10 JAN 2021

EFSA Pesticide Steering Network sub-group

IUCLID HYPERCARE Programme

Terms of Reference (ToR)

Background

With the Transparency Regulation which amends, among others, the General Food Law (GFL)[1], EFSA has new requirements for capturing, managing, handling and distributing Plant Protection Products (PPP) data[2]. These changes require the specification of data formats for regulated product dossiers for adoption in an implementing act/s as well as to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. It was decided to use IUCLID formats and the IUCLID tool (managed by the European Chemicals Agency – ECHA[3]) for data preparation, electronic submission and management of PESTICIDES dossiers, by means of the ECHA Cloud platform. The IUCLID Minimum Viable Product enabling the submission of Pesticides dossiers in IUCLID was released on 28 October 2020. On 23 October 2020, the European Commission and the Member States adopted the Commission Implementing Regulation on Renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 (and repealing Regulation 844-2012) and the amendments for the Implementing Regulation (EC) No 540/2011 as regards the extension of the approval periods of 22 renewal active substances. EFSA launched an EFSA Grant and Procurement call on "IUCLID training" to work with a knowledgeable contractor to support EFSA in developing and providing training materials for all users on the submission and evaluation of PESTICIDE dossiers in IUCLID. Building on from the EFSA Technical Group on IUCLID for PESTICIDES allowing for technical exchanges, for informing and gathering input from participants on a specific technical area, and in addition to the already planned training materials on IUCLID, EFSA is now providing a dedicated support to Member States and applicants involved in the early submission and evaluation of Renewal active substances in IUCLID.

The IUCLID HYPERCARE Programme objectives

The IUCLID HYPERCARE Programme aims to

- Support Member States and applicants involved in the first submission and evaluation in IUCLID of renewal active substances with an extended legal deadline falling between July and August 2021;
- Follow the steps of the workflows in IUCLID (dossier compilation in IUCLID, admissibility check, dossier extraction, data evaluation) with 'real cases' and identify unforeseen issues for resolution and have the possibility to refine the IUCLID implementation for pesticides (in accordance with the IUCLID release schedule) based on this experience;
- Develop and extend IUCLID technical knowledge for Member States and applicants;
- Use the IUCLID Hypercare programme to refine the EFSA helpdesk support, IUCLID training materials and IUCLID implementation

Considering the timeframe of the IUCLID Hypercare programme, the publication of non-confidential dossiers is not part of the HYPERCARE programme.

[1] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

[2] New submissions for approval and renewals of previously submitted pesticides

[3] https://echa.europa.eu/

Terms of Reference

Members of the EFSA IUCLID HYPERCARE Programme are expected to:

- Inform and nominate additional experts from Member States and/or organisations to participate ad-hoc to IUCLID HYPERCARE tele-meetings on specific topics;
- Attend planned tele-meetings, share experience, encountered difficulties and clarifications requested;
- Contribute to the specific thematic topics on the IUCLID format, allowing to clarify points of misunderstanding and discuss issues encountered. Issues must be discussed without touching on confidential information to facilitate sharing of the knowledge on common issues;
- Contribute to the general topics on IUCLID features (e.g. administrative part, validation assistant, annotating, reporting) which will be opened with a presentation/demo by EFSA followed by a Q&A session;
- Share knowledge and expertise with other stakeholders;
- Provide feedback based on experience to contribute to further IUCLID development beyond March 2021 where relevant;
- Member States participating in the IUCLID Hypercare programme will be considered as 'IUCLID MSs super users' and will be requested to proactively share the knowledge gained within their organisation and among other Member States' organisations (e.g. by presenting in EFSA Pesticide Steering Network or by mentoring a co-rapporteur Member States);
- Exceptionally, on demand and based on a case-by-case assessment of the request, one or two new active substances and/or MRL dossiers might be considered for inclusion in the HYPERCARE Programme.

Composition of the EFSA IUCLID HYPERCARE Programme

On 23 October 2020 the final list of renewal active substances with a legal deadline extended by three months was confirmed by the European Commission, allowing to define the list of potential candidate substances for the IUCLID HYPERCARE Programme.

