers

Where active substances used as starting materials in veterinary medicinal products are procured from a manufacturer, importer or distributor established in the Union, the persons referred to in Article 1(2) shall verify that the respective manufacturer, importer or distributor is registered in accordance with Article 95(1) of Regulation (EU) 2019/6.

Article 15

Receipt of active substances used as starting materials

1. Deliveries shall be examined at receipt in order to check that:
 - (a) containers are not damaged;

- (b) all relevant security seals are present with no sign of tampering;
 - (c) labelling is correct, including the correlation between the name used by the supplier and the in-house name, where different;
 - (d) necessary information, such as a certificate of analysis, is available;
 - (e) the active substances used as starting materials in veterinary medicinal products and the consignment correspond to the order.
2. Active substances used as starting materials in veterinary medicinal products with broken seals, damaged packaging, or suspected of possible contamination, shall be segregated physically or, if an equivalent electronic system is available, electronically and the cause of the issue investigated.
3. Active substances used as starting materials in veterinary medicinal products subject to special storage measures, such as narcotics and products requiring a specific storage temperature or humidity, shall immediately be identified and stored in accordance with written instructions and with relevant national law.
4. Where persons referred to in Article 1(2) suspect that an active substance used as a starting material in veterinary medicinal products procured or imported by them is a falsified active substance used as a starting material in veterinary medicinal products, they shall segregate it physically or, if an equivalent electronic system is available, electronically and inform the national competent authority of the Member State in which they are registered.
5. Rejected active substances used as starting materials in veterinary medicinal products shall be identified, controlled, segregated physically or, if an equivalent electronic system is available, electronically to prevent their unauthorised use in manufacturing and their further distribution. Records of destruction activities shall be readily available.

Article 16

Storage

1. Active substances used as starting materials in veterinary medicinal products shall be stored under the conditions specified by their manufacturer, such as controlled temperature and humidity when necessary, and in such a manner as to prevent contamination or mix-up. The storage conditions shall be monitored and records maintained. The records shall be reviewed regularly by the person responsible for the quality system.
2. When special storage conditions are required, the storage area shall be subject to qualification and operated within the specified limits.
3. The storage facilities shall be clean and free from litter, dust and pests and other animals. Adequate precautions shall be taken against spillage or breakage and contamination.
4. There shall be a system to ensure stock rotation, such as 'first expiry or retest date, first out', with regular and frequent checks that the system is operating correctly. Electronic warehouse management systems shall be subject to validation.
5. Active substances used as starting materials in veterinary medicinal products beyond their expiry date shall be segregated physically or, if an electronic system is available, electronically from approved stock and not be supplied.

Article 17

Outsourced activities

1. Where storage or transport of active substances used as starting materials in veterinary medicinal products is contracted out, the persons referred to in Article 1(2) shall ensure that the contract acceptor knows and follows the appropriate storage and transport conditions.
2. There shall be a written contract between the contract giver and contract acceptor, which clearly establishes the duties of each party.

3. The contract acceptor shall not subcontract any of the work under the contract to a third party without the contract giver's written authorisation.

Article 18

Deliveries to customers

1. In the case of supplies within the Union, the persons referred to in Article 1(2) shall only supply active substances used as starting materials in veterinary medicinal products to other distributors, manufacturers, dispensing pharmacies or to persons permitted by national law.
2. Active substances used as starting materials in veterinary medicinal products shall be transported in accordance with the conditions specified by their manufacturer and in a manner that does not adversely affect their quality. Product, batch and container identity shall be maintained at all times. All original container labels shall remain readable. Actions shall be taken to prevent unauthorised access to the active substances used as starting materials in veterinary medicinal products being transported.
3. A system shall be in place by which the distribution of each batch of active substance used as a starting material in veterinary medicinal products can be readily identified to permit its recall.

Article 19

Transfer of information

1. The persons referred to in Article 1(2) shall notify relevant customers of any information or event that they become aware of which has potential to cause an interruption to supply.
2. The persons referred to in Article 1(2) shall transfer all quality or regulatory information about the active substances used as starting materials in veterinary medicinal products received from the original manufacturer of those active substances to the relevant customer and all such information received from the customer to the original manufacturer of those active substances.
3. The persons referred to in Article 1(2) shall provide to the relevant customer the name or company name and permanent address or registered place of business of the original active substance manufacturer and the batch numbers supplied. A copy of the original certificate of analysis from the original active substance manufacturer shall be provided to the customer.
4. The persons referred to in Article 1(2) shall provide the name or company name and permanent address or registered place of business of the original active substance manufacturer to competent authorities upon request. The original active substance manufacturer may respond to the competent authority either directly or through agents it has authorised.

CHAPTER VII

COMPLAINTS, RETURNS AND RECALLS

Article 20

Complaints

1. Complaints, whether received orally or in writing, shall be recorded and investigated according to a procedure.

In the event of a complaint about the quality of an active substance used as a starting material in veterinary medicinal products, the persons referred to in Article 1(2) shall review the complaint with the original active substance manufacturer, as applicable, in order to determine whether any further action shall be initiated either with other customers who may have received that active substance, or with the competent authority, or both. The investigation into the cause for the complaint shall be conducted and documented by the appropriate party.

2. Complaint records shall include the following:

- (a) name or company name and permanent address or registered place of business of complainant;
- (b) name, title, where appropriate, and contact details of the person submitting the complaint;
- (c) nature of the complaint, including name and batch number of the active substance used as a starting material in veterinary medicinal products which is the subject of that complaint;
- (d) date the complaint is received;
- (e) action initially taken, including dates and identity of the person taking that action;
- (f) any follow-up action taken;
- (g) response provided to the originator of the complaint, including the date of the response;
- (h) final decision on the active substance batch concerned.

3. Records of complaints shall be retained in order to evaluate trends, product related frequencies, and severity, with a view to taking additional, and if appropriate, immediate corrective action. Those records shall be made available to the competent authorities during inspections.

4. Where a complaint is referred to the original active substance manufacturer, the record maintained by the person referred to in Article 1(2) shall include any response received from the original active substance manufacturer, including the date and information provided.

5. In the event of a serious or potentially life-threatening situation, the persons referred to in Article 1(2) shall inform, seek advice from and follow the instructions of local, national or international authorities, as appropriate.

Article 21

Returns

1. Returned active substances used as starting materials in veterinary medicinal products shall be identified as such and segregated physically or, if an equivalent electronic system is available, electronically, pending the outcome of an investigation into those returned active substances.

