IUCLID HYPERCARE Programme

Minutes of the Core Meeting

TELE-conference, 23rd November 2021

PARTICIPANTS

- **Network Representatives of Member States:**

Country	Name
Austria (AT)	Klaus LEDER
Czechia (CZ)	Martin BENISEK
Denmark (DK)	Alf AAGAARD
Estonia (EE)	Uku ROONI
Finland (FI)	Päivi ARVILOMMI
France (FR)	Suzanne PIERLOT
Germany (DE)	Friederike BREUER
Latvia (LV)	Liga BRENCE
Netherlands (NL)	Hanneke WESTLAND
Poland (PL)	Aneta CHODERSKA
Slovakia (SK)	Marta GALUSOVA
Spain (ES)	José Luis Alonso PRADOS
Sweden (SE)	Christoffer OSTERWALL

- **Applicants representatives**

Organisation	Name
Drexel Chemical Company	Oluwatobi ONI
Fine Agrochemicals Ltd, Sumitomo Chemical Agro Europe, and Globachem NV (task force)	Michael WATSON
BIOFA AG	Burkhard FUNK
Mitsui; Trifolio; Sipcam Oxon	Martina DUNKER
Arista Life Science/UPL	Stephanie COFFINET
Nisso Chemical Europe	Gertraud WIRZINGER
Dow AgroSciences	Bruce CLEMENTS
Polisenio	Sandro MARRONCELLI
APIS	Adi CORNELESE
- Vivagro - Oro Agri	- Cristina Veltri - Rute Vieira
Syngenta Crop Protection	Michael LENNARTZ
BASF	Marc TEIWES
ASUR Plant Breeding SAS	Dawn WHITE-WILLIAMS
Enhold B.V	Astrid Van Der Meer
Adama	Andrew WHYTE
Bayer CropScience AG	Katja TIMM
Frunol delicia GmbH, Detia Freyberg GmbH (taskforce)	Dagmar PIWANSKI

- **Member States and Applicants additional experts**

MS / Applicant	Expert Name and Surname	Expert Primary Company Organisation
MS - DE	Wolfgang Janzen	UBA
MS - LT	Kristina Valioniene	State Plant Service under the Ministry of Agriculture
MS - LT	Vilma Kludsuveit	State Plant Service under the Ministry of Agriculture
MS - GR	Panagiotis Gatos	Benaki Phytopathological Institute
MS - GR	Vasileia Laskari	Benaki Phytopathological Institute
MS - GR	Dimitra Nikolopoulou	Benaki Phytopathological Institute
MS - GR	Anastasia Repouskou	Benaki Phytopathological Institute
MS - GR	Vasiliki Hatzi	Benaki Phytopathological Institute
MS - GR	Maria Karakosta	Benaki Phytopathological Institute
MS - GR	Eliana Spilioti	Benaki Phytopathological Institute
MS - GR	Theodora Nikolopoulou	Benaki Phytopathological Institute
MS - GR	Ioannis Kandris	Benaki Phytopathological Institute
MS - GR	George Pavlidis	Benaki Phytopathological Institute
MS - GR	Aikaterini Kyriakopoulou	Benaki Phytopathological Institute
Applicant	Viktoria Eriksson	Bayer AG
Applicant	Bernd Brielbeck	SCC GmbH
Applicant	Carla Lorenz	SCC GmbH
Applicant	Jasmin Philippi	SCC GmbH
Applicant	Alexander Feyrer	SCC GmbH
Applicant	Colin Ehnes	BASF
Applicant	Regina Hoefs	BASF
Applicant	Amandine Michel	BASF
Applicant	Natalie Sauer	ADAMA
Applicant	Dawn White-Williams	ASUR Plant Breeding
Applicant	Matthew Liles	ASUR
Applicant	Daniel Wragg	ASUR
Applicant	Kajal Pindoria	ASUR
Applicant	Oliver Landale	ASUR
Applicant	Geraldine Meunier	ASUR
Applicant	Emmanuel Poirot	ASUR

- **European Commission:**
  - Valerio SPINOSI
- **ECHA**
  - François LE GOFF
- **EFSA:**
  - Bénédicte VAGENENDE (*PRES Unit, Chair*)
  - Silvia MAZZEGA (*Application Desk Unit*)
  - Chiara MACCHI (*Application Desk Unit*)
  - Alice GOZZI (*Application Desk Unit*)
  - Jane RICHARDSON (*Evidence Management – DATA Unit*)
  - Alessia SCARLATO (*PRES Unit*)
  - Others: Armando PIERRI, Luca CONTI (Deloitte Consulting)

INTRODUCTION

Core Meeting of IUCLID HYPERCARE took place virtually. The objectives were to

- provide a wrap up of IUCLID Hypercare programme (from November, 2020 to November, 2021);
- provide an update on IUCLID supporting material;
- collect feedback from Member States and Applicants about the IUCLID Hypercare programme and potential improvements;
- provide an overview of the next steps after the IUCLID Hypercare programme.

