

Transition to the new IT tools - how to prepare

Technical information for existing registrants

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Foreword

This document provides a source of information for registrants with existing data in IUCLID 5 format who need to adapt and prepare their information for submission with the new IUCLID and REACH-IT versions. The document targets users that enter and maintain the data, and aims to direct them to the main points of attention before and after migrating the data from IUCLID 5 to IUCLID 6. This is a technical background document and does not intend to serve as a manual for how to prepare a complete and compliant dossier in the IUCLID 6 format. Not all items listed are relevant for all dossier types.

More information on these topics can be found in the dossier preparation manuals and practical guides. Advice on IUCLID installation and migration is available on the IUCLID 6 website.

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Introduction

IUCLID 6

IUCLID 6 is built on new technology. The renewed IT solution enables improved user management and enhanced access security. It allows the development of customised interfaces, as well as to connect IUCLID to other data management systems. For the end user, the user experience has been largely maintained from IUCLID 5: the section numbering and the familiar data elements such as legal entities, reference substances, substance datasets and dossiers remain. To streamline the structure and facilitate more efficient sharing of information, sections 1-3 have been converted from a one-document structure into record-based sections, similarly to sections 4-13. New records are added by right-clicking on the section name in the IUCLID table of contents.

In the Navigation panel of the substance dataset, the former 'Section tree' tab has been renamed 'TOC' (Table of contents). The default selection for the TOC view will be 'REACH Complete table of contents', which displays all sections that are available for REACH dossiers, following the familiar numbering. Other TOC selections can be made for a more specific REACH dossier type, or to view the sections relevant for CLP or biocides dossiers.

All information that users have stored in IUCLID 5.6 will be migrated to IUCLID 6. This can be achieved by the migration of the whole database, during the *upgrade* process. The same migration is also performed when a data element of IUCLID 5.6 format is *imported* into IUCLID 6. Most of the migration will simply keep the information in the same data fields as before; however, in some cases, where the data structure has undergone more significant changes, a more complex migration will be required.

The IUCLID plug-in programs: the Validation assistant, Dissemination preview, Report generator and Fee calculator will be updated in order to continue supporting the IUCLID 6 user in preparing their dossier. These modules will be installed by default with the main application. If an update of a IUCLID 6 module, such as a plug-in, becomes available, the application will notify the user with indications to download the installation package.

REACH-IT

The new version of REACH-IT will introduce changes aiming at an enhanced user experience with a more intuitive user interface, while simplifying the way registrants perform their REACH and CLP regulatory duties. The logic behind the main components of the application will not change and the users will be able to have a clear and immediate overview of all the available functionalities via the enhanced menu in the homepage. In addition, targeted and explicit help will be integrated in the system, ensuring a smooth guide through the application.

The new REACH-IT will allow for a central management of contact persons and TPRs, which will be specified in REACH-IT and be linked with a specific submission. Users will also be able to manage many companies with one user account (no need to log-out and log-in again).

Following the new Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing adopted by the European Commission, REACH-IT has been updated to make sure that dossiers for the same substance cannot be submitted outside of a joint registration (One Substance One Registration (OSOR) principle). The users will be able to access information about (potential) co-registrants and existing Joint submissions, for substances for which they hold a (pre-) registration, or inquiry number, via the optimised search function.

In case of updates, both spontaneous and requested updates will now be accepted by the system via a submission of only one IUCLID 6 dossier, if needed, as long as this is indicated correctly in the IUCLID dossier header. The only exception will be the Technical Completeness Check (TCC) requested update, which needs to be submitted independently.

In addition, the new REACH-IT will provide guidance to users on how to determine their company size via a targeted wizard within the system.

Finally, members of a joint submission will be able to build and submit their IUCLID 6 member dossier online in REACH-IT, through a simplified interface. The scope will be limited to member dossiers with standard information requirements, one composition, where all the hazard information is provided jointly by the lead. If these conditions do not apply, the standard IUCLID application will be needed to build the member dossier.

After the release of the new REACH-IT, only dossiers created with IUCLID 6 will be accepted.