2. Active substances used as starting materials in veterinary medicinal products which have left the care of the persons referred to in Article 1(2) shall only be returned to saleable stock if all of the following conditions are met:

- (a) the active substance used as a starting material in veterinary medicinal products is in its original unopened containers with all original security seals present and is in good condition;
- (b) it is demonstrated by written information provided by the customer that the active substance used as a starting material in veterinary medicinal products has been stored and handled under proper conditions;
- (c) the remaining shelf life is acceptable;
- (d) the active substance used as a starting material in veterinary medicinal products has been examined and assessed by a person trained and authorised to do so;
- (e) no loss of information or traceability has occurred.

3. The assessment under paragraph (2) shall take into account the nature of the active substance used as a starting material in veterinary medicinal products, any special storage conditions it requires and the time elapsed since it was supplied. As necessary and if there is any doubt about the quality of the returned active substance used as a starting material in veterinary medicinal products, advice shall be sought from the original active substance manufacturer.
4. Records of returned active substances used as starting materials in veterinary medicinal products shall be maintained. For each return, documentation shall include the following:
 - (a) name or company name and permanent address or registered place of business of the consignee returning the active substance used as starting materials in veterinary medicinal products;
 - (b) name or designation of the active substance used as a starting material in veterinary medicinal products;
 - (c) batch number of the active substance used as a starting material in veterinary medicinal products;
 - (d) quantity of active substance used as a starting material in veterinary medicinal products returned;
 - (e) reason for return;
 - (f) use or disposal of the returned active substance used as a starting material in veterinary medicinal products and records of the assessment performed.
5. Only appropriately trained and authorised personnel shall release active substances used as starting materials in veterinary medicinal products for return to saleable stock.
6. Active substances used as starting materials in veterinary medicinal products returned to saleable stock shall be placed so that the stock rotation system operates effectively.

Article 22

Recalls

1. There shall be a procedure in place that defines the circumstances under which a recall of an active substance used as a starting material in veterinary medicinal products shall be considered.
2. The recall procedure shall specify:
 - (a) who shall be involved in evaluating the information;
 - (b) how a recall shall be initiated;
 - (c) who shall be informed about the recall;
 - (d) how the recalled material shall be treated.
3. The person responsible for the quality system shall be involved in recalls.

CHAPTER VIII

SELF-INSPECTIONS AND FINAL PROVISIONS

Article 23

Self-inspections

1. The persons referred to in Article 1(2) shall conduct and record self-inspections in order to monitor the implementation of and compliance with good distribution practice for active substances used as starting materials in veterinary medicinal products laid down in this Regulation.

2. Regular self-inspections shall be performed in accordance with a schedule set out in the quality system.
3. Self-inspections shall be conducted in an impartial and detailed way by designated competent company personnel.
4. The results of all self-inspections shall be recorded. Reports shall contain all observations made during the inspection and be presented to the relevant personnel as well as management.
5. Necessary CAPA shall be taken and the effectiveness of the CAPA shall be reviewed.

Article 24

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, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1281**of 2 August 2021****laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 laying down Community Regulation on veterinary medicinal products and repealing Directive 2001/82/EC ⁽¹⁾, and in particular Article 77(6) thereof,

Whereas:

- (1) Good pharmacovigilance practice should cover all activities across the full life-cycle management of veterinary medicinal products in relation to safety authorised in accordance with Article 5 of Regulation (EU) 2019/6 or registered in accordance with Article 86 of that Regulation. Non-compliance with pharmacovigilance obligations could have a potentially serious impact on public and animal health and on the environment.
- (2) Marketing authorisation holders should respect good pharmacovigilance practice by implementing a robust and efficient pharmacovigilance system, supported by a quality management system covering all pharmacovigilance activities, including a risk management system covering all procedures and processes necessary to optimise safe use of their veterinary medicinal products. The quality management system should be updated regularly and checked by audits at risk-based intervals, and should include provisions to identify corrective and preventive actions and manage and document corresponding changes to those actions.
- (3) In order to facilitate the enforcement of pharmacovigilance obligations, the marketing authorisation holder should retain full responsibility for all pharmacovigilance obligations subcontracted to third parties.
- (4) As an important part of a marketing authorisation holder's quality management system, all information on pharmacovigilance data, including standard procedures, should be saved and preserved in a document management system. The document management system should include a record management system to process safety data.
- (5) Adverse event reporting remains the primary information source for post-authorisation safety monitoring and provides most of the data for the evaluation of the benefit-risk balance of a product. Marketing authorisation holders should, within 30 days, record all adverse event reports collected for all their veterinary medicinal products in the Union pharmacovigilance database in order to enable analysis of information received over the full life-cycle of a product.
- (6) Standard terminology in the field of medical science should be used in harmonising the exchange of pharmacovigilance information to improve consistency of data related to adverse event reporting.

⁽¹⁾ OJ L 4, 7.1.2019, p. 43.

- (7) The calculation of incidence of adverse events should allow for the comparison of different products, product groups or different time periods for the same product.
- (8) The signal management process should enable continuous monitoring of the benefit-risk balance of a veterinary medicinal product. It should therefore be a core element of the pharmacovigilance system, allowing appropriate measures to be taken, in accordance with Article 77(4) of Regulation (EU) 2019/6.
- (9) Communication of information about the safe and effective use of veterinary medicinal products should support appropriate use and should be considered throughout the risk management process.
- (10) The pharmacovigilance system master file should contain all relevant information and documents concerning pharmacovigilance activities, including information on tasks that have been subcontracted to third parties. That information should contribute to the appropriate planning and conduct of audits by marketing authorisation holders and the supervision of pharmacovigilance activities by the qualified person responsible for pharmacovigilance. Furthermore, that information should enable competent authorities to verify compliance concerning all aspects of the system.
- (11) Marketing authorisation holders should ensure that they and any third party carrying out pharmacovigilance activities in relation to their veterinary medicinal products make the necessary preparations in order to facilitate controls or inspections by the national competent authorities or the European Medicines Agency.
- (12) This Regulation should apply from 28 January 2022 in accordance with Article 153(1) of Regulation (EU) 2019/6.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

GENERAL PROVISIONS AND PHARMACOVIGILANCE SYSTEM

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) ‘quality management system’ means a formalised system that provides for comprehensive processes, procedures, and responsibilities for achieving quality policies and objectives to coordinate and direct an organisation’s activities and improve its effectiveness and efficiency in this regard on a continuous basis;
- (b) ‘performance indicator’ means an item of information collected at regular intervals to monitor the performance of a system;
- (c) ‘signal’ means information that arises from one or multiple sources, including observations and experiments, which suggests a potentially new causal association, or a new aspect of a known causal association between an intervention and an adverse event or a set of related adverse events, that is judged likely to justify further investigation of possible causality.