AGENDA OF THE MEETING

(*please refer to attached presentation for the detailed contents presented during the meeting*)

1. Welcome and Apologies for absences and adoption of agenda
2. Overview of the Hypercare Programme
3. Overview of the support material
4. Hypercare Programme Satisfaction Survey
5. Have your say – Hypercare stakeholders feedback
6. Next steps after Hypercare Programme
7. Topics for next PSN meetings
8. AOB
9. End of meeting

ADDITIONAL TOPICS DISCUSSED

- **Clarification on publication of personal data** (slide 12-13)
  - Publication of the first IUCLID dossiers by EFSA has triggered concerns from Applicants in relation to the publication of personal data leading to requests for removing the dossiers from the public instance. EFSA invites Applicants to carefully check their Dossiers before submission. The Dissemination Preview and Filtered dossier features work well for personal data and should be used to avoid these situations.
  - A general remark was raised regarding the changes to some filter rules. EFSA clarified that one rule in the mixture composition document had to be changed one week after go-live of IUCLID 6.6. This rule does not impact the publication of personal data and should be discussed separately. EFSA will provide an opportunity to the applicants potentially affected by this change to verify their dossier prior to publication.
  - EFSA holds the responsibility for the data they publish and the topic of the potential disclosure of personal data has been discussed both with the legal department and with the Data Protection Officer. As a general remark, the Practical Arrangement state that EFSA should publish the Dossier as received from the Applicant after it has been declared admissible by the

MS. From an operational perspective, Applicants, RMSs and EFSA have a shared responsibility in this process:

  - Applicants must carefully check the Dossier before submission using the available features (run dissemination preview and simulate the filtered dossier)
  - RMS/EMS, during the admissibility check, has to flag to the applicant any issues related to personal data in view of the proactive publication
  - EFSA has to provide the tools to perform the checks

- When an applicant fills in the Legal Entity details in IUCLID, the contact details should be generic company data (e.g. functional mailbox instead of personal email, switchboard telephone number instead of personal telephone number) and not personal data (unless it is already publicly available) as this information is always published. The personal data as contact person of the Dossier should be inserted in the Contact entity as this section is not published by default.

- **Clarification on CropLife Europe presentation** (slide 22-27)
  - "*The Teams room will not be maintained after the finalization of the Hypercare program*": the IUCLID HC Teams chat will be disabled but the Teams channel will be available for retrieving programme documentation and chats. The relevant documentation will be moved to the PSN group stream and has been used when drafting the manuals and preparing the training material. More details provided in the agenda point *6. Next steps after Hypercare Programme* (slide 37-40).
  - "*The deployment occurred without appropriate testing and communication of consequences on submissions*": EFSA recognised that testing is an important area for improvement for future releases.
  - "C*lear and aligned strategy is essential in moving IUCLID forward*": EFSA agrees and this is one of the main goals of the IUCLID PSN Group meetings. However, EFSA reinforces the importance of receiving feedback from stakeholders to improve IUCLID in the future.

- **Commission feedback**
  - The longer-term vision is that information is inserted once and then is reused in digital way along all the processes that are connected in different regulatory frameworks. The ultimate objective of using structured data and IUCLID (as well as other tools) is to simplify the activities for all stakeholders. Apart from the initial difficulties which are intrinsic of every new system, all actors are coming together with very positive and constructive feedback.

- **Next steps after IUCLID Hypercare Programme – key messages**

- Support will be split between operational tasks, providing support to applicants upon request during the pre-submission advice and to MSs for the admissibility check and during the different phases of handling the dossier. The IUCLID PSN Group is meant to be the place for discussion of IUCLID general topics and to address the future IUCLID improvements.

- Important that the members of industry associations who have participated in the Programme will distribute relevant information to their member companies to clarify how to get support in future IUCLID submissions. The APDESK Toolkit page is the reference place for all latest information on IUCLID.

- **Next updates of IUCLID release** are available at the following link: https://iuclid6.echa.europa.eu/planned-releases
- **IUCLID webinar published by ECHA:** Here is the link to the latest one (November): https://echa.europa.eu/-/webinar-iuclid6-october-release

ATTACHMENTS

- Presentation supporting Core Meeting (link to Teams)

23rd November, 2021

09:30-12:00 AM

IUCLID Hypercare Programme for early submitters

CORE MEETING

(Closure Meeting)

Trusted science for safe food

efsa
European Food Safety Authority

Agenda

Time	No.	Topic	Documents & scope	Presenter
09H30	**1**	**Welcome and Apologies for absences and adoption of agenda**	**-**	**Bénédicte VAGENENDE**
09H40	2	Overview of the Hypercare Programme	Presentation	EFSA
09H55	3	Overview of the support material	Presentation	EFSA
10H00	4	Hypercare Programme Satisfaction Survey	Presentation	EFSA
10H10	5	Have your say – Hypercare stakeholders feedback	Presentation from participants and discussions	All
11H10	6	Break	-	-
11H20	7	Next steps after Hypercare Programme	Presentation	EFSA
11H40	8	Topics for next PSN meetings	Presentation	EFSA
11H50	9	AOB	-	Bénédicte VAGENENDE
12H00	10	End of meeting	-	Bénédicte VAGENENDE

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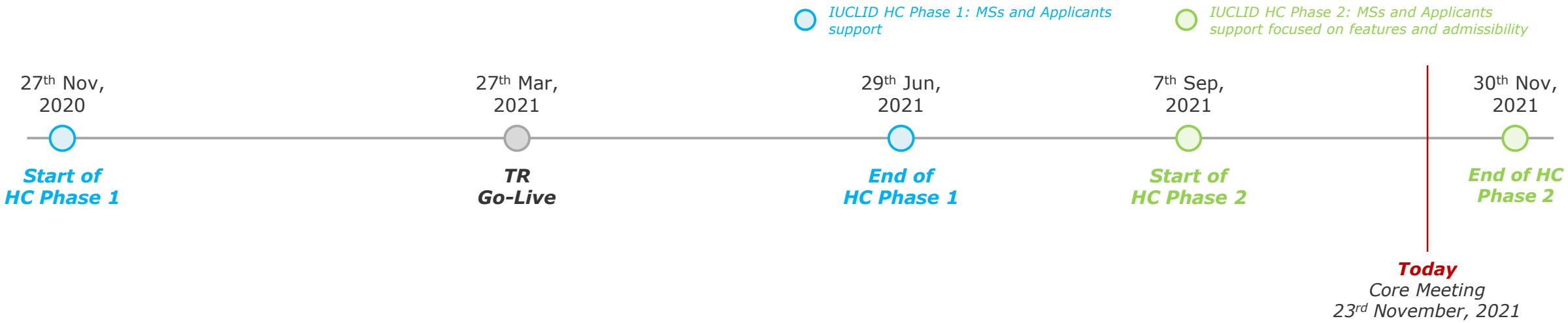
EFSA IUCLID HC Programme in nutshells



