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Notification of substances that benefitted from the derogation for food and feed

A notification must be submitted to ECHA for substances that benefitted from the food and feed derogation and for which a successful declaration was submitted[1]. Substances that benefitted from the food and feed derogation need to comply with two requirements: 1. they must fall within the definitions of food and feed according to Articles 2 and 3(4) of Regulation (EC) 178/2002[2] and 2. they must comply with the definition of substance according to the REACH regulation (Article 3(1))[3]. That means that a notification will not be eligible for food- and feed- material that is not a substance; and it will not be eligible for substances that do not fall under the food and feed definition.

This document is intended to help companies fulfil the notification requirements and submit successfully notifications to ECHA.

Information requirements

The information requirements for notifications according to Article 17 of Regulation (EU) No 1062/2014 (review programme regulation, RPR) are listed in Annex I of the same Regulation. Below we cite the legal text *in italics* with the requirements. Explanations how to fulfil these points are provided in normal text.

A notification for food and feed pursuant to Article 17 shall contain the following information:

- *An indication of the product-type(s) concerned by the notification;*

All substances that benefitted from the derogation belong to the product-type 19 only, repellents and attractants. Therefore the notifiers must indicate "PT-19" in section 7.2 of their IUCLID dossier.

- *Information on any studies that have been commissioned for the purpose of application for approval or inclusion in Annex I to Regulation (EU) No 528/2016, as well as the expected date of completion.*

This information requirements is targeting the future complete dossier for the approval of the active substance. The notifier should indicate studies that have been commissioned to prepare an active substance dossier or an application for inclusion in Annex I and by what dates the completion of these are foreseen. Information on studies already completed or commissioned for the purpose of another legislation do not need to be provided. The notifiers should add this information to chapter 13 "Summary and Conclusions" of their IUCLID dossier.

- *The information referred to in Sections*
  a. *1, 2 and 7.1 to 7.5 of the table in Title 1 of Annex II to Regulation (EU) No*

[1] Substances that benefited from a derogation from food and feed for which a successful declaration was submitted are listed on the ECHA website here https://echa.europa.eu/documents/10162/17158508/list_substances_deadline_en.pdf/7fcf0bf2-8339-4f55-9e98-91c86ad177cd

[2] Link to the food and feed Regulation (EC) 178/2002: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178&rid=1

[3] Link to the REACH Regulation: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20161011&from=EN

528/2012 for chemical substances (see below)

b. *1, 2 and 6.1 to 6.4 of the table in Title 2 of Annex II to Regulation (EU) No 528/2012 for microorganisms.*

This information needs to be provided in the IUCLID dossier as further described below.

Agreement from an evaluating competent authority

Written confirmation from the future evaluating MSCA (Member State Competent Authority) confirming their agreement to evaluate the active substance dossier (or an application for inclusion in Annex I) following the notification must be included. The notifiers need to contact an MSCA to get a signed agreement for evaluating their dossier. The signed agreement provided by the MSCA to the applicant should be attached to chapter 13 "Summary and Conclusions" of their IUCLID dossier.

As Member State competent authorities and the Commission consider including some of the food and feed substances in Annex I of the BPR[4], an active substance application dossier might not be required for all substances notified.

Information in the IUCLID dossier

The mentioned information sections need to be filled in a IUCLID dossier. For chemical substances refer to Title 1 and for micro-organisms refer to Title 2 of Annex II of the BPR. For substances as well as for micro-organisms guidance is provided on each endpoint of the requirements. Volume I of the guidance on the Biocidal Products Regulation describes the requirements for substances. Volume V describes the requirements for micro-organisms. The reference to these guidance documents is provided in the last section of this document. Below we added additional advice for food and feed substance and micro-organisms for each of the required sections.

Section 1 concerns the name, address and contact person of the applicant as well as the active substance manufacturer name, as well the address and location of their manufacturing plant.

The notifiers need to provide the name and address of the manufacturing plant(s) of their substances. The notifiers might need to request the information on the manufacturing plants from the supplier of their substance.

Section 2 Identity of the active substance

This section is the most important one, as the information provided here must enable the active substance or micro-organism to be identified. Such information should be supported by analytical data, certificates of analysis, certificates of control, food grading systems or other information that demonstrates the identity of the substance notified. How to identify a substance and specifically a substance of unknown or variable composition (UVCB), is provided in section 4 of the guidance for identification and naming of substances under REACH and CLP (see reference at the end of this document). The guidance provides specific examples as well. How to identify the essential oil of *Lavendula hybrid grosso* (Lamiacae) is explained in section 7.