*Article 2***Pharmacovigilance system**

1. The marketing authorisation holder's pharmacovigilance system established and maintained in accordance with Article 77(1) of Regulation (EU) 2019/6 shall meet the requirements laid down in this Regulation.
2. The marketing authorisation holder shall ensure that the pharmacovigilance system:
 - (a) is fully functional;
 - (b) is covered by a comprehensive quality management system as provided for in Articles 4 to 9 of this Regulation;
 - (c) includes a risk management system covering all procedures and processes necessary to optimise safe use and monitor benefit-risk balance of their veterinary medicinal products;
 - (d) sets out clearly the roles, responsibilities and required tasks for all parties involved in operating the system;
 - (e) provides for proper control over the system and ensures that, when needed, the necessary changes to the system to improve its operation can be carried out;
 - (f) is clearly and unambiguously documented in the pharmacovigilance system master file.
3. Marketing authorisation holders shall ensure that the qualified person responsible for pharmacovigilance referred to in Article 77(8) of Regulation (EU) 2019/6 has sufficient control over the pharmacovigilance system in order to promote, maintain and improve compliance with Article 78 of that Regulation. They shall ensure that there is an appropriate procedure in place to identify and deal with any conflicts of interest of the qualified person responsible for pharmacovigilance.
4. Marketing authorisation holders shall have a sufficient number of competent and appropriately qualified and trained personnel working for them in the performance of pharmacovigilance activities.
5. All persons involved in the procedures and processes of the pharmacovigilance system established for the performance of pharmacovigilance activities shall ensure the proper functioning of the system when fulfilling their role for the marketing authorisation holder.
6. Marketing authorisation holders shall establish and document back-up procedures to ensure business continuity with regard to the fulfilment of pharmacovigilance obligations.
7. Marketing authorisation holders shall retain full responsibility for all pharmacovigilance obligations subcontracted to third parties as laid down in Regulation (EU) 2019/6 and in this Regulation.

*Article 3***Qualified person responsible for pharmacovigilance**

1. The qualifications and training of the qualified person responsible for pharmacovigilance referred to in Article 77(8) of Regulation (EU) 2019/6 shall include documented experience in pharmacovigilance.
2. The qualified person responsible for pharmacovigilance shall have completed veterinary surgeon training in accordance with Article 38 of Directive 2005/36/EC of the European Parliament and of the Council ^(¹). Where such training has not been completed, marketing authorisation holders shall make arrangements to ensure that the qualified person responsible for pharmacovigilance is assisted by a veterinary surgeon on a continuous basis. That assistance shall be duly documented.

⁽¹⁾ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

CHAPTER 2

QUALITY MANAGEMENT SYSTEM

Article 4

Quality management system for pharmacovigilance

1. Marketing authorisation holders shall establish and implement an adequate and effective quality management system for the performance of their pharmacovigilance activities.
2. The quality management system shall be described in the pharmacovigilance system master file.
3. Marketing authorisation holders shall ensure that the quality management system includes detailed policies, processes and procedures on document management, training, audits, and change management covering the activities in accordance with Articles 5 to 9. Those policies, processes and procedures shall provide for a review of the quality management system at regular risk-based intervals, based on pre-defined criteria.
4. Marketing authorisation holders shall ensure that the quality management system includes detailed policies, processes and procedures for the record management system and data collection in accordance with Articles 10 to 15, for the following pharmacovigilance activities:
 - (a) initial recording of any suspected adverse event;
 - (b) collection of additional data;
 - (c) collation of reports of suspected adverse events and additional data;
 - (d) data handling other than mentioned in points (a) to (c);
 - (e) evaluation of data;
 - (f) monitoring of quality, integrity and completeness of all information registered in the pharmacovigilance system including information reported to the Union pharmacovigilance database and management of duplicates;
 - (g) recording of any adverse event in the Union pharmacovigilance database;
 - (h) archiving of all relevant documents.
5. Marketing authorisation holders shall ensure that the quality management system includes detailed policies, processes and procedures for risk management, monitoring of the benefit-risk balance, signal management and communication to all relevant stakeholders in accordance with Articles 16 to 20.
6. Marketing authorisation holders shall ensure that the quality management system includes detailed policies, processes and procedures for the maintenance and availability of the pharmacovigilance system master file in accordance with Articles 24 and 25.
7. Marketing authorisation holders shall clearly define the roles and responsibilities of those persons involved in pharmacovigilance activities and in documentation in accordance with paragraphs 3 to 6 of this Article.
8. Marketing authorisation holders shall set up a quality management system using the following:
 - (a) quality planning: establishing structures, integrated planning and consistent processes;
 - (b) quality adherence: carrying out tasks and responsibilities in accordance with quality requirements;
 - (c) quality control and assurance: monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are implemented;
 - (d) quality improvements: correcting and improving the structures and processes where necessary.

*Article 5***Document management system**

1. Marketing authorisation holders shall set up and maintain a document management system to keep all documents related to pharmacovigilance activities. Those documents shall be archived and indexed to enable accurate and easy accessibility throughout the period of record-keeping.
2. Documents shall be subject to version control, as appropriate.
3. Documents and pharmacovigilance data relating to individual authorised veterinary medicinal products shall be retained as long as the product is authorised and for 5 years after the marketing authorisation ceases to be valid.

*Article 6***Training**

1. All personnel involved in the performance of pharmacovigilance activities shall receive initial and continuous training for their role and responsibilities in relation to the activities mentioned in Article 4, paragraphs 3 to 6, also including activities related to clinical trials, technical product complaints, standards, sales and marketing.
2. Marketing authorisation holders shall have a training management system in place for maintaining and developing the competences of their personnel. Information on training plans and records for pharmacovigilance activities and a reference to their location shall be kept in Annex IV, point (iv) to the pharmacovigilance system master file.

*Article 7***Performance indicators**

Marketing authorisation holders shall use relevant performance indicators to continuously monitor the performance of pharmacovigilance activities and the outcome of risk minimisation measures. They shall keep a list of those performance indicators including the reason why they have been chosen and a description on how to use them in Annex IV, point (iii) to the pharmacovigilance system master file.

*Article 8***Audits**

1. Marketing authorisation holders shall perform audits of the pharmacovigilance system at regular risk-based intervals to ensure that it complies with the requirements set out in this Regulation and to determine its effectiveness. The audits shall be planned to cover all pharmacovigilance activities for a defined period and verify their conformity with the policies, processes and procedures of the quality management system. They shall be conducted by individuals who have no direct involvement in or responsibility for the matters or processes audited.
2. Any third party contracted to carry out pharmacovigilance activities in whole or in part, on behalf of or in conjunction with marketing authorisation holders, shall accept to be audited by or on behalf of marketing authorisation holders.
3. Marketing authorisation holders shall draw up a risk-based schedule for auditing. The process for risk-based planning shall be described and the rationale for the risk-based schedule shall be documented. A list of scheduled and completed audits, including outstanding critical and major findings, shall be documented in Annex IV, point (ii) to the pharmacovigilance system master file.