Main Objectives

- Provide **targeted support to MSs and applicants** involved in the 1st submission and evaluation of renewal dossiers in IUCLID
- Deliver a IUCLID Hypercare programme for **early submitters of renewal active substances** + few MRL submissions
- The Hypercare programme will be complementary to the training material, which EFSA will make available in the coming months

How

- **Bi-weekly meetings** - on a six-week repeatable schedule, the pattern will be the following:
  - *Meetings 1 & 2*: IUCLID format, specific topics (e.g. specific OHT, residues, GAP)
  - *Meeting 3*: IUCLID features (e.g. annotation, validation assistant, reporting)
- **Q&A management** to provide clarifications (using bi-weekly meetings and dedicated Teams channel)
- Follow up via **one-to-one virtual sessions**, if needed
- No handling of confidential information and no assessment of data

EFSA IUCLID HC – Statistics

- **Main statistics:**

17 Substances in scope, o.w.
- 16 renewal substances
- 1 micro-organism

21 Meetings held, o.w.
- 10 Standard topic meetings
- 9 Features meeting
- 2 Core meeting

120 attendees per meeting on average

~550 Stakeholders involved, o.w.
- 17 Applicants SPOC
- 11 MSs SPOC
- ~500 additional Applicants and MSs experts
- ~28 EFSA coordinators and experts

684 Questions managed, o.w.
- 151 answered and addressed/to be addressed in the Manuals
- 23 answered and added/to be added in the backlog items
- 506 answered
- 4 work in progress

EFSA IUCLID HC – Substances in scope

- **16 selected renewal substances + 1 Micro-Organism, 17 Applicants and 11 MSs involved**

Substance renewal LD July-August 2021		Applicant	RMS
1	**Prosulfuron***	Syngenta Crop Protection	FR
2	**Isoxaben**	Dow AgroSciences	AT
3	**Tau-Fluvalinate**	Adama	DK
4	**1-Decanol**	Drexel Chemical Company	PL
5	**6-Benzyladenine**	Fine Agrochemicals Limited; Sumitomo; Globachem	SE
6	**Aluminium sulphate**	BIOFA AG	NL
7	**Quinmerac**	BASF	EE
8	**Azadirachtin (Margosa extract)***	Mitsui; Trifolio; Sipcam Oxon	DE
9	**Dodine**	Arysta LifeScience/UPL	ES

Substance renewal LD July-August 2021		Applicant	RMS
10	**Tembotrione**	Bayer CropScience AG	AT
11	**Hexythiazox**	Nisso Chemical Europe	FI
12	**Lime sulphur (calcium polysulphid)**	Polisenio	CZ
13	**Sintofen (aka Cintofen)**	ASUR Plant Breeding SAS	CZ
14	**Sodium silver thiosulphate**	Enhold B.V	NL
15	**Zinc phosphide**	Frunol delicia GmbH; Detia Freyberg GmbH	AT
16	**Orange Oil**	- Vivagro - Oro Agri	FR
17	**Micro-Organism**	APIS	DK

** Renewal submission further extended*

EFSA IUCLID HC Phase 1 – Meetings held

- **15 Meetings held (10 Standard topic meetings, 4 Features meetings and 1 Core meeting)**

Date	Session type	High Level Content
15/12/2020	Recurring - Standard Topic	Principles of IUCLID dossiers
12/01/2021	Recurring - Standard Topic	IUCLID Entities, Administrative data
26/01/2021	Recurring - Features	Dissemination preview and confidentiality claims
09/02/2021	Recurring - Standard Topic	Gap and efficacy
23/02/2021	Recurring - Standard Topic	Mammalian Toxicology
09/03/2021	Recurring - Features	Joint submission and Validation assistant
23/03/2021	Recurring - Standard Topic	Residues and MRL
20/04/2021	Recurring - Standard Topic	Physico/chemical properties, Analytical methods & Substance composition
27/04/2021	Recurring - Standard Topic	Micro organism
04/05/2021	Recurring - Standard Topic	Fate and behavior in the environment
18/05/2021	Recurring - Features	Report generator. Submission portal/submission report
01/06/2021	Recurring - Standard Topic	Ecotoxicology assessment
15/06/2021	Recurring - Standard Topic	Other Documents
29/06/2021	Recurring - Features	Use of Annotations, Comparison tool
06/07/2021	Core Meeting	Closing of the Applicants Hypercare cycle

EFSA IUCLID HC Phase 2 – Meetings held

- **6 Meetings held (Focus on Features and Admissibility)**

Date*	Session type	High Level Content
07/09/2021 (RMSs + Applicants)	Recurring - Features	Notification of Study check and pre-application ID
21/09/2021 (RMSs + Applicants)	Recurring - Features	Validation Assistant
05/10/2021 (RMSs + Applicants)	Recurring - Features	Confidentiality and Dissemination Preview features
19/10/2021 (RMSs)	Recurring - Features	Further discussion on Admissibility
16/11/2021 (RMSs + Applicants)	Recurring - Features	Annotation tool in the reporting phase
23/11/2021 (RMSs + Applicants)	**Core Meeting (Closure Meeting)**	**Closing of the Hypercare Programme**

