



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

*TOC_6.6-to-6.7_migration_23 Mar 2023 114647.001.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 (2015/3003121) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_408bb0fb-f6b5-4aff-b874-8e5717f6496): 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 (2015/3005367) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_ef0d40ff-2904-45db-bff6-7b07d73fa305): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Quantitative Determination of Toluene in BAS_720 H (Imazamox TGAT) by HPLC (2013/1275557) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_3c9569a9-cc8b-4c12-ac4e-af3d737687d5): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Validation of analytical method PLAP677/01 for the determination of toluene in technical active Imazamox (2013/1275558) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d1bfef152-80dd-43de-a0a8-d7056b71ef7a): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Determination of FTE in Imazamox by Flame-AAS (2013/1377049) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d1bfef152-80dd-43de-a0a8-d7056b71ef7a): 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.: 40996483, BAS_720 H) study no. 13100085 (confidential) (2013/1377048) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d27447c-4d72-4c21-8add-60b1ba965668): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Determination of FTE in Imazamox using ICP-MS (2013/1377047) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d1bfef152-80dd-43de-a0a8-d7056b71ef7a): 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.: 40996483, BAS_720 H) Study no. 13100081 (confidential) (2013/1377044) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_6a0054ab-b376-4790-bff5-ac8bf6966b): 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 (2022/205711) (FLEXIBLE_RECORD.Manufacturer_EU_PPP_4072a441-0193-4ef4-b66d-91d52c705154f): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Literature data (FLEXIBLE_RECORD.Manufacturer_EU_PPP_1a8ee31-4c20-4159-919d-4325a908c75): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Doc JGH_Confidential data and information for the Active substance (FLEXIBLE_RECORD.Manufacturer_EU_PPP_e617e16-a223-4d5e-a387-5b5e58624204): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Doc JGH_Permission of each formulant in accordance with EU legislation (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d32ae4d5-741-4c46-bf45-694b2c6163c4): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
Doc JGH_Permission of each formulant in accordance with EU legislation (FLEXIBLE_RECORD.Manufacturer_EU_PPP_d32ae4d5-741-4c46-bf45-694b2c6163c4): 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.PhototoxicityInVitro_11e2da1c-9161-45cd-bf52-8e0aa259a493): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
2017_Imazamox_NRU_phototoxicity_in_vitro_(0000085199) (ENDPOINT_STUDY_RECORD.PhototoxicityInVitro_b94ccf68-e9e2-4610-ab5b-2a2a2000151): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
2021_Imazamox_Steriodogenesis_assay_(2021/2011354) (FLEXIBLE_RECORD.IntermediateEffects_e77766d7-a58c-4137-8216-d84cb528722): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
2021_Imazamox_In_Vitro_Aromatase_Inhibition_(2021/2011542) (FLEXIBLE_RECORD.IntermediateEffects_d61baa93-e537-477a-82ec-c9f2a4f48738): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
2021_Imazamox_toxicity_to_non-target_arthropods_on_natural_substrate_F_candida_(2020/2108736) (ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods_93ac0228-5cf0-4678-8e9d-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-bff3-d0390b05424d): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	
EP5_Imazamox_Repeated_dose_toxicity_oral_dermal (ENDPOINT_SUMMARY.RepeatedDoseToxicity_d3ee84bc-646f-4c3d-acf7-6c00b1fe49c): 6.6-to-6.7_migration_dataloss_23 Mar 2023 114647.txt	

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 a 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.