*Article 9***Corrective and preventive action and change management**

1. Marketing authorisation holders shall have a process in place for managing corrective and preventive actions, to mitigate any deviations detected in audits, daily operational work and findings from inspections. Associated corrective and preventative actions shall be documented for the last 5 years.
2. Corrective and preventive action plans requested by the competent authority shall document in writing an effective process, systematically addressing and minimising identified risk or defects. It shall include root cause analysis, address clear possible corrective and preventive measures, address timelines for action, and communication to relevant stakeholders.
3. Marketing authorisation holders shall monitor and assess the effectiveness of corrective and preventive actions. Any changes associated with those actions shall be evaluated.
4. Change management shall provide for a controlled process of change, including monitoring and documenting the effectiveness of the corrective or preventive actions and communication to relevant stakeholders.

CHAPTER 3

RECORD MANAGEMENT SYSTEM, DATA COLLECTION AND MONITORING*Article 10***Record management system**

1. The document management system referred to in Article 5 shall include a record management system for receiving, recording, collating and assessing information on adverse events and for recording safety information.
2. The description of the record management system for recording adverse events and safety information in Section D of the pharmacovigilance system master file shall include the following information:
 - (a) type of record management system used for adverse event reports, including the name of the database used, if applicable;
 - (b) location where the record management system is kept;
 - (c) description of functionality of the record management system;
 - (d) operational responsibility of the personnel responsible for the record management system;
 - (e) summary of the assessment of its fitness for purpose.
3. Marketing authorisation holders may use the Union pharmacovigilance database as their electronic record management system for recording adverse events. In that case, Section D of the Pharmacovigilance system master file shall indicate that the record management system being used is the Union pharmacovigilance database.

*Article 11***Suspected adverse events**

Marketing authorisation holders shall collect and maintain detailed records of all suspected adverse events from all sources within or outside the Union in accordance with Article 77(1) of Regulation (EU) 2019/6. Those records shall include post-marketing surveillance studies and literature relating to their veterinary medicinal products, and suspected adverse events concerning use of their veterinary medicinal products outside the terms of the marketing authorisation.

*Article 12***Recording of adverse events**

1. Information concerning suspected adverse events shall be recorded and coded using internationally agreed standards. The latest version of the standards shall be used in line with the specified implementation dates.
2. Records of adverse events shall include at least the following:
 - (a) an identifiable reporter or source (including the country code);
 - (b) details of identifiable animals, humans or environment;
 - (c) veterinary or human medicinal product names;
 - (d) details on the adverse events.
3. Where the name of the product is not included in the initial report from the primary source, marketing authorisation holders shall make reasonable efforts to obtain the name or at least part of the trade name of the medicinal product concerned. If neither the name nor the trade names are known and cannot be obtained, the name of the active substances shall be recorded in the record management system.
4. Marketing authorisation holders shall make reasonable efforts to request further information, as necessary, to enable investigation of suspected adverse events, including the results of appropriate diagnostic tests, to ensure that adverse event data reported are complete.

*Article 13***Adverse event recording in the Union pharmacovigilance database**

1. Marketing authorisation holders shall record adverse events in the Union Pharmacovigilance database.
2. A language customary in the field of medical science shall be used to record non-coded information in the Union pharmacovigilance database, including such information related to adverse events originating outside the Union.
3. Marketing authorisation holders shall regularly monitor the scientific literature to identify any adverse events concerning their veterinary medicinal products. The method for monitoring literature and the frequency with which monitoring is conducted shall take into account the risk-based approach. It shall at least cover the following topics: active substance, type of product, the stability in number and incidence of reports observed over time on the market and the stability of the pharmacovigilance profile.

*Article 14***Provision of additional data**

1. To enable comprehensive analysis of adverse event reports from third countries, marketing authorisation holders shall record in the Union product database the corresponding product names and authorisation numbers for the same product or, if the same product is not authorised in the Union, for a similar product authorised in the Union, as defined in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Guideline 24 ⁽³⁾. Marketing authorisation holders shall update the information when necessary.
2. The total number of animals displaying an adverse event during a defined period of time, multiplied by 100 and divided by an estimate of the number of animals treated during that period, shall provide the incidence of reported adverse events. To calculate the estimated number of animals treated from the information on volume of sales required under Article 58(12) of Regulation (EU) 2019/6, marketing authorisation holders shall identify and provide a factor to the Union

⁽³⁾ https://www.ema.europa.eu/en/documents/scientific-guideline/vich-gl24-guideline-pharmacovigilance-veterinary-medicinal-products-management-adverse-event-reports_en.pdf

product database for each of their veterinary medicinal products according to country, target species and pack size. According to the posology of the product, the factor will determine how many animals can be treated with one package of a given pack size, regardless of the formulation. To calculate the incidence for adverse event reports from third countries via the estimated number of animals treated, marketing authorisation holders shall provide information on volume of sales for each of their veterinary medicinal products, combined for all third countries according to target species, and in regard to the same or a comparable pack size.

3. The Agency shall publish guidance on the mathematical formula to calculate the factor. Marketing authorisation holders shall record their assumptions on distribution of sales per target species and treatment regimen per target species that they use for the calculation of the factor in the pharmacovigilance system master file. Marketing authorisation holders shall update the factor when necessary.

Article 15

Post-marketing surveillance studies

1. Post-marketing surveillance studies may be conducted by marketing authorisation holders on their own initiative or shall be conducted by marketing authorisation holders on request of a competent authority or the Agency in accordance with Article 76(3) and (4) of Regulation (EU) 2019/6.

2. Voluntary post-marketing surveillance studies shall be notified to the responsible competent authority or the Agency immediately after initiation. The marketing authorisation holder shall submit the protocol and the final report within one year after completion of the data collection to the competent authority or the Agency, as applicable.

3. For a requested post-marketing surveillance study, the marketing authorisation holder shall submit the draft study protocol to the competent authority or the Agency who requested the study, as applicable, for approval at the latest two months before the trial is conducted.

4. The marketing authorisation holder shall notify the competent authority of the territory in which the post-marketing surveillance study is conducted, where that competent authority did not request the study.

5. The marketing authorisation holder shall submit the study protocol, the summary of the final study report and the final study report after finalisation of the study to the competent authority or the Agency who requested the post-marketing surveillance study, as applicable, and to the competent authority of the territory in which the study was conducted.

6. The marketing authorisation holder shall submit all relevant documents in a language customary in the field of medical science, except for studies to be conducted for veterinary medicinal products that are authorised only in one Member State. For those studies, the marketing authorisation holder shall provide a translation of the title, the summary of the study protocol and a summary of the final report of the study in a language customary in the field of medical science.