EFSA IUCLID HC – Useful link

- **All useful links are available at dedicated IUCLID Hypercare Teams channel**

Document	Link
Applicants Toolkit	*https://www.efsa.europa.eu/en/applications/toolkit*
Admin guidance	*https://www.efsa.europa.eu/en/supporting/pub/en-6464*
Practical arrangement	*https://www.efsa.europa.eu/en/news/new-rules-transparency-detailed-arrangements-stakeholders*
Q&A Practical Arrangements	*https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements*
Cross walks	*https://zenodo.org/record/4312896#.X9HXEthKiUl%E2%80%8B*
Cross walks m.o.	*https://zenodo.org/record/4313303#.X9HX4NhKiUl%E2%80%8B*
Pesticides evaluation tools	*https://www.efsa.europa.eu/en/applications/pesticides/tools*
IUCLID filter rules for EU PPP	*https://zenodo.org/record/4627148#.YFzCWa9KiUk*
ECHA Accounts tutorials	*https://www.youtube.com/playlist?list=PLOPGDACSd6qxDGftn6jyCDlbxiuYS2uQ8*
IUCLID YouTube playlist	*https://www.youtube.com/playlist?list=PLGDvgn1aAEEbL7dMwwWAjoAiKDgoJmZrY*

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EFSA IUCLID HC – Manuals

4 Manuals published and currently being updated

4 Manuals published

- **MRL Application manual**
  https://doi.org/10.5281/zenodo.4630194
- **Microbial Active Substances manual**
  https://doi.org/10.5281/zenodo.4773527
- **Active Substances manual**
  https://doi.org/10.5281/zenodo.5091464
- **Basic Substances manual**
  https://doi.org/10.5281/zenodo.5172131

Next Updates

4 Updates to the manuals in the pipeline

- **MRL and Active Substance manuals**
  December, 2021
- **Microbial and Basic Substances manuals**
  January, 2022

EFSA IUCLID HC – Personal data in IUCLID

- Publication of the first IUCLID dossiers by EFSA has triggered concerns from applicants in relation to **the publication of personal data leading to requests for removing the dossiers from the public instance**
  - *Some examples: personal data included in the Legal Entity section, confidential attachments included in the dossier header, etc*

REMINDER

- **Applicants must carefully follow the instructions in the Manual** when compiling their dossiers and use the available tools before submitting a dossier and ideally declare that they have completed these tests when submitting their dossier:
  - *Run Dissemination preview*
  - *Simulate the filtered dossier*

EFSA IUCLID HC – Personal data in IUCLID (contd)

- MSs should detect these issues **before declaring admissibility** as EFSA should publish the dossier as declared admissible and not request further changes
  - *As per Article 39b(1)(a) of Regulation No 178/2002, upon admissibility of validity of an application, EFSA 'shall make public the non-confidential version of the application as submitted by the applicant'*

- These issues are being collected and will be included in the "Admissibility checklist" that EFSA has started to compile in support of the MSs. In the meantime, **we invite both applicants and MS to pay particular attention to these aspects as withdrawing published dossiers and amending /resubmitting after admissibility has been declared** (and after confidentiality assessment has begun) **is not in alignment with the provisions of the TR** and is generating confusion and additional burden for all actors

EFSA IUCLID HC – Training

- **What was delivered?**

Applicants

2 Sessions held

- 18th March 2021
- 22nd March 2021

~350 Attendees

Session recording
https://zenodo.org/record/4626979#.YLo0KagzaUk

Self-learning module
https://zenodo.org/record/4778345#.YLowWagzaUk

Regulators

2 Sessions held

- 11th May 2021
- 20th May 2021

~200 Attendees

Session recording
https://zenodo.org/record/4778930#.YLo0gagzaUk

Self-learning module
https://zenodo.org/record/4890632#.YLowFKgzaUk

EFSA IUCLID HC – Training & Support

- **What is in the pipeline?**

FAQ on IUCLID
(based on input from Hypercare, Ask.EFSA, Service Desk, etc)
January 2022

IUCLID for the General public
Spring 2022

IUCLID for applicants
The 20 most frequent errors in IUCLID submissions and how to avoid them
Spring 2022

Other trainings
Sponsored in official EFSA webpage

Any suggestions/requests from applicants/MS?