Items for attention

1. Other identifiers (IUCLID section 1.1)

Description	<p>In IUCLID 5, the section 1.1 table 'Other names' contained entries to report the Trade names for the registered substance and the Alternative names for substances in mixtures requested under Article 24 of the CLP regulation.</p> <p>In IUCLID 6, this table has been renamed 'Other identifiers' and has been extended to cover more types of identifiers. In addition to capturing the entries described above, the 'Other identifiers' table will document identifiers (for the purpose of transparency and traceability) by which the substance was previously known but were later replaced/refined for identification under REACH (e.g. historical EC number), or identifiers which are used to identify the substance under other regulatory schemes (e.g. INCI name). Chemical (scientific) synonyms should not be listed here, but should be indicated in the reference substance information.</p> <p>All entries in the 'Other identifiers' table will be published unless claimed confidential, with the exception of the CLP alternative name and the CAS name (never published) and the UN name/number (always published).</p>
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	If you wish to indicate identifiers under which the substance was previously known, or under which it is known under other legislations, you can report these in the IUCLID 6 section 1.1 table 'Other identifiers'. Unless you indicate that you wish to keep the information confidential, it will be published on the ECHA website.

2. Type of composition (IUCLID section 1.2)

Description	<p>All existing section 1.2 composition blocks in IUCLID 5 will become separate composition <i>records</i> in IUCLID 6, and all the information will be migrated as provided. A new field is introduced in the composition record: 'Type of composition'. This field allows users to indicate more precisely the nature of the composition they have provided.</p> <p>The field will be automatically populated with the value 'legal entity composition of the substance' during migration or creation of a new section 1.2 composition record. This type of composition is expected to reflect the composition of the registered substance as manufactured / imported by the registrant and is an information requirement subject to completeness check and dissemination. The first legal entity composition record will be used by REACH-IT to determine the substance identity of the registration.</p> <p>Other composition types available are 'boundary composition of the substance' (see next item), and 'composition of the substance</p>
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	generated upon use'. The latter composition type may be reported when the registrant wishes to specify a composition / form (for clarifying the classification and labelling, hazard assessment, or the related use), which has been produced by e.g. purification or grinding of a composition manufactured / imported, and still corresponds to the registered substance. These compositions are not subject to completeness check, but will be published, unless the relevant confidentiality flags are set (the same flags as for other composition types).
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	If you have reported a composition in section 1.2 which is not intended to reflect a composition of the registered substance as manufactured/reported by your legal entity, please revise the 'Type of composition' as appropriate in IUCLID 6.

3. Boundary composition – Substance identity profile (IUCLID section 1.2)

Description	<p>IUCLID 6 enables the reporting of so-called boundary compositions of the substance. These compositions describe the boundaries of the collectively registered substance of the joint submission, and should reflect the hazard information and classification provided for the substance. The boundary compositions should be reported in the lead registrant dossier and linked to relevant information (C&L, PBT). More than one boundary composition can be provided; together, these compositions are expected to reflect the Substance Identity Profile (SIP).</p> <p>As it was previously not possible to indicate a composition as a boundary composition, there is no migration of existing IUCLID 5 information to this composition type.</p> <p>Information provided in boundary composition records is extracted to the REACH-IT Joint submission page and displayed to the participants of the joint submission. Boundary compositions are subject to certain business rule checks during submission, which verify that minimum information is present for a meaningful extraction. Boundary compositions will be considered volunteered for publication, unless the relevant confidentiality flags are set (the same flags as for other composition types).</p>
Relevance	Lead registrant dossiers
Action	To indicate a composition as a boundary composition, select the value 'boundary composition of the substance' in the IUCLID 6 section 1.2 field 'Type of composition'.