7. The marketing authorisation holder shall ensure that all information concerning the study is handled and stored in such a way that it can be correctly reported, interpreted and verified. The marketing authorisation holder shall ensure that the analytical dataset and statistical programmes used to generate the data contained in the final report of the study are stored electronically and are available for audits and inspections upon request of the competent authority or the Agency, as applicable.

*Article 16***Risk management system**

1. Marketing authorisation holders shall ensure that the pharmacovigilance system includes a risk management system to take appropriate action to minimise identified risks, when necessary.
2. The risk management system shall include a process for monitoring the benefit-risk balance of products and performing signal management. It shall also include a communication system in accordance with Article 20.
3. Marketing authorisation holders shall ensure continuous assessment and document the risk management measures and the outcome of risk minimisation measures in the pharmacovigilance system master file.

*Article 17***Signal management process**

1. The signal management process shall consist of at least pharmacovigilance processes of signal detection, prioritisation, validation, assessment and documentation of outcome.
2. Where marketing authorisation holders are responsible for the same or a similar veterinary medicinal product as defined in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Guideline 24 ^(*), authorised in different Member States through different authorisation procedures, the signal management process may be performed at active substance level for all the products combined.
3. Marketing authorisation holders shall perform signal management using a risk-based approach and monitor the data with a frequency proportionate to the identified risk. The risk-based approach shall take into account the following topics: type of product, length of time on the market and stability of the pharmacovigilance profile, identified and potential risks and the need for additional information. The risk-based approach shall be applied to determine the methodology, extent and frequency of the signal management process and the rationale shall be documented.
4. Signal assessment shall analyse and evaluate the potential impact of a signal on the benefit-risk balance of a product and shall allow for relative comparison between different products or product groups, including analysis at active substance level and stratified analyses.
5. The Agency shall publish guidance on best practice for signal management.
6. The outcome of the signal management process shall be recorded and the rationale shall be kept ready for inspection.
7. Marketing authorisation holders shall conduct at least one signal detection analysis per year for each of their active substances or products in the Union pharmacovigilance database.
8. Marketing authorisation holders using the Union pharmacovigilance database as their record management system for adverse event reports shall perform signal management in the Union pharmacovigilance database.
9. When marketing authorisation holders do not use the Union pharmacovigilance database for signal management, they shall ensure that their record management system for adverse event reports contain all adverse event reports for which they are responsible. In particular, they shall ensure that adverse event reports concerning their veterinary medicinal products reported to the Union pharmacovigilance database from other sources are recorded in their own database.

^(*) https://www.ema.europa.eu/en/documents/scientific-guideline/vich-gl24-guideline-pharmacovigilance-veterinary-medicinal-products-management-adverse-event-reports_en.pdf

*Article 18***Monitoring benefit-risk balance**

1. Marketing authorisation holders shall continuously monitor the benefit-risk balance of their products in light of all available information from veterinarians, other healthcare professionals, the general public, adverse event reports by other marketing authorisation holders or competent authorities recorded in the Union pharmacovigilance database, and scientific literature.
2. Marketing authorisation holders shall continuously monitor the benefit-risk balance and take necessary risk minimisation measures to optimise the safe use of their veterinary medicinal products.
3. Marketing authorisation holders shall consider the potential impact of each adverse event on the benefit-risk balance of their products, unless there is no causal link between their products and the adverse event.

*Article 19***Conclusion on the benefit-risk balance**

1. Marketing authorisation holders shall annually record a conclusion on the benefit-risk balance for each of their products in the Union pharmacovigilance database and confirm that the signal management process has been conducted.
2. The outcome of the signal management process shall be included in the conclusion referred to in paragraph 1 if a new validated signal or signals related to medically important Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terms have been identified, even if no further action is considered necessary. The conclusion shall explain whether the benefit-risk balance is still considered as favourable and if any actions to improve the benefit-risk balance are deemed necessary.
3. When marketing authorisation holders identify a new risk or a change of the benefit-risk balance of one of their products, a summary of the analysis and a conclusion on the benefit-risk balance shall be recorded in the Union pharmacovigilance database. This shall be done in accordance with the timelines in Article 81(2) of Regulation (EU) 2019/6, notifying the competent authority or the Agency, as applicable.

*Article 20***Communication**

1. Marketing authorisation holders shall have an overarching communication plan that identifies the relevant stakeholders in the Union, including veterinarians, other healthcare professionals, customers and the general public. In cases of urgent safety concerns, it shall outline the approach to be taken to communicate in a timely manner concerns arising from pharmacovigilance data or in relation to other relevant pharmacovigilance information.
2. The communication plan shall include information on how marketing authorisation holders:
 - (a) identify the target audience;
 - (b) identify effective means for communication with the intended target audience;
 - (c) identify the specific objectives of the communication;
 - (d) define a timetable for the communication;
 - (e) ensure the relevance and clarity of the information for the intended target audience;
 - (f) identify and coordinate all stakeholders involved in the communication;
 - (g) give prior or simultaneous notification to the competent authority or the Agency, as applicable, of any public announcement on pharmacovigilance information, in accordance with Article 77(11) of Regulation (EU) 2019/6;
 - (h) measure the effectiveness of the communication.

3. Marketing authorisation holders shall use the data-processing network of the Union pharmacovigilance database for communication of alerts related to pharmacovigilance data.

CHAPTER 4

THE PHARMACOVIGILANCE SYSTEM MASTER FILE

Article 21

General requirements for the pharmacovigilance system master file

1. The information in the pharmacovigilance system master file required under Article 77(2) of Regulation (EU) 2019/6 shall be accurate and reflect the pharmacovigilance system in place.
2. The contractual arrangements between marketing authorisation holders and third parties concerning pharmacovigilance activities shall be clearly documented, detailed and up-to-date.
3. Marketing authorisation holders may, where appropriate, use separate pharmacovigilance systems for different categories of veterinary medicinal products. Each such system shall be described in a separate pharmacovigilance system master file.

Article 22

Content and structure of the pharmacovigilance system master file

1. The pharmacovigilance system master file shall consist of a main part describing the pharmacovigilance system, together with annexes containing detailed information.
2. The main part of the pharmacovigilance system master file shall contain the following Sections:
 - (a) Section A containing general information regarding the pharmacovigilance system master file:
 - (i) pharmacovigilance system master file reference number;
 - (ii) pharmacovigilance system master file location for the purpose of pharmacovigilance inspections in accordance with Article 126(4) of Regulation (EU) 2019/6;
 - (b) Section B containing information regarding the qualified person responsible for pharmacovigilance, assistant veterinary surgeon and associated back-up procedures:
 - (i) information on the qualified person responsible for pharmacovigilance including name, contact details and a signed statement from the marketing authorisation holder and the qualified person confirming that the qualified person concerned has the necessary means to fulfil the tasks and responsibilities required by Regulation (EU) 2019/6;
 - (ii) documentation on the marketing authorisation holder arrangements concerning the assistant veterinary surgeon referred to in Article 3(2), if applicable, including the contact details;
 - (iii) a description of back-up arrangements that apply in the absence of the qualified person responsible for pharmacovigilance or the veterinary surgeon, assisting the qualified person responsible for pharmacovigilance referred to in Article 2(6);
 - (c) Section C containing information on the marketing authorisation holder:
 - (i) a detailed description of the organisational structure of the marketing authorisation holder, including a parent company or group of companies associated;
 - (ii) the position of the qualified person responsible for pharmacovigilance within the organisation.