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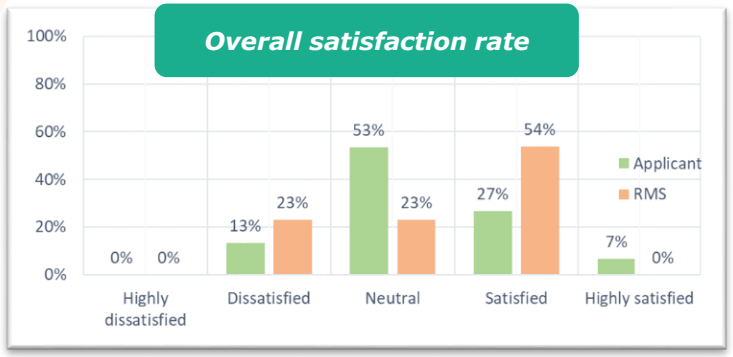
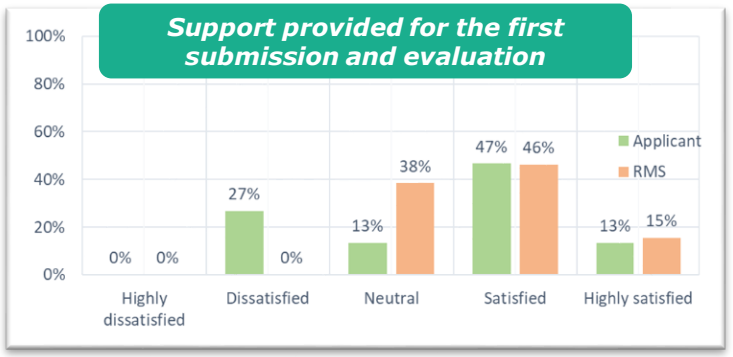
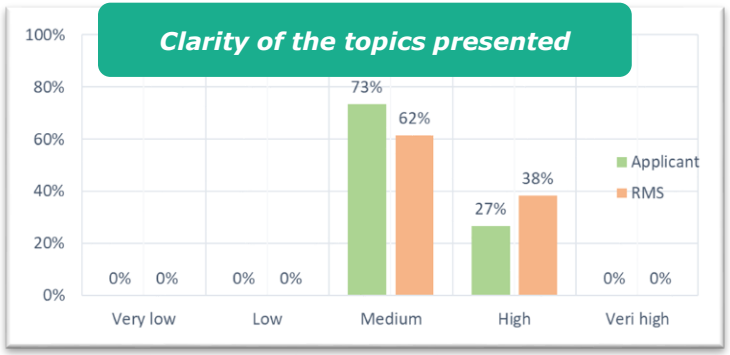
EFSA IUCLID HC – Satisfaction survey

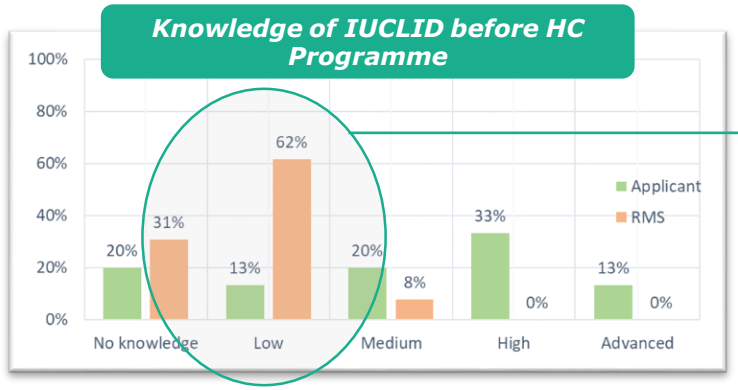


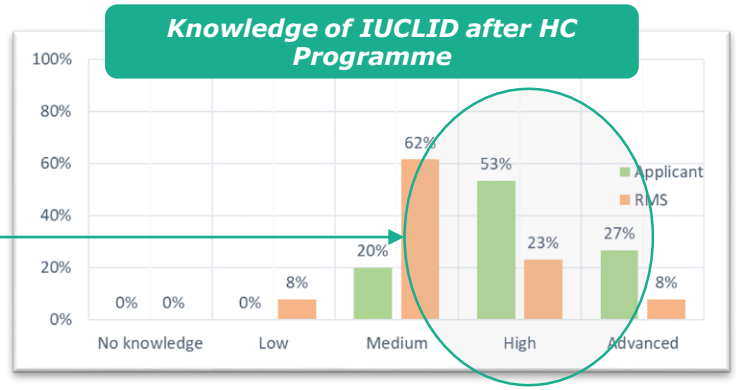


Participation rate: 5,6%

28 Surveys submitted (15 Applicants and 13 MSs) out of around 500 participants







Top 3 Strengths

- ✓ **Holistic Programme** involving all the relevant stakeholders and providing overall understanding of IUCLID
- ✓ **Prompt support from EFSA staff** to address all questions and issues
- ✓ **IUCLID features** use has been facilitated thanks to the training provided during the bi-weekly meetings

Top 3 Weaknesses

- – **Programme for IUCLID experienced users** (hard to follow by beginner users)
- – **Programme supporting documentation** were spread in different collaboration tools (MS Teams, Zenodo) generating some confusion
- – **Bi-weekly sessions duration** was not enough to cover in details all topics

