IUCLID and microbial metabolites

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

WP on microorganisms

- New data requirements on microorganisms

  ✓Implemented in IUCLID release since May 2023

- Inclusion of requirements of SANCO/2020/12258 metabolite guidance

  ✓ How to implement in IUCLID

Identify MoPC

- Stage 2:

  Literature search to identify all secondary metabolites possibly produced by the species

  ✓ Outcome: List `A`

  ✓ In practice: List `A` >>100 compounds

Stage 2 step 3-6

- ✓ Check: hazardous effects in studies that may be caused by metabolites.

- ✓ For each metabolite, is there any indication of hazardous effect(s) in the published literature?

  - ❖ Literature search for hazardous effects for metabolites from list `A`

Stage 2 step 7 and 9

- ✓ Is analytical chemistry data available which indicate presence of metabolites of potential concern?
- ✓ Does a genomic analysis show absence of the gene encoding the metabolite?

Outcome of Stage 2: metabolites of potential concern

IUCLID

Current discussion in working party:

Which metabolites in IUCLID as (reference)substance?

- All List `A` compounds

  Currently requested during the meeting

- All compounds from `outcome of stage 2` - metabolites of potential concern

  Favoured by IBMA due to the burden of >>100 compounds in IUCLID with no impact on the risk assessment

IUCLID

Relevant for risk assessment:

- ✓ Determine which metabolites are of concern
  - ❖ Produced by the strain
  - ❖ Present in the product
  - ❖ Exposure to human and/or the environment

Compounds identified as MoC → substance database in IUCLID
Compounds identified as MoPC → reference substance in IUCLID

Conclusion

- Understandable that evaluators want the whole picture
- Implementing >>100 compounds in IUCLID is time/cost consuming work not necessary to conclude on the risk

- Search for support from MS authorities to change the order of the steps of the GD in dossier preparation to more logic order of steps (i.e. genome analysis before literature searches for hazards)
- Provide enough information for evaluation instead of filling a database with information that will not be used

Thank you!

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