4. State / form of the composition (IUCLID section 1.2)

Description	<p>In IUCLID 5, the information on the physical state and form of the registered substance was provided in relation with the classification and labelling, in section 2.1 – GHS. As a consequence of this, only those registrants who included the section on the classification and labelling in their dossiers (lead and individual registrants) could provide this information.</p> <p>In IUCLID 6, the field to indicate the state or form of the substance has been moved to the top of the composition record in IUCLID section 1.2, where it now constitutes a part of the identification of the registered substance. While not subject to any submission checks, it is strongly advised to provide this information, in particular when the substance can exist in different states and / or forms and when these may have an impact on the properties and classification of the substance. The information on state / form is, as previously, subject to dissemination.</p> <p>During migration, existing information on the state / form will be migrated from section 2.1 to section 1.2. Migration is straightforward whenever only one block exists in section 1.2 and / or 2.1 and whenever 1.2 / 2.1 blocks have been linked. When multiple blocks exist in both sections, and have not been linked, migration will move all state / form selections available to all compositions.</p>
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	<p>If in IUCLID 5 you provided multiple compositions in section 1.2 and multiple classification blocks in section 2.1, ensure that they have been appropriately linked before migration.</p> <p>Verify the migration result in IUCLID 6 for section 1.2 and ensure that the appropriate state / form selection is made for each composition. If you had not provided this information in the past (e.g. if you are a member registrant), you are advised to select the relevant state(s) and form(s) for your manufactured / imported substance in IUCLID 6 section 1.2.</p>

5. Compositional information (IUCLID section 1.2)

Description	<p>The composition record in IUCLID 6 contains certain structural improvements.</p> <p>The field 'Description of composition' has been enhanced to accommodate a detailed definition of each composition. For UVCB substances, a text template has been prepared to support the user in reporting the main parameters of the production process, a key substance identifier of complex substances. The field will be subject to completeness check for UVCB substances, but will not be published. Migration will populate the field from the IUCLID 5 fields 'Brief description' (section 1.2) and 'Methods of manufacture of substance' (section 3.1).</p>
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	<p>A new field 'Justification for deviations' has been included. In this field, all explanations as to why the registrant deviates from agreed conventions in the description of the substance composition should be provided. For example, if the registered substance is considered to be a mono-constituent substance, but the main constituent is present at less than 80%, the explanation should be given in this field. No migration takes place to the 'Justification for deviations' field. The field will be checked at completeness check when deviations take place, but will not be published.</p>
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	<p>Verify the migration result in IUCLID 6 for the field 'Description of composition' and, especially for UVCB substances, check that it reflects the production process of the substance.</p> <p>Make sure you include an explanation in the field 'Justification for deviations' if you deviate from the conventions on the number of constituents, and the concentration ranges of constituents and impurities for mono- and multi-constituent substances.</p>

6. Use description – general (IUCLID section 3.5)

Description	<p>In IUCLID 6, the section on use description has been split into sub-sections according to the different life cycle stages. Each use is reported as a separate record.</p> <p>The format for describing uses has been harmonised under the OECD and now includes the concept of <i>Contributing activities / techniques</i>. These correspond to the activities that take place within the use in relation to workers, consumers and the environment. The contributing activities include the use descriptors (process category – PROC; product category – PC; Article category – AC; environmental release category – ERC).</p> <p>When an exposure assessment of the use is performed, each of the contributing activities is assessed to demonstrate that its conditions of use are safe. Uses and contributing activities will translate into exposure scenarios and contributing scenarios in the chemical safety assessment.</p> <p>Migration will move all information from the IUCLID 5 section 3.5 life cycle tables into records under the appropriate sub-section 3.5.1 – 3.5.6. Each provided use descriptor of the type PROC/PC/AC/ERC will be located in a separate contributing activity block inside the use. The remaining use descriptors will be migrated directly to the corresponding fields.</p> <p>A field entitled 'Registration / Notification status for the use' has been introduced at the top of each use record. An indication in this field highlights to the authorities the registration status of the use (something which is particularly relevant e.g. when the substance is registered with uses of both REACH Article 10, and Article 17/18 status). Such information, in combination with further information</p>
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	<p>on the use descriptors, number of sites and tonnage for that use can be used in prioritisation of chemicals for various regulatory processes.</p> <p>The 'Registration / Notification status for the use' selection also conditions the available fields in the record to fit the purpose of the use description, and to help the registrant in locating the relevant fields to be provided. For example, by indicating that the use relates to <i>REACH Article 10; <10 tonnes/year/registrant</i>, the fields relevant for use as an intermediate under Article 17/18, and the exposure scenario information (relevant at >10 tonnes/year), will be inactivated.</p> <p>Migration will not populate the 'Registration / Notification status for the use' field. Uses that are indicated to be registered according to other provisions than Article 10 registrations are not subject to completeness check.</p>
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	Indicate in IUCLID 6 the appropriate 'Registration / notification status for the use'.

