Dossier Quality Assistant

- This document gives an overview of the rules covered by the Dossier Quality Assistant (DQA), which is incorporated in the IUCLID Validation Assistant plug-in. The rules are divided into two rule sets:
  - **Substance identity rules** (applicable for registration, inquiry)
  - **Dossier quality rules** (applicable for registration)
- The rules reflect what ECHA expects from a high-quality dossier.
- This document will be updated to be kept in line with the development of the DQA.

Users should analyse the warnings given by the DQA to see if these are relevant to the registrant's own situation; exceptions may apply.

DQA – Substance identity rules

- Further information needed
- Inconsistent information
- Mass balances
- Mono- and multi-constituent conventions
- UVCB

DQA – Substance identity rules

Further information needed

Section 1.1/1.2

- All reference substances should contain a IUPAC name

Section 1.2

- Complete degree of purity ranges
- Complete concentration ranges
- Typical concentrations provided

Section 1.4

- Indication of optical activity provided*

* Only for Article 10 registrations.

DQA – Substance identity rules

Inconsistent information

Section 1.1/1.2

- Consistent CAS numbers inside reference substance

Section 1.2

- Consistent use of concentration units within a composition – preferably % (w/w)
- Sound concentration values, 0 – 100 %
- Typical concentration inside of concentration ranges
- Only additives with stabilising function to be reported
- Each reference substance to appear only once inside a composition

DQA – Substance identity rules

Mass balances*

Section 1.2 – consistency main constituents / purity

- Main constituent concentrations to be consistent with purity:

$\sum_{i=1}^{n} c_i^{max} \geq purity^{max}$	Sum of max. concentrations not below maximum purity.
$\sum_{i=1}^{n} c_i^{min} \leq purity^{min}$	Sum of min. concentrations not above minimum purity.
$c_i^{typ,max} \leq purity^{max}$	No main constituent concentration should be above the maximum purity.
$c_i^{max} + \sum_{j=1, j\neq i}^{n} c_j^{min} \leq purity^{max}$	Each main constituent should be able to adopt its maximum value without compromising the maximum purity.

* Only for mono- and multi-constituent substances

DQA – Substance identity rules

Mass balances*

Section 1.2 – consistency impurities / purity

- Impurity concentrations to be consistent with purity:

$purity^{max} + \sum_{i=1}^{n} c_i^{min} \leq 100\%$	Sum of min. concentrations should be consistent with maximum purity.
$purity^{min} + \sum_{i=1}^{n} c_i^{max} \geq 100\%$	Sum of max. concentrations should be consistent with minimum purity.
$purity^{min} + c_i^{typ,max} \leq 100\%$	No impurity concentration should violate the minimum purity.
$purity^{min} + c_i^{max} + \sum_{j=1,\, j \neq i}^{n} c_j^{min} \leq 100\%$	Each impurity should be able to adopt its maximum value without compromising the minimum purity.

* Only for mono- and multi-constituent substances

DQA – Substance identity rules

Mono- and multi-constituent substances

Section 1.2, mono-constituent substances

- One main constituent reported at ≥ 80%
- Concentration of individual impurities ≤ 20%
- Sum of impurity minimum concentrations ≤ 20%

Section 1.2, multi-constituent substances

- Main constituents reported at 10 – 80%
- Concentration of individual impurities ≤ 10%

DQA – Substance identity rules

UVCB substances

Section 1.1

- Description of manufacturing process provided in 1.1 reference substance

Section 1.2

- Section 1.1 reference substance not used as a constituent in the composition
- As impurities are not relevant for UVCB, only constituents and additives (if relevant) are reported

DQA – Dossier quality rules

- Tonnage information
- Use description
- Composition / Classification
- Endpoint study record approach
- Other

DQA – Dossier quality rules

Tonnage information

Section 3.2

- Recent tonnage information provided when creating a dossier
- Years consistently reported (no duplicates, gaps)
- Information on intermediate tonnages provided
- Phase-in substances contain at least three years of tonnage information

Dossier header / section 3.2

- Section 3.2 tonnage consistent with registered tonnage (dossier template/header)

DQA – Dossier quality rules

Use description (1)

Section 3.5 – intermediates*

- No uses should be reported in last three tables (professional uses, consumer uses, article service life)
- Uses with PROC codes consistent with Article 17/18 definition
- Uses with ERC codes consistent with Article 17/18 definition
- JS LEAD dossiers (standard template, only intermediate own uses, providing joint CSR) can include uses contradicting the above rules if they correspond to uses from a full member registration, and are flagged as 'Use covered by a joint CSR but not a lead own use'

* Only SCC-intermediate tonnage bands covered in own registration.

DQA – Dossier quality rules

Use description (2)

Section 3.5 – all

- Uses flagged as 'Use covered by joint CSR' only if dossier is covered by joint CSR (dossier header)
- Manufacture table only filled when legal entity roles include manufacturer (section 1.1)
- If uses are indicated to have subsequent service life, entries are provided in the article service life table, and vice versa
- If uses have ERC codes indicative of inclusion in article, entries are provided in the article service life table

DQA – Dossier quality rules

Composition / Classification

Section 1.2, composition on CLP Annex VI*

- If section 1.1 or 1.2 constituent reference substance is listed on CLP Annex VI, this needs to be considered in the C&L
- If impurity or additive is listed on Annex VI, this should be considered in the C&L and indicated if relevant for the classification and labelling of the substance

Section 2.1

- C&L blocks indicated as 'not classified' should not contain a classification
- C&L blocks in 2.1 with hazard statement in the Labelling part should contain a classification
- If an impurity/additive is marked as 'relevant for the classification and labelling of the substance' in section 1.2, this should be reflected by a classification in section 2.1**

* The rules do not compare against the harmonised classification or the cut-off concentration value, they just alert the user that the substance has a harmonised classification because a match with Annex VI was found. ** Does not concern JS MEMBER dossier with no section 2.1

DQA – Dossier quality rules

Endpoint study record approach (1)

Administrative data – purpose flag

- Study report, data waiver and/or testing proposal should be provided in separate endpoint study records
- Each endpoint study record has an indicated purpose
- Key studies have a high reliability
- Key studies do not have the reference type 'secondary source'
- Weight of evidence approach is based on more than one endpoint study record
- Disregarded studies are of low reliability
- Disregarded studies contain a rationale for reliability

DQA – Dossier quality rules

Endpoint study record approach (2)

Administrative data – waiving

- Data waiving records should only contain information in justification field
- Justification for data waiving should only be provided in records indicated as data waiving
- Approach to waive all requirements in sections 5, 6, 7 needs to be carefully considered and justified

Inconsistent information

- Recent study (2009->) provided in in sections 5, 6, 7 should be performed according to GLP
- When a test guideline was used with deviations, explanation on deviations needs to be given

DQA – Dossier quality rules

Other

General inconsistencies

- EINECS substances should be registered as phase-in
- Only representative should not have manufacturing sites inside the EEA
- All manufacturing sites are expected to be located in the same country as the legal entity

Section 7, endpoint summary

- If the route of exposure does not match original study, a justification needs to be provided
- The overall assessment factor (AF) should match the product of individual AFs