- (d) Section D containing a description of the document management system referred to in Article 5, including the record management system for adverse event recording referred to in Article 10;
 - (e) Section E containing a description of the quality management system for pharmacovigilance activities, including all of the following:
 - (i) a description of the processes used for pharmacovigilance activities referred to in Article 4(3), (4), (5) and (6);
 - (ii) a description of the training management system in place referred to in Article 6(2);
 - (iii) a description of the system used for documenting or archiving information referred to in Article 5(2);
 - (iv) a description of the system for monitoring the performance of the pharmacovigilance system as referred to in Article 7;
 - (v) a description of the responsibilities for quality assurance auditing of the pharmacovigilance system as referred to in Article 8 including, where appropriate, auditing of subcontractors;
 - (vi) a list of audits associated with unresolved critical or major findings;
 - (vii) a description of the corrective and preventive action plan management and change management in place as referred to in Article 9;
 - (f) Section F containing a description of the contractual arrangements between marketing authorisation holders and third parties concerning pharmacovigilance activities, where applicable.
3. The pharmacovigilance system master file shall contain the following Annexes:
- (a) Annex I: a logbook containing records of all changes to the main part of the pharmacovigilance system master file;
 - (b) Annex II: additional information regarding the qualified person responsible for pharmacovigilance, assistant veterinary surgeon, and associated back-up arrangements:
 - (i) curriculum vitae including information on qualifications and training of the qualified person responsible for pharmacovigilance as referred to in Article 3(1) and, if applicable, the assistant veterinary surgeon as referred to in Article 3(2);
 - (ii) a description of the tasks and responsibilities of the qualified person responsible for pharmacovigilance;
 - (iii) proof of registration with the pharmacovigilance database;
 - (iv) a list of the pharmacovigilance activities that have been delegated by the qualified person responsible for pharmacovigilance to third parties;
 - (c) Annex III: additional information on the marketing authorisation holder:
 - (i) a list of all veterinary medicinal products covered by the pharmacovigilance system master file, including the international non-proprietary name (INN) of the active substances, if applicable, the Member States in which the product is authorised or registered, the type of procedure for authorisation and the authorisation numbers in each Member State where the product is authorised;
 - (ii) a list of reference numbers for other pharmacovigilance system master files held by the same marketing authorisation holder, where applicable;
 - (iii) a list of local or regional representatives for the purpose of receiving reports of suspected adverse events, including their contact details, responsibilities and territories, where applicable;
 - (iv) a list of the sites where pharmacovigilance activities listed in Article 4(3), (4), (5) and (6) are carried out;
 - (d) Annex IV: further details about the quality management system:
 - (i) a list of documents, policies, procedures and processes used for the pharmacovigilance activities referred to in Article 4(3), (4), (5) and (6);

- (ii) a list of all scheduled and completed audits including outstanding critical and major findings;
 - (iii) a list of performance indicators and how to use them, as referred to in Article 7, as applicable;
 - (iv) the information on training plans and records referred to in Article 6(2);
 - (v) the methodology to calculate the factor referred to in Article 14(2);
 - (vi) a list of risk management measures and the outcome of risk minimisation measures;
- (e) Annex V: further information on contractual arrangements between marketing authorisation holders and third parties concerning pharmacovigilance activities:
- (i) a list of the activities or services subcontracted by the marketing authorisation holder to third parties to fulfil pharmacovigilance obligations and information on who the activities or services are subcontracted to, including the name and address any subcontractors, where applicable;
 - (ii) a list of the tasks of the qualified person responsible for pharmacovigilance referred to in Article 78 of Regulation (EU) 2019/6 that have been totally or partially outsourced and the information on who the activities or services are subcontracted to, including the name and address of the subcontractor(s), where applicable;
 - (iii) a list of existing contracts and agreements with third parties, where applicable, including the products and territories concerned.
4. Where appropriate, information may be provided in the form of charts or flow diagrams.

Article 23

Summary

The summary of the pharmacovigilance system master file shall contain the following information:

- (a) the pharmacovigilance system master file reference number;
- (b) the pharmacovigilance system master file location;
- (c) name, contact details and place of operation of the qualified person responsible for pharmacovigilance;
- (d) the signed statement referred to in Article 22(2)(b), point (i);
- (e) the type of record management system used for adverse events reports including the name of the database, if applicable.

Article 24

Maintenance

1. Marketing authorisation holders shall keep the pharmacovigilance system master file up to date and revise it, where necessary, to take account of experience gained, and of technical and scientific progress.
2. Marketing authorisation holders shall ensure that the qualified person responsible for pharmacovigilance has permanent access to the pharmacovigilance system master file to fulfil the tasks referred to in Article 78 of Regulation (EU) 2019/6.
3. The pharmacovigilance system master file shall be subject to version control and indicate the date when it was last updated.
4. Marketing authorisation holders shall record in a logbook any alteration to the content of the main part of the pharmacovigilance system master file made within the last 5 years. Marketing authorisation holders shall indicate in the logbook the changed Section, the kind of change, the date, the person responsible and, where appropriate, the reason for the alteration.

5. Marketing authorisation holders shall, upon request, submit a copy of their logbook or another requested part of the pharmacovigilance system master file to the competent authorities or the Agency, as applicable, within 7 days.
6. Marketing authorisation holders shall notify the relevant competent authority or the Agency of any change in the information provided in the summary of the pharmacovigilance system master file by submitting a variation in accordance with Article 61 of Regulation (EU) 2019/6.
7. After the system as described in the pharmacovigilance system master file has been formally terminated, marketing authorisation holders shall keep an electronic version of it for 5 years.

Article 25

Location and availability

1. The pharmacovigilance system master file shall be located in the Union at the site where the main pharmacovigilance activities of the marketing authorisation holder are performed or at the site where the qualified person responsible for pharmacovigilance operates.
2. The pharmacovigilance system master file may be stored or made available in electronic form. The media used for storage or making available shall be searchable and shall remain readable over time.
3. When requested, a printed copy of the pharmacovigilance system master file arranged in accordance with Article 22(2) and (3), or parts thereof, shall be made available for audits and inspections. The printed copy or the requested part shall be complete and legible.
4. The pharmacovigilance system master file shall be permanently and immediately available for inspection at the site where it is kept. If the pharmacovigilance system master file is kept in electronic form, it is sufficient that the data stored in electronic form are directly available.