7. Use description – Article 10 registrations (IUCLID section 3.5)

Description	<p>As described in item #6, the concept of Contributing activities / techniques has been introduced in section 3.5 of IUCLID 6. The contributing activities include the use descriptors PROC, PC, AC, and ERC, and link to the contributing scenarios of the exposure scenario.</p> <p>Migration will move all information from the IUCLID 5 section 3.5 tables into records under the appropriate sub-section 3.5.1 – 3.5.6. Each provided use descriptor of the type PROC/PC/AC/ERC will be located in a separate contributing activity block inside the use. The remaining use descriptors will be migrated directly to the corresponding fields.</p> <p>The completeness check on section 3.5 has been streamlined to require that for each use*, at least one contributing activity / technique for the environment, and one for the workers / consumers has been created, including the use descriptor of the relevant type. In addition, whenever available in the IUCLID 6 section, the technical function of the substance, and the existence of a subsequent service life relevant for the use, must be indicated.</p> <p>Registrants can also now make use of new fields to highlight that the use takes place under rigorously controlled conditions, or that a specific regulatory status applies to the use. This information will be published if not claimed confidential.</p> <p>*Uses that are indicated in the field 'Registration/Notification status for the use' to be registered according to other provisions than Article 10 registrations are not</p>
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	subject to completeness check.
Relevance	All Art. 10 registration dossiers (individual, JS lead, JS member)
Action	<p>It is recommended to review in IUCLID 6 the migration of use descriptors under the contributing activity / technique blocks, and to add an appropriate contributing activity name to each block. If you have used Chesar to carry out your chemical safety assessment, by re-importing the uses from Chesar to IUCLID, the names of the contributing activities will be automatically populated.</p> <p>In order to ensure completeness, verify that each use record contains a contributing activity / technique for the environment with an environmental release category (ERC), as well as the technical function of the substance during the use, and the indication of whether there is a subsequent service life relevant for the use (this information was previously checked as optional to other fields in the use description section).</p> <p>You may also take this opportunity to verify that your use is properly reported, in particular that it has been included under the correct life cycle stage.</p>

8. Use description – Article 17/18 registrations (IUCLID section 3.5)

Description	<p>IUCLID 6 features a set of fields for documentation of the use as the substance as an intermediate (chemical reaction, reaction products), and the strictly controlled conditions. This information is essential to confirm the status of the substance as an intermediate, and to demonstrate strict control during use; the key factors behind the reduced requirements granted to this type of registration.</p> <p>Migration will move all information from the IUCLID 5 section 3.5 tables into records under the appropriate sub-section. Migration will not populate the 'Registration / Notification status for the use' field.</p> <p>Registrations which only refer to Article 17/18 will not be checked for completeness for this section. However, it is highly recommended to make use of the updated structure to transparently document the intermediate use.</p>
Relevance	All Art. 17/18 registration dossiers (individual, JS lead, JS member)
Action	Indicate in IUCLID 6 the appropriate 'Registration / notification status for the use' to activate the fields relevant for Art. 17/18 intermediate uses. Provide further information on the intermediate status and the strictly controlled conditions in the designated fields in support of your Art. 17/18 registration.

