

Pesticide Steering Network

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IUCLID HYPERCARE **DRAFT** Programme

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- **DRAFT** programme

- TIMELINE: NOV 2020 – NOV 2021
- TEAM: APDESK (lead) + team composed APDESK, PESTICIDE, DATA, ECHA, EC
- SCOPE: early submitters and evaluators of renewal active substance with legal deadline extended to July-August 2021

■ Objectives:

- provide a **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
- **Around 15 substances (tbc)** with extended legal deadline = legal deadline between July-August 2021 (selection pending)
- Develop and extend IT technical knowledge of IUCLID for MSs and applicants
- Use this IUCLID Hypercare programme to refine EFSA help desk support, EFSA IUCLID training materials, IUCLID implementation (link to IUCLID release schedule)



■ WHO



- Participants to the “IUCLID Hypercare programme” are **nominated by EFSA** (end OCT 2020)
- Participants representing “applicants” are owners of the selected applications for renewal of active substance and are **active participants**
- The lead Rapporteur Member States are **active participants**
- Co-RMS and observer MS are **observers**
- MSs participating to the “IUCLID Hypercare programme” will be considered as ‘**IUCLID MSs super users**’

■ HOW



- Create a **sub-group** of the **EFSA Pesticide Steering Network** with all MSs, applicants owners of the selected renewal dossiers (with a legal deadline in July-August 2021)
- Biweekly tele-meeting - specific topics, IUCLID format
 - Example: data on residues, specific OHT
- Every 6-weeks tele-meeting – generic topics, IUCLID feature
 - Example: annotation, validation assistant, reporting
- Follow up via one-to-one virtual session if needed
- 2 tele-meetings dedicated to MRL + prioritised **training materials on MRL**
- Planning of topics discussed in tele-meetings (biweekly, monthly) is **established in advance**
- No handling of confidential information



■ BENEFITS

- **Smooth transition** of submission and evaluation of PESTICIDES renewal dossiers via IUCLID
- User driven prioritisation of **amendments for inclusion in future IUCLID releases** and earlier identification and subsequent fix of potential issues.
- **Training materials updated** and adjusted and made available to all (publicly available)

■ SELECTED Renewal substances



■ Conditions

- Renewal expiration date on or after 27 March 2021
- Newly extended deadlines (EC extension **to be confirmed**) fall between July-August 2021 (22 substances)
- EFSA has received the application form for renewal (YES/NO)
- Joint submission are selected with preference
- One application per applicant
- Application for renewal including MRL is selected with preference

EFSA IUCLID Hypercare Programme



■ TO SELECT Renewal substances

Substance renewal DL July-August 2021	Applicant	RMS	App. form received (30/09)	Substance renewal DL July-August 2021	Applicant	RMS	App. form received (30/09)
Prosulfuron*	Syngenta Crop Protection	FR		Dodine	Arysta Life Science; Certiplant	ES	
Bupirimate	ADAMA Agriculture B.V.	NL	YES	Tembotrione	Bayer CropScience AG	AT	
Dithianon	BASF SE	AT	YES	Flutriafol	FMC CHEMICAL	SK	YES
Fluometuron	ADAMA Agriculture B.V.	EL	YES	Hexythiazox	Nisso Chemical Europe ; JDDA	FI	YES
Isoxaben	Dow AgroSciences	AT		Lime sulphur (calcium polysulphid)	Polisenio; Tessengerlo	CZ	YES
Spirotetramat	Bayer CropSciences	AT		Azadirachtin (Margosa extract)	Mitsui; Trifolio; Sipcam Oxon	DE	YES
Tebufenozide	Nisso Chemical Europe	ES	YES	Orange oil	Oro Agri International Ltd	FR	
tau-Fluvalinate	Adama	DK	YES	Quinmerac	BASF; ADAMA	EE	YES
1-Decanol	Drexel Chemical Company	PL	YES	Sintofen (aka Cintofen)	ASUR Plant Breeding SAS	CZ	YES
6-Benzyladenine	Fine Agrochemicals Limited; Valent Biosciences Corporation	SE	YES	Sodium silver thiosulphate	Enhold B.V	NL	
Aluminium sulphate	BIOFA AG	NL	YES	Zinc phosphide	frunol delicia GmbH; Detia Freyberg GmbH	AT	YES

Legend: In **yellow**, applicants owner of several applications; in **blue**, RMS

■ NEXT STEPS

- **Select substances renewal** falling within the scope of the HYPERCARE programme
- Create the sub-group Pesticide Steering Network (IUCLID HYPERCARE PSN)
- Inform the Pesticide Steering Network (6 OCT – AM)
- Nominate members of the IUCLID HYPERCARE PSN
- Define planning and topics of tele-meetings
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OVERVIEW

- **IUCLID Hypercare Programme** (NOV 2020 – NOV 2021)
- IUCLID Helpdesk: queries to be sent to APDESK
<http://www.efsa.europa.eu/en/applications/askaquestion>
- IUCLID G&P Training IUCLID (end OCT 2020 – OCT 2022)
- IUCLID Technical Group IUCLID (NOV 2019 – JUNE 2021)
- IUCLID testing (14 SEPT- 5 OCT)