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Annex to a news release

Revised completeness check to be launched in April 2020

Helsinki, 11 December 2019

This annex outlines the main changes to the completeness check in the revised implementation of April 2020.

The manual verification of the chemical safety report will contain the following items:

- If the substance is classified as hazardous or with PBT properties, the chemical safety report must include an exposure assessment and risk characterisation.
- All uses reported in the IUCLID dossier must have corresponding exposure scenarios in the chemical safety report.
- Each exposure scenario must contain contributing scenarios corresponding to the contributing activities of the uses (described by the assigned process categories and environmental release categories) reported in the IUCLID dossier.
- Each contributing scenario must contain:
    - operational conditions and risk management measures;
    - emission estimates for the environment;
    - exposure estimates for human health; and
    - risk characterisation ratios, corresponding to the hazards identified.
- If any of these elements are missing, the presence of a justification that is relevant for its purpose is checked.

Improved checks of hazard data will ensure that the following endpoints are explicitly covered in the IUCLID dossier. The changes listed below will all take place by modification of the computer-based completeness check rules, and registrants will be able to verify them ahead of the submission with the IUCLID Validation assistant tool.

- Mutagenicity
    - 8.4.1: *in vitro* gene mutation study in bacteria is addressed (Annex VII and above.
    - 8.4.2: *in vitro* cytogenicity study in mammalian cells or in vitro micronucleus study is addressed (Annex VIII and above).
    - 8.4.3: *in vitro* gene mutation study in mammalian cells is addressed (Annex VIII and above); waiving possible if no negative results from 8.4.1 and 8.4.2.
    - 8.4: *in vivo* genotoxicity is addressed in case of a positive result in any of the *in vitro* genotoxicity studies required at Annex VII and VIII (Annex VIII and above).

- Reproductive toxicity
  - 8.7: adaptation of the reproductive toxicity endpoints must follow the appropriate REACH annex provisions.
  - 8.7.2: developmental toxicity must be addressed with a different species than at Annex IX (Annex X).

- Degradation
  - 9.2.1.2/9.2.1.4: *simulation testing on ultimate degradation in surface water* and *sediment simulation testing* must be separately addressed in the dossier (Annex IX and above).
  - 9.2.3: *identification of degradation products* must be explicitly addressed (Annex IX and above).