9. Exposure scenarios – Article 10 registrations (IUCLID section 3.5)

Description	<p>As mentioned above, in IUCLID 6 the section on use description has been split into sub-sections according to the different life cycle stages. Each use is reported as a separate record. Furthermore, the section on exposure scenarios (section 3.7.1 in IUCLID 5) has been incorporated with the life cycle description in such a way that each use record also contains the fields for the related exposure scenario.</p> <p>Migration will move all information from IUCLID 5 section 3.7.1 into the appropriate sub-section.</p> <p>No completeness check is foreseen for the exposure scenario information.</p> <p>Use information will, as previously, be published unless claimed confidential. With IUCLID 6, the exposure scenario information will also be subject to dissemination. Numerical fields and fields that contain the information on use conditions, measures and technologies will be published unless claimed confidential, while the 'Details on...' fields will not be published. Confidentiality can be indicated for the entire use information, in which case also the related exposure scenario is removed from publication. Alternatively, confidentiality can be claimed only for the exposure scenario part. Until 2018, information on exposure scenarios will only be published from updated and new dossiers.</p>
Relevance	All Art. 10 registration dossiers which include a Chemical safety report with exposure scenarios (individual, JS lead, JS member)
Action	<p>If you had provided information in section 3.7.1 of IUCLID 5, before migration, ensure that the 3.7.1 records have been linked to the appropriate uses in section 3.5. After migration, provide appropriate names in IUCLID 6 for the different contributing activities / techniques taking place within each use and connect the contributing scenarios to the relevant contributing activities. If Chesar was used for the chemical safety assessment, re-importing the information into IUCLID will carry out the above steps.</p> <p>Before submission to ECHA, verify with the IUCLID 6 Dissemination preview plug-in that you have entered the information in such a way that no confidential information will be published on the website.</p>

10. Endpoint study record – indication of endpoint (IUCLID sections 4-7)

Description	The updated Administrative data block of the OECD harmonised templates (IUCLID sections 4-7) includes a new picklist field to indicate the endpoint addressed by the document. The new 'Endpoint' field replaces fields such as 'Type of method' or 'Test type' that were previously available in the 'Materials and methods'
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	<p>chapter of some of the sections.</p> <p>For 'simple' sections, such as <i>Boiling point</i>, this field corresponds to the name of the harmonised template or section. For sections which cover different types of studies, such as <i>Toxicity to reproduction</i>, the field contains options to indicate the precise type of requirement addressed.</p> <p>When a new endpoint study record is created in sections with only one 'Endpoint' option, this value will be selected by default. When more than one option exists, the user needs to indicate the appropriate one.</p> <p>Migration will populate all 'Endpoint' fields whenever the endpoint study record is not completely empty. When multiple options are available, migration will be based on information on the indicated guideline, as well as the fields that were replaced by the 'Endpoint' field. In the case that no contextual information is available in the record to determine the appropriate 'Endpoint', a default migration phrase will be selected.</p> <p>The 'Endpoint' field will be subject to completeness check in all endpoint study records created in sections covering REACH information requirements. The field will always be published.</p>
Relevance	All registration dossiers that contain information in sections 4-7 (individual, JS lead, JS member)
Action	Verify the migrated 'Endpoint' value in IUCLID 6 for endpoint study records in sections where multiple types of studies could be reported, and records that correspond to data waivers or testing proposals, where limited contextual information would have been available to support migration.

11. Endpoint study record – Justification for type of information (IUCLID sections 4-7)

Description	<p>In IUCLID 6, the Administrative data block of the OECD harmonised templates (IUCLID sections 4-7) has been updated to include a new text field 'Justification for type of information' to store documentation specifically relevant for the type of information provided. The text field contains templates which support the user in filling in the field with meaningful information.</p> <p>In particular, the field is expected to be populated when the 'Type of information' of the endpoint study record is the following:</p> <ul style="list-style-type: none"> - <i>experimental study planned</i>: in the case of proposing a test on vertebrates, considerations for adaptation possibilities - <i>experimental study planned (based on read-across)</i>: in the case of proposing a test on vertebrates, considerations for adaptation possibilities - (Q)SAR: endpoint-specific documentation - <i>read-across based on grouping of substances (category</i>
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approach): endpoint-specific documentation

- *read-across from supporting substance (structural analogue or surrogate)*: endpoint-specific documentation

The field will be subject to completeness check for all endpoint study records of the above types (for QSAR and read-across, when the record is indicated as key study or weight of evidence).

For endpoint study records with the 'Type of information' set to '(Q)SAR', during migration, a placeholder text will be included in the field 'Justification for type of information'. This means that such records will not fail the completeness check after migration. However, it is strongly recommended to include in the record the endpoint-specific documentation on the QSAR prediction the next time the registration dossier is being updated.