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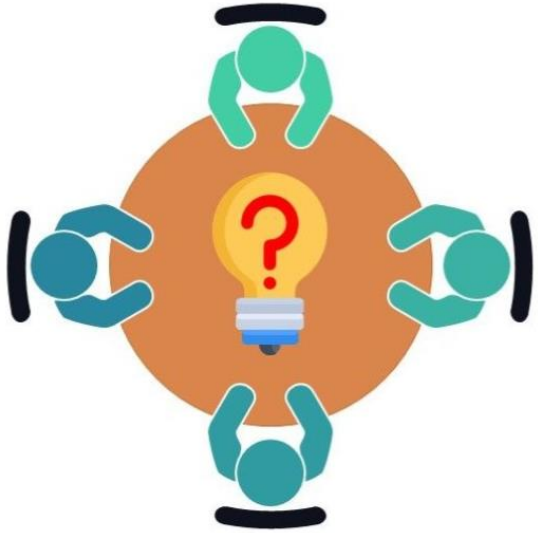
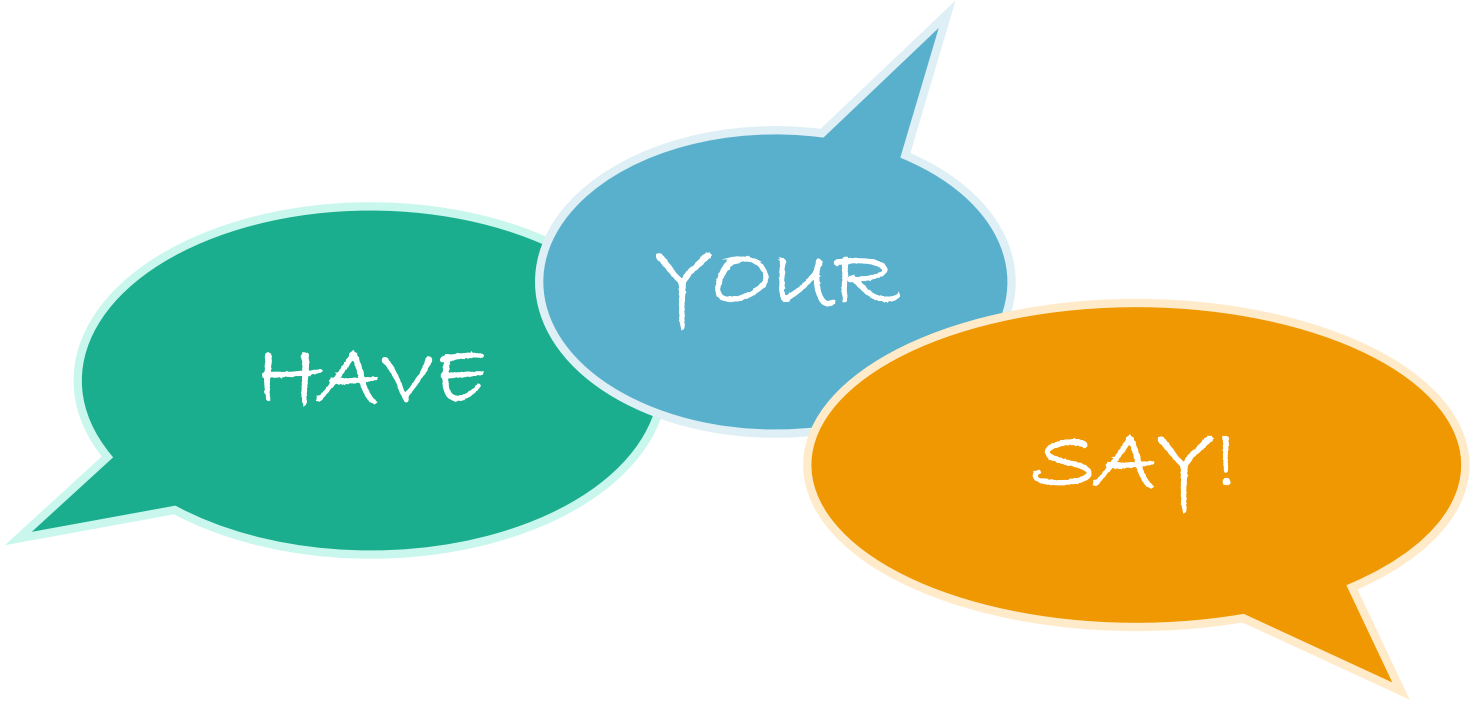
EFSA IUCLID HC - Have your sayc (1/4)

- **Open discussion to collect general feedback from MSs and Applicants**

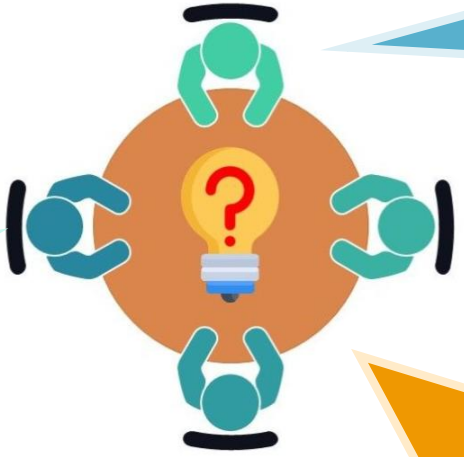




EFSA IUCLID HC - Have your say (2/4)

- **Feedback provided by e-mail**

NoS-DB extraction for renewal dossiers includes all the studies from all companies (also who does not take part in the renewal process)



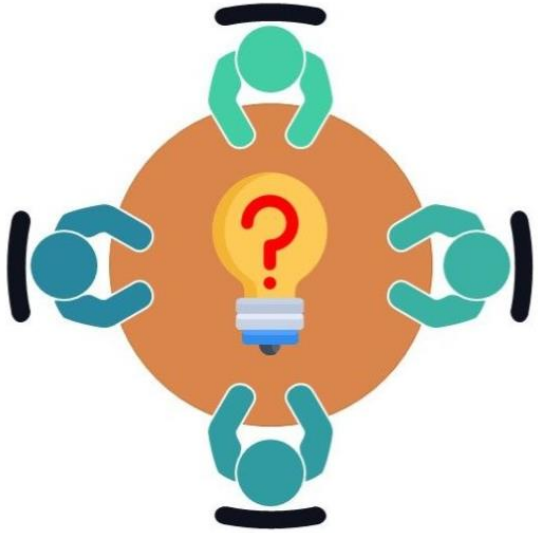
Frequent updates of Applications (e.g. MRL) in IUCLID during the admissibility check

