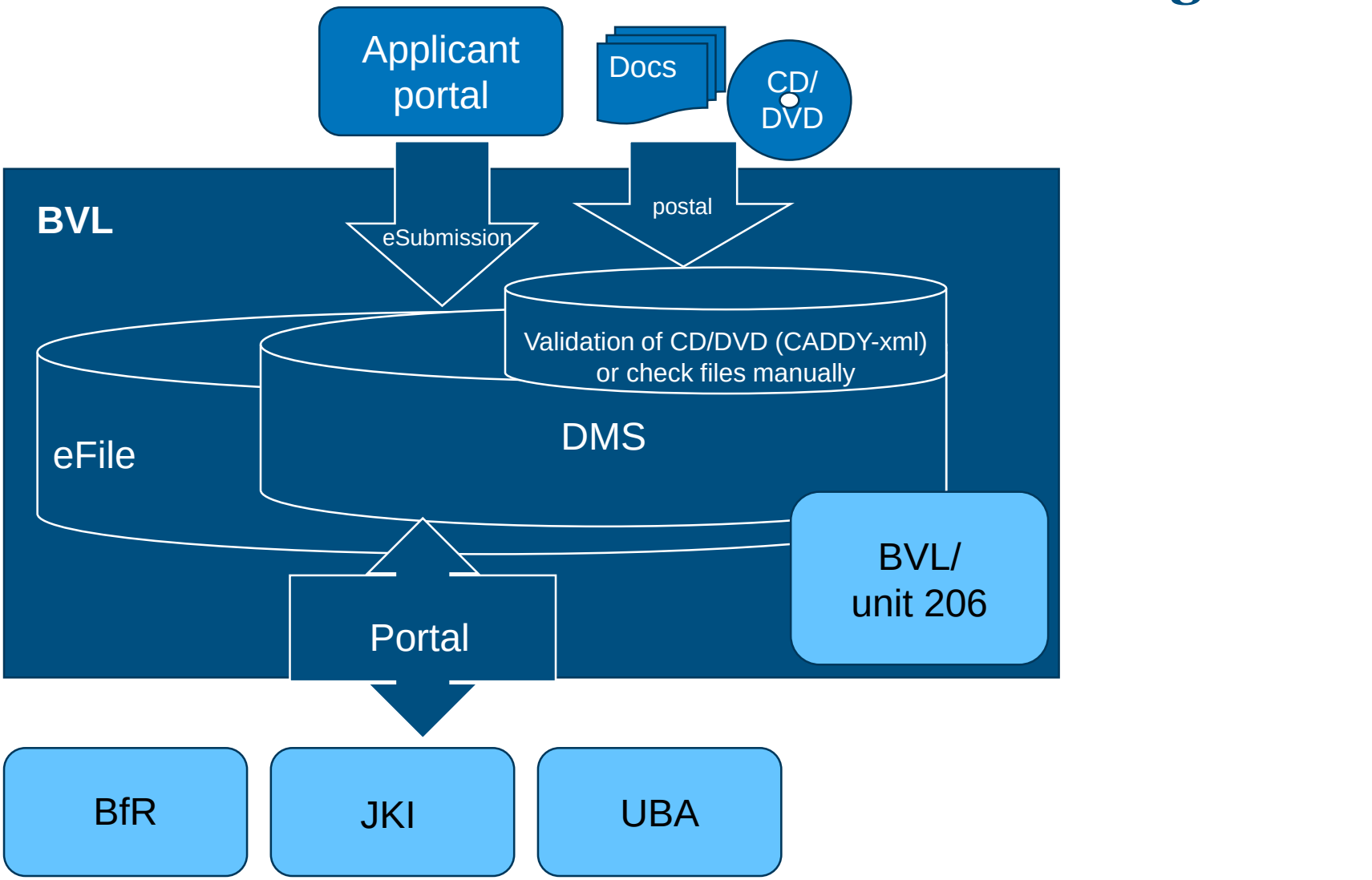
Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

IUCLID pilot

Insight from Germany

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

BVL – a simple overview of data management



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Why we still need an interface?

For now, all submitted data have to be imported in the BVL in-house system

- To archive the application process due to administrative order
- Create legally binding files with “one click”
- Study management (e.g. generate reference lists according to annex points)
- To distribute submitted data to other authorities/evaluators
- Use information for in-house tools (e.g. classification and labelling is generated automatically in the national authorisation letter)

That is why in our opinion,

- IUCLID should be a transport medium in the first step
- and in a second step an advanced feature for evaluation (including the generation of DAR/RAR).

Feedback from experts

- **There are too many fields for an annotation, it is not clear where the assessment should be entered.**

- **Preparation of more complex sections of the DAR/RAR (e.g. Volume 4) is not possible in the required quality.**
  - Necessary for evaluation (e.g. manufacturing process, 5-batch data, specification, product composition, analytical methods) is an editable annotation
  - Evaluation files as part of the DAR/RAR not only attachments.

- **Missing overview on evaluated information and related assessment.**
  - The assessment requires often data and conclusions that are related to other data points. However, a fast and easy access to already evaluated data is not given.

- **The additional use of IUCLID in the evaluation will cause an extra workload to the RMS beside the preparation of the word-based DAR/RAR.**
  - The evaluation and amendment of 'endpoint study records', 'endpoint summaries' and study meta data is laborious and time-consuming. Therefore, the evaluation of IUCLID data should be limited to those that are really needed for further processing (e.g. for classification).

Practical issues

- Transferring data from studies to the OECD templates is sensitive to errors
- Lifecycle management issue is not resolved
- IUCLID (i6z) does not support delta/incremental dataset updates for subsequent deliveries
- For integration in other software systems, "offline tools" for editing and reading a dataset (i6z) should be available, instead of being dependent on a large IUCLID server application (which takes several minutes to start) and then use its REST API to edit or read the dataset
- Will there be access to the notification register to validate studies?

Basic technical problems

- IUCLID cloud service does not run stable and crashes often

  Repeated waiting for the service to restart to re-enter the text in the data field

- Datasets get too big, due to the missing central study register → submission on CD/DVD still necessary

Implementation of IUCLID

- What about the timeline for the planned implementation?

- Which regulations will be affected?

Please note that the implementation of changes in regulations resides with the European Commission and the in consequence with all Member States in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

- Until the legislation remains the same, Germany requires the same:

➢ Preferably, CADDY.xml dossiers for the approvals of new active substances and within the renewal procedure

➢ Mandatorily, CADDY.xml dossiers for national authorisation procedures

Once IUCLID is implemented

- New interface for IUCLID needed

- How to deal with different regulations for national authorisations, new active substance approvals and renewals?
  - ➢ Germany is not able to deal with different systems

- What about a transitional period for the implementation? What timeline is realistic?

- Legal binding documentation required. In consequence, we have to ensure the archiving of the whole procedure (submission, communication, evaluation output).

Summary of the pilot project

Let us summarise the Pros and Cons of IUCLID with the following questions:

1. Is **transparency** given by IUCLID? Is the regulation fulfilled?

2. How is the **efficiency** increased by the use of IUCLID?

3. Is there more **harmonisation** with IUCLID?

4. Will the **quality** of evaluation remain, improve or decline?

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Thank you for your attention & the German delegation wants to thank all participants for their commitment!

Kontakt:
Friederike Breuer

Friederike.Breuer@bvl.bund.de