2.1. Common name proposed or accepted by ISO and synonyms (usually name, trade name, abbreviation)
In this field the most specific name of the notified substance needs to be provided.

[4] Member State competent authorities and the Commission consider including some of the food and feed substances on Annex I of the BPR. Information about this initiative is available in the document "CA-Sept16-Doc.5.3 - Proposal for food&feed under Art 15(b) of RR.doc" on the CIRCABC website here: https://circabc.europa.eu/w/browse/33e03006-3940-4df1-a5e4-663913bcf114.

2.2. Chemical name
For food and feed substances there may be no specific chemical name. If this is the casethe notifier should state that there is no specific chemical name for their substance.

2.3. Manufacturer's development code number(s)
This field may remain empty, unless the manufacturer uses a certain code number.

2.4 CAS number plus EC, INDES and CIPAC numbers
CAS, EC, INDES and CIPAC numbers might not exist for food and feed substances. If this is the case these fields will remain empty. If any identification number system exists, that number and the system should be added in the "descriptions" field in IUCLID.

2.5. Molecular and structural formula (including SMILES notation, if available and appropriate)
If the active substance contains more than one constituent no structural formula needs to be provided in the reference substance referring to the active substance. The structural formula would be provided for each of the constituents of the reference substance.

2.6. Information on optical activity and full details of any isomeric composition (if applicable and appropriate)
Measurements of optical activity and information on the isomeric composition (e.g. "racemic mixture") must be provided if the substance has a stereocenter.

2.7. Molar mass
If the active substance contains more than one constituent no molar mass (g/mol) needs to be provided in the reference substance referring to the active substance. The molar mass would be provided for each of the constituents of the reference substance..

2.8. Method of manufacture (synthese pathway) of active substances including information on starting materials and solvents including suppliers, specfifications and commercial availability
The method of manufacture is in the case of the food and feed substance one of the most important identification parameters. All information should be provided about the ingredients, the process conditions (temperature, pH, pressure), the outcome of the process, etc.

2.9. Specification of purity of the active substance as manufacturured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit.
All information provided should be substianted by analytical data. For UVCB substances a specification of purity might not be relevant, as impurities for UVCB substances are not defined. In that case relevant norms, analytical quality controlmeasurements or other specification information should be provided. Therefore notifiers should provide all available information on concentrations of individual constituents or groups of constituants of their substance in this section.

2.10. The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVCB substances

For UVCB substances this field should remain empty, as UVCBs do not have impurities per definition. However, the chemical composition and the identity of the constituents should be given as far as known.

2.11. Analytical profile of at least five representative batches (g/kg active substance) including information on content of the impurities referred to in 2.10.
for micro-organisms section *2.9 analytical profile of batches.*

For certain food and feed substances or micro-organisms an analytical profile of at least five batches might not be relevant or technically feasible. However, a non-submission need to be

scientifically justified. If norms, analytical quality control measurements or other specification informations are used they should be mentioned here. Therefore all the analytical information that notifiers can gather to specify their substance or micro-organism needs to be provided and presented in this section.

The Commission document mentioned in footnote 4 states that certain food and feed substances might be considered for inclusion into Annex I.

2.12. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower.
Especially for food and feed substances, that are extracted from plants or animals this field needs to name the botanical origin (botanical name of the plant) of the active substances.

Section 7 Intended uses and exposure

7.1 Field of use(s) envisaged for biocidal products and, where appropriate, treated articles
See Volume I of the Guidance on the Biocidal Product Regulation.

7.2 Product-type(s)
For a notification of a food and feed substance product-type PT 19 must be chosen.

7.3. Detailed description of the intended use pattern(s) including in treated articles the detailed description
See Volume I of the Guidance on the Biocidal Product Regulation.

7.4 Users e.g. industrial, trained professional, professional or general public (non-professional)
See Volume I of the Guidance on the Biocidal Product Regulation.

7.5 Likely tonnage to be placed on the market per year and, where relevant, for the envisaged major use categories.
See Volume I of the Guidance on the Biocidal Product Regulation.

References to guidance documents

Guidance on the Biocidal Product Regulation
Volume I: Identity/physico-cemical properties/analytical methodology – Part A: Information Requirements

https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=vol1partA#vol1

Volume 5: Guidance on Active Micro-organisms and Biocidal Products

https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=vol5partC#vol5

Guidance on substances
Guidance for the identification and naming of substances under REACH and CLP

https://echa.europa.eu/guidance-documents/guidance-on-reach?panel=ident_nam_subst#ident_nam_subst