

Updated completeness check

Information session on updated
registration process

04 November 2015

Javier Sanchez Saez
Directorate of Registration
European Chemicals Agency



Outline

- Background: Why this revision?
- Review of completeness check rules
- Introduction of manual verification
- Take home messages

Completeness check?

REACH defines

- the format of the registration dossier
- the information that has to be provided
- and establishes the obligation for ECHA to check that all the required elements have been provided

Only if all information is complete, a registration number is issued

Background – Why this revision?

- Experience from two registration deadlines
- Indication that certain revisions to the initial completeness check should be made
- Timing – stable implementation before deadlines
- Process established in 2008, never modified

Background – Why this revision?

Aspects considered:

- Review of IUCLID formats
 - Improved structuring of information, CLP/GHS integration
- Changes in some regulatory requirements
- Increase the level of availability of expected information:
 - Avoid having to do 'completeness check' at compliance check
 - Very limited number of dossiers bypassing the system

Scope of the revision

- Review the automatic completeness rules
- Manual verification to certain extent

Consultations

- ECHA Management Board
- Member States (CARACAL meetings)
- European Commission
- Industry associations

Review of the completeness check

1 – Review of the rule set



Principles for the rules review (1/2)

- Legal basis:
 - each new or modified rule connected to REACH requirements
 - no change in legal requirements
- Usefulness: new or modified rules address information necessary for achieving aims of REACH
- Robustness: rules check fields with a clear purpose and format

Principles for the rules review (2/2)

- Simplicity: clear rules to be understood by non-expert users (even if certain level of cross-checking of information is unavoidable)
- Proportionality: assessment of impact of the revised rules on registrants

Result of the review

- Revised data formats and rules will give increased transparency on requirements for registrants
- Most rule changes relate to format changes
 - Covered by migration
- Impact on existing dossiers (proportionality)
 - When information could not have provided (e.g. new field), and data migration cannot resolve it, changes implemented only if low impact or high benefit (limited cases).
 - When the information should and could have been there in the first place, accept higher impact.
- Discussed with industry working group

Key elements in ESR – results

Results – IUCLID 6

- Table – structured values, units and parameters;
- Table – Remarks (on absence of quantitative result);
- ~~Rich text~~

Effect levels (offspring of P generation)

Key result	Dose descriptor	Generation	Effect level	Based on	Sex	Basis for effect le...	Remarks on result
<input type="checkbox"/>	NOAEC	F1	1.0 - mg/kg bw/day (nominal)	act. ingr.		mortality, clinical signs	

Effect levels (offspring of P generation)

Key result	Dose descriptor	Generation	Effect level	Based on	Sex	Basis for effect le...	Remarks on result
<input type="checkbox"/>	NOAEC						not determinable due to absence of adverse toxic

Key elements in ESR – test material

Test material – IUCLID 5

- 'yes' = same as substance in section 1
- Identifier + free-text identity
- Details on test material






Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

yes ▾

Test material identity

Identifier	Identity
EC number	XXX
CAS number	50-00-0

 Add...  Edit...  Delete  Move up  Move down

Details on test material



Registered substance
Batch 12345

Key elements in ESR – test material

Test material – IUCLID 6

- ~~'yes' = same as substance in section 1 (field removed)~~
- Identifier + ~~free-text~~ identity
- ~~Details on test material~~

Name*

Test material ID XXX

- REUSABLE
- CENTRALLY MANAGED
- STRUCTURED
- COMPOSITION-BASED

Composition

Type	Reference substance	Concentration	Remarks
Constituent	formaldehyde / 200-001-8	35.0 - 38.0 % (w/w)	
Constituent	methanol / 200-659-6	10.0 - 15.0 % (w/w)	
Constituent	water / 231-791-2	50.0 - 55.0 % (w/w)	

⊕ Add... ✎ Edit... ✕ Delete ⬆ Move up ⬇ Move down ➤ Go to link target

Composition / purity: other information

... Other ... Remarks ...

Other characteristics

Test material form

liquid ... Other ... Remarks ...

Details on test material

⌵ | ✕

Batch 12345 ...

Use description

IUCLID 5

- Use description consists of a name and a list of use descriptors
- Descriptors required depend on use type
- Remarks accepted instead of technical function (old formats)

IUCLID 6

- Use description includes contributing activity/technique with related use descriptor (from IUCLID 5)
- Each use type requires at least one contributing activity for the environment (ERC), and one for workers or consumers (PROC/PC/AC).
- ~~Remarks accepted instead of~~ technical function ~~(old formats)~~

Use description

IUCLID 5


Uses at industrial sites

Flags	Id...	Identified Use name	Brief description o...	Environmental Rel...	Process Category	Product Category ...	Sector of end use
	1	Use of vehicle cleanin...	Spraying and rinsi...			ERC 4: Industrial u...	PROC 7: Industrial...	PC 35: Washing an...	SU 17: General ma...

Technical func...	Substance s...	Subsequent ...	Link t...	Exposure scenario ref...	Use coverage in CSR ▲	Remarks
Surface active ...	n a mixture	no				

Use description


IUCLID 6



Use name

Use of vehicle cleaning product

Further description of use



Spraying and rinsing of cleaning product at car manufacturing lines

Regulatory status

Explanation for the regulatory status

Related composition

M

M

Use description

IUCLID 6

Contributing activity / technique for the environment	
Name of activity / technique	Automated water based washing of large articles ...
Environmental release category (ERC)	▼ ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles

M

Contributing activity / technique for workers	
Name of activity / technique	Transfer of industrial detergent(charging/discharging) to a dedicated cleaning equipment (machine/vessel) ...
Process category (PROC)	▼ PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

M

Contributing activity / technique for workers	
Name of activity / technique	Spraying of a diluted industrial cleaning product. ...
Process category (PROC)	▼ PROC 7: Industrial spraying

