

Towards one substance one assessment: Future of IUCLID for PPP ?

Focus on biologicals



- Introduction to biocontrols
- Challenges faced in biologicals evaluations
- IUCLID for biologicals
- Future of IUCLID for PPP ?



What is a biocontrol?



Invertebrates



Semiochemicals



REGULATIONS

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009
concerning the placing of plant protection products on the market and repealing Council Directives
79/117/EEC and 91/414/EEC



Microbials



Natural substances



Under Reg (EU) 1107/2009, an Active Substance is any chemical, plant extract, pheromone or microorganism that has action against 'pests' or on plants, parts of plants or plant products.

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→ specific fields in IUCLID



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- Conventional dossiers size typically >2x the biologicals
→ all fields to be filled in IUCLID
- Fewer data/studies are available than for chemicals
→ waivers in IUCLID



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- It can be frustrating trying to get natural and low-risk status through a system designed for synthetic chemicals

→ specific working context in IUCLID



While this can make working with biologicals challenging, it also makes working on these products an interesting experience !



- To date, there are 197 dossiers [published](#):
 - 7 microbials: *Streptomyces lydicus* WYEC 108, *Bacillus thuringiensis* RTI545, *Beauveria bassiana* R444, *Paecilomyces fumosoroseus* FE9901, Baculoviruses, *Candida oleophila* O, *Beauveria bassiana* BOV1
 - 7 natural substances: Margosa 3x, Antoferine, *Quassia amara*, Black Pepper Oleoresin, *Lupinus albus*
 - 4 semiochemicals: Rescalure in CheckMate CRS 2x and Saturel CRS 2x
 - 4 others (PGRs, sugars, peptides ...)



Biologicals represent 11% of all dossiers published.

IUCLID for biologicals

- Active substance working context used for all the biochemicals:
 - IUCLID fields generally fit with the requirements

▼	Chemical_Test	
▼	1 Identity of the active substance and applicant	1
>	1.1 Identity of the active substance and applicant	1
>	1.2 Producer	
	1.3 (Cf. 1.1) Common name proposed or ISO-accepted and synonyms	
	1.4 (Cf. 1.1) Chemical name (IUPAC and CA nomenclature)	
	1.5 Producer's development code numbers	
	1.6 (Cf. 1.1) CAS, EC and CIPAC numbers	
	1.7 (Cf. 1.1) Molecular and structural formula, molar mass	
	1.8 Method of manufacture (synthesis pathway) of the active substance	
	1.9 Specification of purity of the active substance in g/kg	
	1.10 (Cf. 1.9) Identity and content of additives (such as stabilisers) and impurities	
	1.11 Analytical profile of batches	
	1.12 Isomeric composition	

Working context

Please select ▼

EU PPP Active substance information

EU PPP Microorganisms - active substance information ✓

- BUT there are not really placeholders for scientific assessments, so that the 'story' can be less easily developed and followed by the evaluators
- Except for pheromones where mostly waivers are added: new working context could be helpful



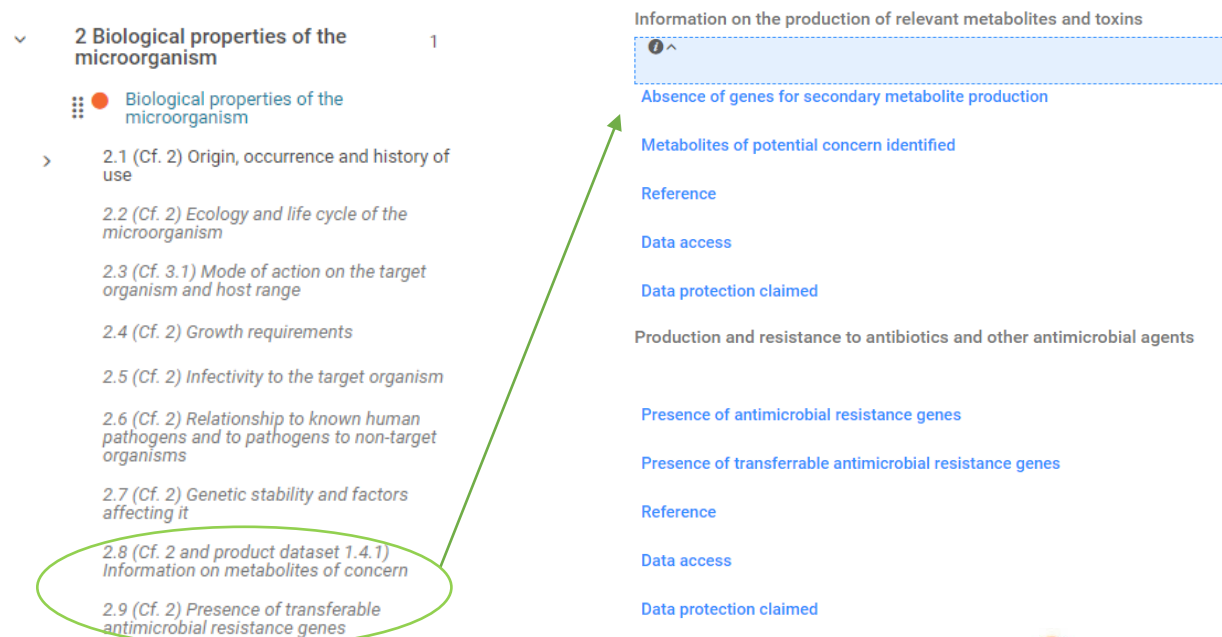
Example: Characterisation of botanical extracts is tricky as they may be complex mixtures of many plant components



- Microorganisms working context :

The new data requirements [Reg \(EU\) 2022/1438](#) and [Reg \(EU\) 2022/1439](#), applying from 21 Nov 2022, have been implemented in IUCLID since May 2023

But how to input in IUCLID remains in discussion (see Pesticides Steering Committee of the IUCLID sub-group (29th Feb 2024))



The screenshot displays the IUCLID interface for biological properties. On the left, a tree view shows '2 Biological properties of the microorganism' expanded, with sub-items 2.1 through 2.9. Item 2.8, 'Information on metabolites of concern', is circled in green. An arrow points from this circle to a detailed view on the right. The right panel, titled 'Information on the production of relevant metabolites and toxins', contains a search bar and a list of data requirements: 'Absence of genes for secondary metabolite production', 'Metabolites of potential concern identified', 'Reference', 'Data access', and 'Data protection claimed'. Below this, a section for 'Production and resistance to antibiotics and other antimicrobial agents' lists 'Presence of antimicrobial resistance genes', 'Presence of transferrable antimicrobial resistance genes', 'Reference', 'Data access', and 'Data protection claimed'.

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- Understandable that evaluators want the whole picture
- Logical step to move forward with national authorisation



- Aim of IUCLID must be to provide accurate and accessible information to support an efficient evaluation (& not filling a database with information that will not be used)
- Specific working contexts necessary
- The active substance dossiers in IUCLID need to be user friendly for evaluators, applicants and public



100% women !

Competition: running trail, mountain bike, canoe, run&bike, archery, orienteering

Charity and meet people

Raise gifts for children

Pot to raise money for the local children hospital



Help Cambodian Children



In partnership with all the pediatric departments of the Montpellier University Hospital, [Haut les Cœurs](#) supports sick children in order to improve their daily lives and offer them their dearest dreams

Thank you

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