CHAPTER 5

CONTROLS AND INSPECTIONS BY COMPETENT AUTHORITIES

Article 26

Controls

1. Marketing authorisation holders shall be ready for controls in accordance with Article 123 of Regulation (EU) 2019/6 and shall also ensure the following are ready for those controls:
 - (a) their qualified person responsible for pharmacovigilance in accordance with Article 77(8) of Regulation (EU) 2019/6; and
 - (b) their representatives responsible for the reporting of adverse events in accordance with Article 14(1)(a) and (l) and Article 77(3) of Regulation (EU) 2019/6;
 - (c) any other natural or legal person carrying out pharmacovigilance activities in whole or in part, on behalf of or in conjunction with marketing authorisation holders.
2. Pharmacovigilance inspections carried out in accordance with Article 123(6) of Regulation (EU) 2019/6 may be performed as on-site or remote inspections.

*Article 27***Pharmacovigilance inspections**

1. Marketing authorisation holders shall be prepared for inspections of their pharmacovigilance system and the corresponding pharmacovigilance system master file in accordance with Article 123(6) and Article 126 of Regulation (EU) 2019/6 and shall ensure the same for any person mentioned in Article 26(1).
2. Marketing authorisation holders may be inspected on the site where the pharmacovigilance system master file is located or at any other site of those persons inspected in accordance with paragraph 1. With regard to a third party carrying out pharmacovigilance activities, the site to be inspected may be located within or outside the Union.
3. Marketing authorisation holders shall provide the necessary information requested by the competent authorities or the Agency in accordance with Article 79(6) of Regulation (EU) 2019/6 for on-site or remote inspections.
4. Pharmacovigilance inspections may be either routine inspections or targeted inspections; they may be product-specific or inspections of the general pharmacovigilance system. On the occasion of an inspection, marketing authorisation holders shall:
 - (a) present proof that they have personnel, systems and facilities in place to meet their pharmacovigilance obligations and that they are ready for inspection at any time;
 - (b) present proof in regard to their contractual arrangements, including a clear description of the roles and responsibilities of third parties to whom pharmacovigilance activities are subcontracted and provisions for their inspection and audit;
 - (c) demonstrate that the pharmacovigilance system is in compliance with legislation or relevant pharmacovigilance guidelines;
 - (d) provide information on the corrective and preventive action plan management and demonstrate the functionality and the implementation of any change management.
5. Marketing authorisation holders may be required by the competent authority or the Agency to communicate the corrective and preventive action plan in accordance with Article 9(2).

*Article 28***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*.

It shall apply from 28 January 2022.

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2021/1282

of 30 July 2021

appointing an alternate member, proposed by the Czech Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

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

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

Having regard to the proposal of the Czech Government,

Whereas:

- (1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.
- (2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ⁽²⁾, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the death of Mr Pavel HEČKO.
- (4) The Czech Government has proposed Mr Arnošt ŠTĚPÁNEK, representative of a regional body who holds a regional authority electoral mandate, *Zastupitel Královéhradeckého kraje, Česká republika* (Representative of the Hradec Králové Region, Czech Republic), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Arnošt ŠTĚPÁNEK, representative of a regional body who holds an electoral mandate, *Zastupitel Královéhradeckého kraje, Česká republika* (Representative of the Hradec Králové Region, Czech Republic), is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

⁽¹⁾ OJ L 139, 27.5.2019, p. 13.

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

Article 2

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

Done at Brussels, 30 July 2021.

For the Council
The President
G. DOVŽAN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1283

of 2 August 2021

on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 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 the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes in its Annex II a list of active substance/product-type combinations included in the review programme of existing active substances in biocidal products on 30 March 2019.
- (2) For a number of active substance/product-type combinations included in that list, all the participants have withdrawn or are considered to have withdrawn their support in a timely manner.
- (3) In accordance with Article 14(1) of Delegated Regulation (EU) No 1062/2014, the European Chemicals Agency ('the Agency') published an open invitation to take over the role of participant for those active substance/product-type combinations for which the role of participant had not previously been taken over. For some of those combinations no notification has been submitted or the notification has been rejected pursuant to Article 17(4) or (5) of that Regulation. Those active substance/product-type combinations which, in accordance with Article 20, first paragraph, point (b), of Delegated Regulation (EU) No 1062/2014, should not be approved for use in biocidal products are the following: metam-sodium (product-types 9 and 11); thiram (product-type 9); bronopol (product-type 9); peroxyoctanoic acid (product-type 2, 3, 4); Malt, ext. – Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Hordeum*, *Gramineae* (product-type 19); 2,2-Dibromo-2-cyanoacetamide (product-type 13).
- (4) In addition, in accordance with Article 12(3) of Delegated Regulation (EU) No 1062/2014, the Agency informed the Commission of those active substance/product-type combinations for which all participants have withdrawn or are considered to have withdrawn their support in a timely manner, and for which the role of participant had previously been taken over. Those active substance/product-type combinations which, in accordance with Article 20, first paragraph, point (a), of that Regulation, should not be approved for use in biocidal products are the following: silver, as a nanomaterial (product-types 2, 4, 9); *Eucalyptus citriodora* oil and citronellal, hydrated, cyclized (product-type 19); 2-Hydroxy- $\alpha,\alpha,4$ -trimethylcyclohexanemethanol (product-type 19); chlorine dioxide generated from sodium chlorite and sodium persulfate (product-types 2, 3, 4, 5, 11); amines, C10-16-alkyldimethyl, N-oxides (product-type 4); *Capsicum oleoresin* (product-type 19); *Capsicum annuum*, ext. (product-type 19); reaction mass of (6E)-N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnon-6-enamide and N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnonanamide (product-type 19).

⁽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).