On 29 October 2020 EFSA contacted all Member States and all applicants for the 22 renewal active substances to confirm their interest in participating in the programme, to collect their nominations as well as their preferences for the substances to be included (to the extent to which it will be possible to satisfy these requests). Based on the preferences expressed and the selection criteria listed below, EFSA compiled the final list of substances subject to the HYPERCARE Programme with the associated representatives from the Member States and the applicants.

Based on the 22 substances initially identified, EFSA applied the following selection criteria:

- One substance per applicant
- Substance with joint submissions were prioritised
- Substance including MRL applications were prioritised
- Member States were consulted
- Application forms submitted or intentions to submit received by EFSA or by the Member State

On 20 November 2020 the composition of the EFSA IUCLID HYPERCARE Programme was finalised with representatives from Member States, applicants, ECHA, EC, EFSA. The lead Rapporteur Member States (RMS) and applicant representatives are active participants, the Co-RMS and observer Member States are observers. Each nominated contact point can attend all meetings of the IUCLID HYPERCARE Programme with the option to nominate additional experts for each session on a case-by-case basis depending on the topic.

On 10 December 2020, a micro-organism (M.O.) new active substance was exceptionally added to the Hypercare programme for the following reasons:

- No micro-organism renewal dossiers among the 22 renewal active substances dossiers
- The inclusion of micro-organism dossier enlarges the diversity of substances and of applicants (e.g. Small and Medium Enterprise)

- IUCLID 6.5 is was developed to also support the submission of micro-organism dossiers
- The training material for micro-organisms dossier will be optimised with the experience gained on the real data by means of the EFSA IUCLID HYPERCARE programme

On 15 December 2020, the composition of the EFSA IUCLID HYPERCARE Programme was updated accordingly. To maintain confidentiality, the identity of the micro-organism new active substance will not be disclosed.

Timelines

The EFSA IUCLID HYPERCARE Programme will last for 12 months, between December 2020 and December 2021, with a kick-off meeting at the end of November 2020, one milestone set at the end of March 2021 to report back experience and to review planned topics.

EFSA will organise biweekly meetings on specific topics related to the IUCLID format such as OHTs, TOC, etc and related to IUCLID features such as the validation rules, filtering or the comparison tool. While the planning for the first months will be decided prior to the start of the programme, there will be the possibility to adjust the topics for following meetings also based on the course of the programme and/or specific requests from the participants. Every three months, a core meeting will be held and the following documents will be made available on the EFSA Pesticide Steering Network webpage: agenda, participants list, presentations and a summary of the main issues discussed.

EFSA IUCLID HYPERCARE Programme planning:

- Kick-off meeting: end November 2020 MILESTONE 1
- On a six-week repeatable schedule, the pattern of the biweekly meetings will be the following:
    - Meetings 1 & 2: IUCLID format
    - Meeting 3: IUCLID format or feature
- Every 12 weeks: IUCLID HYPERCARE core meetings MILESTONE 2
- Closing meeting: end November 2021 MILESTONE 3

Annex: List of selected substances

	Substance	**Applicant**	**RMS**	**Co-RMS**
1	**Azadirachtin (Margosa extract)**	Mitsui; Trifolio; Sipcam Oxon	DE	ES
2	**6-Benzyladenine**	Fine Agrochemicals Limited, Sumitomo, Globachem (taskforce)	SE	NL
3	**Quinmerac**	BASF; (ADAMA)	EE	FI
4	**1-Decanol**	Drexel Chemical Company	PL	IT
5	**Lime sulphur (calcium polysulphid)**	Polisenio; Tessenderlo	CZ	NL
6	**Sintofen (aka Cintofen)**	ASUR Plant Breeding SAS	CZ	FR
7	**Hexythiazox**	Nisso Chemical Europe; JDDA	FI	SE
8	**Dodine**	Arysta LifeScience; Certiplant	ES	DE
9	**Prosulfuron***	Syngenta Crop Protection	FR	SK
10	**Isoxaben**	Dow AgroSciences	AT	FI
11	**Tembotrione**	Bayer CropScience AG	AT	FR
12	**Zinc phosphide**	frunol delicia GmbH, Detia Freyberg GmbH (taskforce)	AT	DE
13	**Aluminium sulphate**	BIOFA AG	NL	CZ
14	**Sodium silver thiosulphate**	Enhold B.V	NL	LV
15	**tau-Fluvalinate**	ADAMA	DK	DE
16	**Substance M.O. xx**	APIS	DK	-