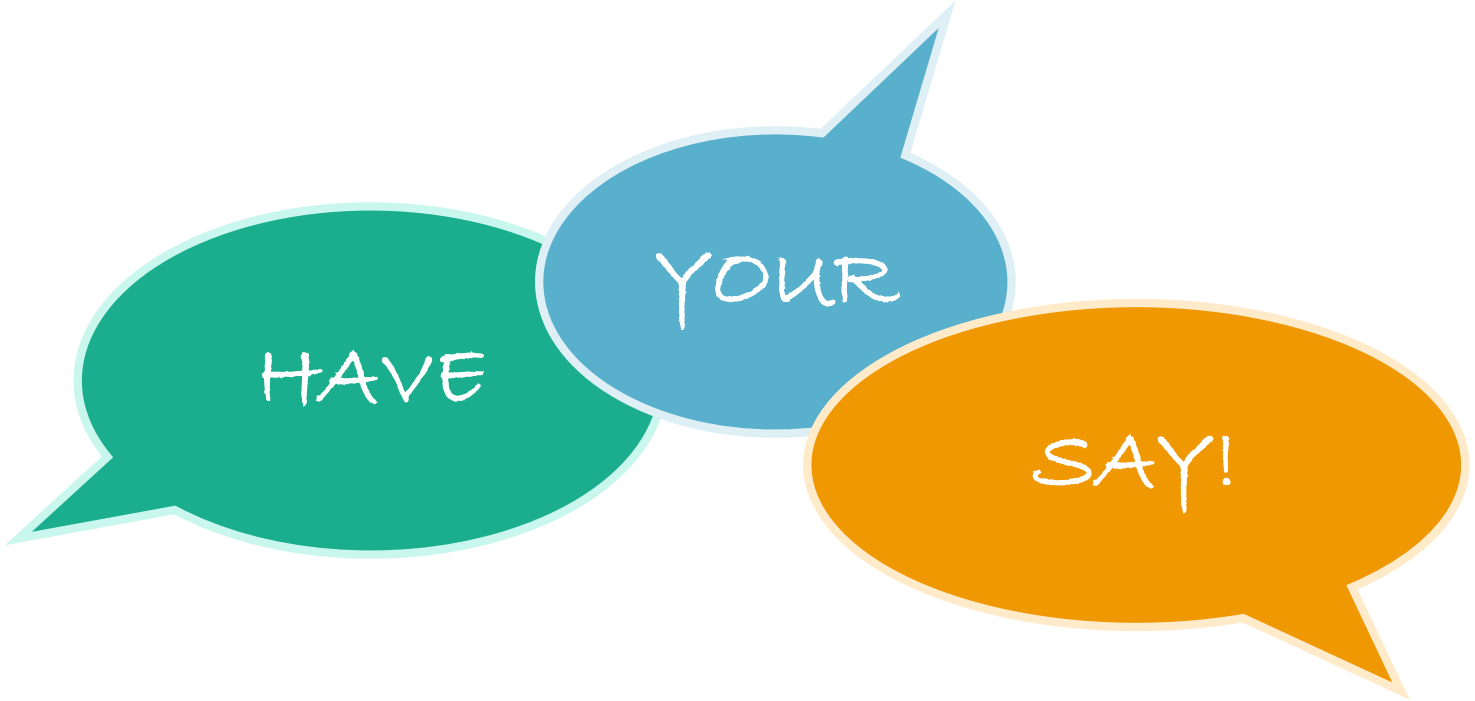
Regular review of improvements in IUCLID would be important to present to MSs (and applicants) for example in a Teams session once or twice a year. Also a functional email address for questions would be good.

EFSA IUCLID HC - Have your say (3/3)

- **CropLife EUROPE**

Michael LENNARTZ/Marc TEIWES





IUCLID / Hypercare Feedback: Industry Perspective

IUCLID Hypercare meeting – 16 November 2021

Industry feedback

Hypercare and Guidance

- In general, the Hypercare Programme was welcome and provided a wealth of information for applicants;
  - BUT: The quality of sessions varied, with short timeframes for both submitting questions and for providing comprehensive answers
    - ☹: Efficacy (not discussed)
    - ☺: Residues and MRL
    - Often examples were missing but just general guidance provided
- Some information presented would have been relevant to any stakeholder involved in the submission of IUCLID dossiers (not limited to Hypercare related activities) and should have been provided well in advance
    - Example: Handling of study notifications in IUCLID submissions
- Our general expectation:
  - Provide relevant information with at least a 6-9 months lead time prior to enforcing changes in submissions and
  - Make updates publicly available and known (i.e., via EFSA alert emails or similar, other EFSA publication channels)

Industry feedback

Hypercare and Guidance

- Beneficial to be able to ask questions and have a response to those rather quickly; high level of support by EFSA was highly appreciated
- Hypercare Teams chat now intensively used by applicants and EFSA for exchange on urgent submission questions (also related to the new IUCLID release)
  - BUT: According to EFSA's information, the Teams room will not be maintained after the finalization of the Hypercare program.
  - Our expectation: Keep the MS Teams Chat open for exchange on urgent topics
- Lots of valuable information is now included in the MS Teams Room
  - BUT: The information is widespread and hard to find.
  - Our expectation: Consolidation of information in **one official** channel using also alerts rather than applicants being requested to check zenodo/open efsa/knowledge junction/toolkit frequently
    - Publicly available to all stakeholders
    - Sorted by topic – Q & A outside of MS Teams room
- **An overarching pain point**: some relevant information was only provided when dossiers were already completed/ under preparation, requiring significant rework

Industry feedback

IUCLID moving forward – release of new versions

- In October, IUCLID 6.5 (MVP) was replaced by IUCLID version 6.6 containing multiple features from the backlog files.
  - BUT: The deployment occurred without appropriate testing and communication of consequences on submissions (e.g. migration, validation and filter rules). Specifically, renewal dossiers could no longer be submitted in IUCLID 6.5 as of Oct. 28th
  - Our expectation for future:
    - Clear and transparent communication related to the release of IUCLID concerning all aspects (including submission portal)
    - Provide applicants with relevant guidance significantly prior to release
    - Ensure dossiers created in previous release(s) can be submitted for an appropriate transition period – make IUCLID backwards-compatible
    - Support stakeholders with periodic update of the crosswalk tables and manuals

Industry feedback

IUCLID moving forward – release of new versions

- IUCLID and especially the release cycles are not compatible with the Regulations 1107/2009 and 2020/1740.
  - According to both regulations, dossiers are “frozen” after submission. The need for dossier updates is driven by the evaluation schedule. In IUCLID, the dossiers seem to continually require updates by the release of new versions.
  - First experience with the new process indicates that there are several admissibility checks resulting in delays and additional resource demands:
    - Study notifications (NoS ID),
    - Confidentiality / CBI
    - IUCLID validation check
    - Actual check
  - Our expectation: The process should be driven by the applicable Regulations and not by the software itself.