- (5) 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 active substances listed in the Annex are not approved for the product-types indicated therein.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Active substance/product-type combinations not approved:

Entry Number in Annex II to Regulation (EU) No 1062/2014	Substance name	Rapporteur Member State	EC number	CAS number	Product-type (s)
9	Bronopol	ES	200-143-0	52-51-7	9
206	Thiram	BE	205-286-2	137-26-8	9
210	Metam-sodium	BE	205-293-0	137-42-8	9, 11
1023	Silver, as a nanomaterial	SE	231-131-3	7440-22-4	2, 4, 9
494	2,2-Dibromo-2-cyanoacetamide (DBNPA)	DK	233-539-7	10222-01-2	13
1047	<i>Eucalyptus citriodora</i> oil and citronellal, hydrated, cyclized	CZ	n/a	n/a	19
609	2-Hydroxy- α , α ,4-trimethylcyclohexanemethanol	CZ	255-953-7	42822-86-6	19
813	Peroxyoctanoic acid	FR	n/a	33734-57-5	2, 3, 4
1044	Chlorine dioxide generated from sodium chlorite and sodium persulfate	DE	n/a	n/a	2, 3, 4, 5, 11
1064	Malt, ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Hordeum</i> , <i>Gramineae</i>	AT	232-310-9	8002-48-0	19
692	Amines, C10-16-alkyldimethyl, N-oxides	PT	274-687-2	70592-80-2	4
1059	<i>Capsicum oleoresin</i> Extractives and their physically modified derivatives. It is a product which may contain resin acids and their esters, terpenes, and oxidation or polymerization products of these terpenes. (<i>Capsicum frutescens</i> , <i>Solanaceae</i>)	BE	Not available	8023-77-6	19
1060	<i>Capsicum annuum</i> , ext. Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Capsicum annuum</i> , <i>Solanaceae</i> .	BE	283-403-6	84625-29-6	19
1061	Reaction mass of (6E)-N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnon-6-enamide and N-(4-hydroxy-3-methoxy-2-methylphenyl)-8-methylnonanamide	BE	Not available	Not available	19

COMMISSION IMPLEMENTING DECISION (EU) 2021/1284**of 2 August 2021****postponing the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance aluminium phosphide was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-types 14 and 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 will expire on 31 August 2021 and 31 January 2022, respectively. On 26 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18.
- (3) On 25 May 2020, the evaluating competent authority of Germany informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

- (6) Consequently, for reasons beyond the control of the applicant, the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 to 31 July 2024.
- (7) Except for the expiry date of approval, aluminium phosphide remains approved for use in biocidal products of product-types 14 and 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 is postponed to 31 July 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1285**of 2 August 2021****postponing the expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance magnesium phosphide was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of magnesium phosphide for use in biocidal products of product-type 18 will expire on 31 January 2022. On 28 July 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of magnesium phosphide.
- (3) On 1 October 2020, the evaluating competent authority of Germany informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of magnesium phosphide for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 July 2024.
- (7) Except for the expiry date of approval, magnesium phosphide remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of magnesium phosphide for use in biocidal products of product-type 18 is postponed to 31 July 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1286**of 2 August 2021****postponing the expiry date of approval of dinotefuran for use in biocidal products of product-type 18****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance dinotefuran was approved as an active substance for use in biocidal products of product-type 18 ⁽²⁾.
- (2) The approval of dinotefuran for use in biocidal products of product-type 18 will expire on 31 May 2022. On 11 November 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of dinotefuran.
- (3) On 25 March 2021, the evaluating competent authority of Belgium informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of dinotefuran for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of dinotefuran for use in biocidal products of product-type 18 for a period sufficient to enable the examination of the application. Considering the time limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 30 November 2024.
- (7) Except for the expiry date of approval, dinotefuran remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/416,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2015/416 of 12 March 2015 approving dinotefuran as an active substance for use in biocidal products for product-type 18 (OJ L 68, 13.3.2015, p. 30).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of dinotefuran for use in biocidal products of product-type 18 is postponed to 30 November 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1287**of 2 August 2021****postponing the expiry date of approval of indoxacarb for use in biocidal products of product-type 18****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance indoxacarb was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 18, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) On 26 June 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of indoxacarb for use in biocidal products of product-type 18.
- (3) On 12 November 2018, the evaluating competent authority of France informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) As the competent authority is carrying out a full evaluation of the application, in accordance with Article 14(3) of Regulation (EU) No 528/2012, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance within 270 days of receipt of the recommendation from the evaluating competent authority.
- (5) Pursuant to Implementing Decision (EU) 2019/1030 ⁽³⁾, the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 has been postponed to 30 June 2022 in order to allow sufficient time for the examination of the application. However, the evaluating competent authority has not yet finalised the examination and has not yet submitted its assessment report and the conclusions of its evaluation to the Agency.
- (6) On 29 October 2020, the evaluating competent authority has requested the applicant to submit additional information to carry out the evaluation in accordance with Article 8(2) of Regulation (EU) No 528/2012 and has set the deadline of 30 September 2022 for submitting this information.
- (7) Consequently, for reasons beyond the control of the applicant, the approval of indoxacarb for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 for a period of time sufficient to enable the completion of the examination of the application.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Commission Implementing Decision (EU) 2019/1030 of 21 June 2019 postponing the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 (OJ L 167, 24.6.2019, p. 32).

- (8) Considering the time necessary for the completion of the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 30 June 2024.
- (9) Except for the expiry date of approval, indoxacarb remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of indoxacarb for use in biocidal products of product-type 18 is postponed to 30 June 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1288**of 2 August 2021****postponing the expiry date of approval of boric acid for use in biocidal products of product-type 8****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance boric acid was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of boric acid for use in biocidal products of product-type 8 will expire on 31 August 2021. On 28 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of boric acid.
- (3) As boric acid is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾, it meets the exclusion criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012.
- (4) On 2 July 2020, the evaluating competent authority of the Netherlands informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (7) Consequently, for reasons beyond the control of the applicant, the approval of boric acid for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of boric acid for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p.1).

⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of boric acid may therefore be renewed, it is appropriate to postpone the expiry date of approval to 28 February 2024.

- (8) Except for the expiry date of approval, boric acid remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of boric acid for use in biocidal products of product-type 8 is postponed to 28 February 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1289
of 2 August 2021
postponing the expiry date of approval of dazomet for use in biocidal products of product-type 8
(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance dazomet was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of dazomet for use in biocidal products of product-type 8 will expire on 31 July 2022. On 26 January 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of dazomet.
- (3) On 24 March 2021, the evaluating competent authority of Belgium informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of dazomet for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of dazomet for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 January 2025.
- (7) Except for the expiry date of approval, dazomet remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of dazomet for use in biocidal products of product-type 8 is postponed to 31 January 2025.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1290**of 2 August 2021****postponing the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8****(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 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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance disodium tetraborate was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of disodium tetraborate for use in biocidal products of product-type 8 will expire on 31 August 2021. On 28 February 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of disodium tetraborate.
- (3) As disodium tetraborate is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾, it meets the exclusion criteria set out in Article 5(1), point (c), of Regulation (EU) No 528/2012.
- (4) On 2 July 2020, the evaluating competent authority of the Netherlands informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (7) Consequently, for reasons beyond the control of the applicant, the approval of disodium tetraborate for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of disodium tetraborate may therefore be renewed, it is appropriate to postpone the expiry date of approval to 28 February 2024.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (8) Except for the expiry date of approval, disodium tetraborate remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of disodium tetraborate for use in biocidal products of product-type 8 is postponed to 28 February 2024.

Article 2

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

Done at Brussels, 2 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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