M

Use description

IUCLID 6

Product category used	▼ PC 35: Washing and cleaning products (including solvent based products) [X]	M
Sector of end use	▼ SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment [X]	M
Technical function of the substance during use	▼ Surface active agents [X]	M
Substance supplied to that use in form of	▼ in a mixture [X]	M
Subsequent service life relevant for this use	no [v]	M
Subsequent service life name	[]	M
	[+] Add... [X] Delete [↑] Move up [↓] Move down [→] Go to link target	
Tonnage of substance for this use (tonnes/year)	[] []	M
Details on tonnage reported	[]	
<input type="checkbox"/> Limited number of sites for this use		M
Details on limited number of sites	[]	
Remarks	[Rich Text Editor: Normal, Aharoni, 8, A, B, I, U, ...]	M

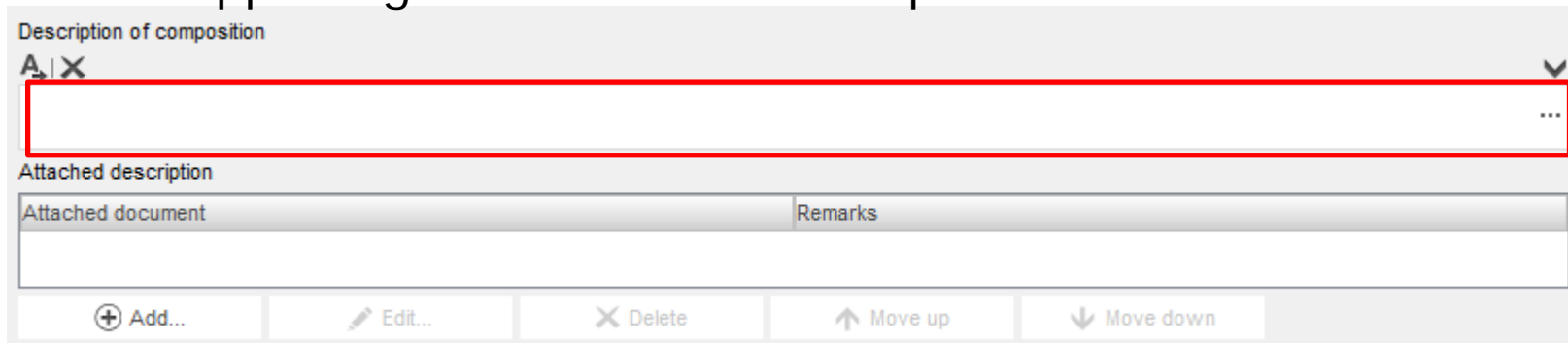
UVCB manufacturing process

IUCLID 5

- Various locations (section 1.1 reference substance, section 1.4, section 3.1...)
- Varying level of detail.

IUCLID 6

- Improved field 'Description of composition' in section 1.2; free-text templates available
- Required for UVCB substances as key SID information;
- Supporting attachments can be provided.



Description of composition

A | X

Attached description

Attached document	Remarks

+ Add... ✎ Edit... ✕ Delete ↑ Move up ↓ Move down

Concentration ranges

IUCLID 5/6

- No change in format;
- Previously required as alternative to typical concentration, and only one range field;
- Now full range always required; exceptions when reporting 100% or 0%.



The screenshot shows two input fields for concentration data. The top field is labeled "Typical concentration" and contains a dropdown arrow, an empty text box, and a "..." dropdown arrow. The bottom field is labeled "Concentration range" and is highlighted with a red border; it contains a dropdown arrow, an empty text box, another dropdown arrow, another empty text box, and a "..." dropdown arrow.

Review of the completeness check

2 – Manual verification



Objectives of manual verification

- Stopping dossiers where manifestly irrelevant data is provided instead of required information
- Preventing that registrants with such data bypass the system
- The procedure will stay within the scope of completeness check

Areas in focus

Checking if a plausible justification exists when deviating from standard information requirements, e.g.:

- Manifestly irrelevant data waivers for hazard data
- Deviations on substance identity requirements (e.g. no analytical information provided)
- Justification if CSR is waived

Implementation

- Certain criteria will trigger dossiers that will be stopped for manual verification
- Integral part of the current completeness check procedure
- Implemented with the go-live of the new IUCLID and REACH-IT (mid 2016)
- Invalidation of registration numbers
 - Well justified cases


The target:

Endpoint study record: Vapour pressure.003

Detail level: all fields

[Administrative Data](#) [Data source](#) [Materials and m](#)
[Results and discussions](#) [Overall remarks, attachments](#) [Applicant's sum](#)



Administrative Data





Purpose flag:

Data waiving: other justification

Justification for data waiving: no comment

Study result type:  

Reliability:  


Rationale for reliability incl. deficiencies:



Endpoint study record: Flash point.002



Detail level: all fields

[Administrative Data](#) [Data source](#) [Materials and m](#)
[Results and discussions](#) [Overall remarks, attachments](#) [Applicant's sur](#)




Administrative Data





Purpose flag:  

Data waiving: other justification  

Justification for data waiving: No relevant data

Study result type:   

Reliability:  

Rationale for reliability incl. deficiencies:

Take home messages



Take home messages

- The revised process will be launched in one go
 - Revised rules
 - Manual verification
 - Together with IUCLID 6 and new REACH-IT version
- It applies equally to existing and new registrations
 - New dossiers: reported info expected to be clearer
 - Existing dossiers: certain rework needed. Minimal if consistent information provided in the past (examples)
- Support will be available
 - IUCLID Validation assistant with revised rules
 - Manual verification – non acceptable examples

Thank you!

javier.sanchez-saez@echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
[@EU_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)