Conclusion

- IUCLID will require further and significant changes before adding most of its potential value and being fit-for-purpose for crop protection submissions. For making IUCLID work, further process changes are mandatory.

- IUCLID in its current state of implementation results in significant delays and is rather inhibiting innovation due to the imposed workload and lack of guidance at MS level

- **Our expectation:**

  - clear and aligned strategy is essential in moving IUCLID forward;

  - significant further releases, revisions and subsequent actions (including training) are required, as was an objective described for Hypercare in the IUCLID TG announcement

Hypercare programme

Seen from ECHA

23.11.2021

Francois Le Goff
European Chemicals Agency

Background for the Hypercare programme

End of 2019

IUCLID Technical Group

- Setting-up the tools and guidance
- With stakeholders

Hypercare Programme

- Support for first users
- Focus on applicants (preparing dossiers) and Member States (receiving dossiers)

End of 2020

Benefits

Issues could be reported faster, and all relevant actors informed

Safety net for the first months of implementation of newly created working processes

Example of actions

- Large dossiers handling (creation, submission)
- Filtering and validation assistant questions, issues
- Contribution to the format and table of contents (e.g. other representative products)

In the future

Training materials

Helpdesks
(EFSA and ECHA)

Feedback from stakeholders
(IUCLID PSN subgroup)

Service + project + product management

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you!

Agenda

Time	No.	Topic	Documents & scope	Presenter
09H30	1	Welcome and Apologies for absences and adoption of agenda	-	Bénédicte VAGENENDE
09H40	2	Overview of the Hypercare Programme	Presentation	EFSA
09H55	3	Overview of the support material	Presentation	EFSA
10H00	4	Hypercare Programme Satisfaction Survey	Presentation	EFSA
10H10	5	Have your say – Hypercare stakeholders feedback	Presentation from participants and discussions	All
11H10	**6**	**Break**	**-**	**-**
11H20	7	Next steps after Hypercare Programme	Presentation	EFSA
11H40	8	Topics for next PSN meetings	Presentation	EFSA
11H50	9	AOB	-	Bénédicte VAGENENDE
12H00	10	End of meeting	-	Bénédicte VAGENENDE

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Targeted support to **Applicants**

DURING THE PROGRAMME

- Dedicated sessions (December 2020 – June 2021) and discussion, documents (ppt, word) developed for the programme, answers to questions during sessions and in the Teams chat.

→ **Objective accomplished**: dossiers submitted in Summer 2021.

AFTER HYPERCARE

- There is a need to support applicants for submission of large dossiers through SFTP server
- Hypercare FMB will remain active until end of March 2022 with scope limited to SFTP server submissions
- The chat in MS Teams will not be active anymore while being taking over by the IUCLID PSN subgroup
- General support to applicants before submission will be provided upon request trough PSA/GPSA

Targeted support to **RMSs/EMSs**

DURING THE PROGRAMME

- Dedicated sessions (Sept/Nov2021), discussion, documents (ppt, word), answers during sessions and in the Teams chat;
- One closed session with MSs on admissibility;
- Preparation of the validation assistant documents for the July dossiers

DURING AND AFTER HYPERCARE

- Preparation of the validation assistant documents for applications upon request;
- Support via APDESK FMB on questions about validation/NoS;
- Teleconferences to clarify additional points upon request.

Refine the **IUCLID enhancements** and **Training material** for pesticides

DURING THE PROGRAMME

- Issues/questions related to IUCLID enhancements have been added to the IUCLID backlog
- Issues/questions raised during the Programme have been included in the Manuals where relevant

AFTER HYPERCARE

- The Manuals are currently being updated and will include relevant Hypercare inputs

Forum for discussion with Applicants and MSs;

DURING THE PROGRAMME

- Discussion/exchanges occurred during sessions and in the Teams chat
- Participants were Industry associations, individual applicants/consultants (owner of the 1st dossier to be submitted in IUCLID), MSs, COM, EFSA, ECHA

AFTER HYPERCARE

- Discussion/exchanges to occur within the IUCLID PSN Subgroup (next meeting planned on January 2022) to be the place for exchange views, issues, best practices, identify backlogs, topics for training material refinement
- Participants: Industry Associations, MSs, COM, EFSA, ECHA

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EFSA IUCLID HC – Topics for next PSN meetings

- **2nd PSN IUCLID sub-group meeting is planned for January 2021**, doodle will be launched for availability
- **2 sessions:** one for **all participants,** one for **MS only**
- Agenda is under development, **proposals for topics can be submitted using the form available on Teams until December 17**

- **EFSA proposals for Agenda:**
  - *Re-use of existing validation assistant rules in the EU PPP context*
  - *Test case / working party on use of annotation*
  - *Filtering rules to manage document J content*
  - *Admissibility check: further discussion on best practices from MSs*
  - *Report generator (MRL report)*

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Stay connected

Thanks for your attention!

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