

IUCLID: PSN Meeting March 2023

CropLife Europe

Migration to IUCLID 6.7

- IUCLID format changes are necessary and overall welcome
- Data Migration is a difficult task and can never achieve 100 %

IUCLID 6.7 situation

- About 300 documents changed
- Migration impact massive
 - All PPP EP summaries moved to obsolete
 - Long List of individual documents where complete data loss occurs

	bioconcentration in prey of birds and mammals.001	
▼	8.1.4 Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	2
⋮	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	
▼	Obsolete	1
ⓘ	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians).002	

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*TOC_6.6-to-6.7_migration_23 Mar 2023 114647 (3).txt - Editor
Datei Bearbeiten Format Ansicht Hilfe
Amendment No. 1 - Complete validation of the method CAV-PA.2068 for determination of the assay of impurities in Imazamox by HPLC (2015/3903121) (FLEXIBLE_RECORD.Manufacturer_EU_PPP 40bb0bf6-f6b5-4aff-b074-8e65717f6496): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Complete validation of the method CAV-PA.2068 for determination of the assay of impurities in Imazamox by HPLC (2012/3005367) (FLEXIBLE_RECORD.Manufacturer_EU_PPP ef04d0f7-29be-45db-bffe-7b07d73fa305): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Quantitative Determination of Toluene in BAS 720 H (Imazamox TGA) by HPLC (2013/1275557) (FLEXIBLE_RECORD.Manufacturer_EU_PPP 3c9569a0-ccb8-4c12-ac4e-af3d737687d5): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Validation of analytical method AP10677701 for the determination of toluene in technical active Imazamox (2013/1275558) (FLEXIBLE_RECORD.Manufacturer_EU_PPP d1bfe152-80dd-43de-a8a8-d7b56b71ef47): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Determination of FTE in Imazamox by Flame-AAS (2013/1377040) (FLEXIBLE_RECORD.Manufacturer_EU_PPP a054c8bd-5ce4-4e13-ac46-c10f4b220a2): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Development and validation of an analytical method for the determination of sodium in Imazamox (Reg.No. 4096483, BAS 720 H) study no. 131.00085 (confidential) (2013/1377048) (FLEXIBLE_RECORD.Manufacturer_EU_PPP d2744a7c-4472-4c21-8add-60b1ba965668): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Determination of FTEE in Imazamox using ion chromatography (2013/1377045) (FLEXIBLE_RECORD.Manufacturer_EU_PPP 2fde5d99-d1ab-4837-9d78-801646a6ff02): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Development and validation of an analytical method for the determination of sulfate in Imazamox (Reg.No. 4096483, BAS 720 H) Study No. 131.00081 (confidential) (2013/1377044) (FLEXIBLE_RECORD.Manufacturer_EU_PPP 6a9054ab-b376-4790-bff5-ac81fb6966b): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
QSAR assessment of the genotoxic potential of Imazamox (BAS 720 H) and relevant impurities (2021/2837113) (FLEXIBLE_RECORD.Manufacturer_EU_PPP 4b72a441-9119-4ef4-b66d-91652c79354f): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Literature data (FLEXIBLE_RECORD.Manufacturer_EU_PPP 1a8ee31-4c20-4159-919d-43255a908c75): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Doc 3CA_Confidential data and information for the Active substance (FLEXIBLE_RECORD.Manufacturer_EU_PPP e0617e16-e323-4d5e-a387-a5be58642404): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Doc 3DH_Permission of each formulation in accordance with EU legislation (FLEXIBLE_RECORD.Manufacturer_EU_PPP 432ae4d5-c741-4c46-bf46-6-694b26103c4): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
Doc 3CP_Confidential data and information for the PPP (FLEXIBLE_RECORD.Manufacturer_EU_PPP c0c6c761-6578-43ca-b133-c343a79b8e2b): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2012_Imazamox_NRU_phototoxicity_in_vitro_(2012/1264018); 2016/1121662) (ENDPOINT_STUDY_RECORD.PhototoxicityVitro 11e2dalc-9168-45c6-b5f2-8e0aa4250485): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2017_Imazamox_NRU_phototoxicity_in_vitro_(000085199) (ENDPOINT_STUDY_RECORD.PhototoxicityVitro b90cfe8e-e9e2-4610-ab50-2a2a23009151): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2021_Imazamox_Steroidogenesis_assay_(2021/2011354) (FLEXIBLE_RECORD.IntermediateEffects ef7766d7-ab50-4137-8216-d06105287b22): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2021_Imazamox_In_Vitro_Aromatase_Inhibition_(2021/2011542) (FLEXIBLE_RECORD.IntermediateEffects d6baa93-e537-477a-82ec-c9f244f48738): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2021_Imazamox_toxicity_to_non-target_arthropods_on_natural_substrate_F._candida_(2020/2108720) (ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods 93aca228-5cfd-4678-8e9d-6c778de5409a): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
2021_Imazamox_toxicity_to_non-target_arthropods_on_natural_substrate_H._aculeifer_(2020/2108736) (ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods 60e2b79a-a3f1-4bc5-b0f3-d0330805424d): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
EFS_Imazamox_Repeated_dose_toxicity_oral,_dermal_(ENDPOINT_SUMMARY.RepeatedDoseToxicity dbee640c-649f-4c3d-cf7f-6c001f0c49c): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt
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Migration to IUCLID 6.7

Impact

- Submitted and Published Dossiers will be altered
- Several required Data will be gone completely

Solution ?

- No adhoc solution, manual rework needed
 - Resource intensive and time consuming (> 6 months for ai Dossier realistic considering number of Dossier submitted)
 - In line with applicable regulations?
 - Mistakes and data inconsistencies are given
 - Additional delays of regulatory processes triggered

Better Solution Going Forward

- IUCLID needs a toolbox for enabling parallel version support keeping submitted Dossiers stable for as long as required

IUCLID and Parallel Process

Issue

- Industry now have several dossiers using the same dataset in different stages of the process
 - Renewal (AIR) dossier, Art 12 MRL Confirmatory Data, Art 10 MRL Application
 - Pending admissibility, Admissible, Admissible respectively
 - The underlying dataset in these cases uses the same study reports and is “live”, needing to be updated as requested by the different stakeholders (RMS, eMS, EFSA)
 - Within the confidentiality stage EFSA have indicated that the dossier should not be modified, but resulting questions from the RMS on yet-admissible applications, or version changes prohibit this.
 - This could be future complicated with submissions via a LoA by a 3rd party, or different MS for MRL v Renewal
- **It is therefore not possible within the same dataset to amend according to these requests and resubmit without changing the dossier in all processes**

IUCLID and Parallel Process

Current Workaround

- Industry are in many cases forced to ***duplicate datasets*** to overcome these issues;
 - This results in many versions of the same information
 - Is increasingly impossible to administratively manage what data is in what process, what is the “approved” version and what version should be used moving forward, this will get increasingly difficult over time
 - Goes against the one substance, one assessment principle
 - Will prevent a succinct overview of data for any useful purposes within agency IUCLID as the same molecule, study reports with differing UUIDs and contents will be available

Request

- IUCLID should have sufficient data management tools and lifecycle management across competing processes to enable one substance, one assessment principles and allow for datasets to not require duplication to achieve stakeholder requests across projects.