Commission Implementing Regulation (EU) 2017/12 of 6 January 2017 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/12

of 6 January 2017

regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 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 (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[(1)], and in particular Article 13(1) thereof,

Whereas:

(1) Pharmacologically active substances are classified on the basis of opinions on maximum residue limits (MRLs) issued by the European Medicines Agency (EMA).

(2) An application for an opinion to establish the MRL is submitted to EMA. It is necessary to provide a standard format for submitting such applications and to list the information requested to accompany such applications.

(3) Under certain circumstances, the Commission, a Member State, an interested party or organisation may submit a request to EMA for an opinion to establish the MRL. It is necessary to provide a standard format for such requests and to list the information that should accompany them.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/12. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Article 1

Form and content of applications and requests

1 An application or a request for the establishment of maximum residue limits (MRLs) shall be submitted to European Medicines Agency (EMA) electronically.

2 The particulars and documents accompanying an application or a request for the establishment of MRLs shall be presented in accordance with the requirements set out in the Annex.

Article 2

General requirements for applications and requests

1 The information and documentation submitted as part of an application or a request for the establishment of MRLs shall be accurate and conform to the current state of scientific knowledge and the scientific guidance issued by EMA relating to the safety of residues.

2 An application or a request for the establishment of MRLs shall include any information relevant to the evaluation of the safety of residues of the substance concerned, whether favourable or unfavourable to the substance. In particular, all relevant details shall be given of any incomplete or abandoned test or trial relating to the active substance.

3 An application or a request for the extension of existing MRLs to other animal species or other food commodities shall consist of an application or request form and a residue file. EMA may request safety data if the risk assessment performed with regard to the establishment of the existing MRL is not applicable to the extension proposed.

Article 3

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, 6 January 2017.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

APPLICATION/REQUEST FOR THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1. The application or the request shall include all administrative information and scientific documentation necessary for demonstrating the safety of the residues of the substance in question and risk management considerations.

2. All volumes of the dossier shall be clearly numbered and paginated. Particular care shall be taken to ensure that there is adequate cross-referencing between volumes and between the detailed and critical summaries and the original data. Electronic submissions shall comply with guidance on veterinary e-Submissions published by the EMA.

3. Where reference is made to published information, complete copies of the relevant articles should be inserted in the relevant section of the dossier.

4. The application or the request shall be submitted in accordance with the requirements specified below respecting the order of presentation indicated.

5. Pharmacological, toxicological and residue tests, results of which are accompanying an application or a request for the establishment of MRLs, shall be carried out in conformity with Directive 2004/10/EC of the European Parliament and of the Council[(2)] and Directive 2010/63/EU of the European Parliament and of the Council[(3)].

CHAPTER 1

ADMINISTRATIVE INFORMATION

The administrative information shall comprise two parts, one providing the administrative data and the second providing a summary of the evaluation proposed by the applicant/requestor.

The following details shall be included:

Part 1 — Administrative data:

- name of the substance for review, using international non-proprietary name (INN) where attributed;
- name and address of the applicant/requestor;
- name and address details of the applicant/requestor contact point for all correspondence related to the application;

Part 2 — Summary of the evaluation proposed by the applicant/requestor:

- name of the substance for review, using INN where attributed;
- clarification on whether the substance is used in the product as active ingredient, excipient, preservative, etc.;
- summary of anticipated pattern of veterinary use (target species, major indications, dose-regimen);
- information on any applications to other Union or international bodies, the dates of these applications and the outcome;
- summary of the findings:
  - relevant no-observed (adverse) effect levels (NO(A)EL) or an accepted alternative for the safety evaluation,
  - reference to relevant study,

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— uncertainty factor proposed,
— Acceptable Daily Intake (ADI) proposed, or an alternative in accordance with Article 6 of Regulation (EC) No 470/2009,
— marker residue (where relevant),
— MRLs proposed (where relevant),
— method of analysis proposed (including limit of quantification and reference, where relevant).

CHAPTER 2

DATA FOR SCIENTIFIC RISK ASSESSMENT

A. **Safety file**

The dossier of safety tests shall include the following documents:
— an index of all studies included in the dossier,
— a statement confirming that all data known to the applicant/requestor at the time of submission, whether favourable or unfavourable, are included,
— a justification for the omission of any type of study,
— an explanation for the inclusion of an alternative type of study,
— in cases where a study pre-dates Directive 2004/10/EC or Good Laboratory Practice status is unknown, a discussion of the contribution that any non-GLP study can make to the overall risk assessment.

Each study report shall include the following documents:
— a copy of the study plan (protocol, including amendments and deviations),
— a signed statement of compliance with good laboratory practice, where applicable,
— a description of the methods, apparatus and materials used,
— a description and justification of the test system,
— a description of the results obtained, in sufficient detail to allow the results to be critically evaluated independently of their interpretation by the author,
— a statistical analysis of the results where appropriate,
— a discussion of the results, with comment on observed (adverse) effect levels and NO(A)ELs, and on any unusual findings,
— a detailed description and a thorough discussion of the results of the study.

A.0. Detailed and critical summary

The detailed and critical summary shall be signed and dated. Information about the author's educational background, training and occupational experience shall be attached. The professional relationship of the author with the applicant/requestor shall be declared.

All the important data shall be summarised in an Annex, in tabular or graphic form whenever possible and the relevant bibliographic references shall also be included in the Annexes to the document. The relevance of the studies provided for the evaluation of potential risks presented by residues to humans shall be addressed. The detailed and critical summary and its Annexes shall contain precise cross-references to the information contained in the main documentation. This section shall not introduce new studies that are not included in the main documentation.

A.1. Precise identification of the substance concerned by the application/request: