

BVL / GERMANY

Federal Office of Consumer Protection and Food Safety

BVL

Federal Office of Consumer
Protection and Food Safety
Competent Authority; Assessment of Identity

Risk Management



UBA

German Environment Agency
Environment

JKI

Julius Kühn-Institut
Efficacy and Honey Bees

BfR

German Federal Institute for
Risk Assessment
Human and Animal Health

Risk Assessment

Risk Management at BVL

Department 2 - Plant Protection Products

Procedure Management
Products

Procedure Management
Active Substances

Environment

Applications of Plant
Protection Products

Product Chemistry
and
Analytical Methods
(also assessment)

Health

General affairs

PROCESS OVERVIEW ACTIVE SUBSTANCE AT BVL

- Submission of notifications by letter and digital files on CD/DVD (best case: CADDY.xml dossier).
- Validation of CADDY.xml CD/DVD (self made software) or check files manually.
- Communication with applicant via the coordination unit at BVL.
- Justified requests for confidentiality will be implemented.
- No automatic sanitisation process (no software).
- Multiple applicants are displayed with different dossier processes in our inhouse system, followed by a common RAR process.
- After data collection, distribution of documents/studies including metadata to the respective authorities, exchange of documents between the authorities (according to xml-scheme to BfR, JKI, UBA; Product Chemistry and Analytical Methods work with BVL inhouse system).

PROCESS OVERVIEW ACTIVE SUBSTANCE AT BfR/JKI/UBA/BVL

- Authorities evaluate the studies and write DAR/RAR using empty EU Microsoft Word templates.
- To ensure transparency of the process, e.g. paragraphs copied from applicant are highlighted or disclaimers are used
- Parallel editing of different units within the authorities (separate chapters)
- Send final report chapters to management authority including updated reference lists incl. public literature

PROCESS OVERVIEW FOR PLANT PROTECTION PRODUCT

- National digital application form with detailed information on product and applied uses
 - Obligatory submission of CADDY.xml dossier on CD/DVD (following the procedure described above)
 - Check of application by BVL units (incl. chemical identity and uses)
 - Communication via applicant portal system
 - Authorities evaluate the studies and perform risk assessment using an empty EU Microsoft Word dRR/RR templates OR edit applicants' dRR with disclaimers (boxes) to ensure the transparency of the process
- National authorisation for each use per product

For now,

- German authorities do not use OHTs in IUCLID dossier for the evaluation.
- to use IUCLID dossiers, all documents according to the list of end points are needed.
- Documents M/dRRs are still needed.

IT SOLUTIONS USED FOR APPROVAL OF A.S. / AUTHORISATIONS (PPP)

	BVL	BfR	JKI	UBA
Case processing system	MACHVBS/DMS	DocForMS	MACHVBS/DMS	Fabasoft eGov-Suite, Share Point
Records management	MACHVBS/DMS	-	MACHVBS/DMS	Fabasoft eGov-Suite
Study register	MACHVBS/DMS	eASB	MACHVBS/DMS	ICS
Evaluation tools (most important ones)	INFOZUPF, CADDY validation and Import, ESCRIBA	Ruedis, Prosafe, eASB	RIBEZUPF	ICS

At least interfaces to the BVL and the respective evaluation tools in each authority are required.

POINTS FOR DISCUSSION

Regarding IUCLID:

- Will IUCLID only be a transport medium?
- For evaluation with IUCLID, protected areas for each authority are necessary in Germany
- Is the applicant asked to fill in OHTs whenever the possibility is given that OHTs are usable (e.g. residues)?
- Many OHTs are currently not suitable to depict PPP applications in the evaluation process.
- Will the format of study summaries change?
- A processing management is required (ref. R4BP), additionally, export of data from work flow should be possible
- Possibility to use IUCLID offline should be implemented.
- Who will administrate the central portal for applications (with access for all involved parties)?

POINTS FOR DISCUSSION

Regarding the notification register:

- Which documents should be included? Only animal studies (ref. to animal study register at BfR)? DE suggests including all K Docs plus MSDS.
- Central archiving, enable central access for all parties
- Handling of public literature
- What about a second step to create also a study register(e.g. can be used to create reference lists)?
- Implementation timeline of Transparency regulation
- Study register required to ensure identity of studies to avoid duplications (not possible with IUCLID)