In connection with the launch of IUCLID 6, the approach for reporting the results of read-across has been clarified (see item 14). Current read-across outcomes have been reported in various ways, leading to the fact that it is currently not possible to automatically deduce the type of read-across applied nor the meaning of the provided information. Therefore, a decision was taken to migrate existing read-across records with an indication in the 'Type of information' field that the record itself was migrated from a previous version of IUCLID. These records will not trigger a completeness check failure even if the 'Justification for type of information' field is empty. It is, however advisable for the sake of transparency and consistency, to align the current read-across reporting with the clarified approach, as soon as feasible.

The field 'Justification for type of information' is subject to dissemination. The field will always be published as part of the third party consultation for endpoint study records indicated as testing proposals ('Experimental study planned'). For other types of information, the field will always be published unless confidentiality has been claimed on the endpoint study record, on the test material of the study, or on the IUPAC name of the substance.

Relevance	All registration dossiers that contain information in sections 4-7 of the type QSAR, read-across or testing proposals (individual, JS lead, JS member)
Action	<p>For testing proposals concerning testing on vertebrate animals, provide the considerations for adaptations. For QSAR records, provide the endpoint-specific documentation in IUCLID 6 in the field 'Justification for type of information', and/or attached in the field 'Attached justification'. For read-across records, revise the reporting in line with the clarified approach (see item #14 and manuals/guides). Provide the endpoint-specific considerations in this field for each read-across target record.</p> <p>When entering information in the field, bear in mind that the content will always be published for testing proposals; and for other types of information unless confidentiality is claimed.</p>

12. Endpoint study record – Justification for data waiving (IUCLID sections 4-7)

Description	<p>In the updated Administrative data block of the OECD harmonised templates (IUCLID sections 4-7), the field 'Justification for data waiving' has been converted from a free text field to a multi-select picklist. The picklist contains endpoint-specific standard phrases to justify data waiving based on REACH Annexes VII-X, and aims to help the registrants in documenting clearly and concisely the basis on which data waiving is applied.</p> <p>It is important to bear in mind that the availability of standardised data waiving phrases does not mean that all, or any, of the data waiving justifications are applicable to the particular case of the registrant; the phrases are provided to assist registrants in <i>documenting</i> their decision. It is always up to the registrants to analyse their situation and decide whether waiving is applicable. If the registrant considers that data waiving is possible for a certain information requirement, but a suitable standard phrase is not available, the picklist also includes the option 'other:' with which another explanation can be provided.</p> <p>Note that depending on the waiving justification and the properties of the particular substance, it may be necessary to provide additional information in the dossier in support of the waiving. Such information can imply further explanations, and, when used as basis for waiving a particular classification, studies for other endpoints in the same IUCLID section or studies in other IUCLID sections. This applies both to the use of the standard phrases and to the option of selecting 'other:' and providing the data waiving justification in free text.</p> <p>Migration from the corresponding 'Justification for data waiving' free text field in IUCLID 5 will result in the selection 'other:' in the new picklist field, and with the provided free text inserted in the adjacent text field.</p> <p>The completeness check will, as before, require that the field 'Justification for data waiving' is filled in all endpoint study records indicated as data waivers. The revised completeness check rules and manual verification will, in addition, check that further requirements implied by the waiving justification are fulfilled.</p>
Relevance	<p>All registration dossiers that contain endpoint study records in sections 4-7 of the type data waiving (individual, JS lead, JS member)</p>
Action	<p>When updating the dossier in IUCLID 6, consider to use the standard phrases for the data waiving justifications. If not applicable, revise free-text justifications to ensure that they reflect the data waiving possibilities offered by REACH Annexes VII-XI.</p>

13. Endpoint study record – Test material information (IUCLID sections 4-7)

Description

The reporting of the test material in the 'Materials and methods' chapter of the OECD harmonised templates (IUCLID sections 4-7) has been improved. The qualitative picklist field 'Identity of test material same as for substance defined in section 1 (if not read-across)' has been removed, as the test material is a concrete sample of a chemical substance, while section 1 contains a more regulatory definition of the compositions and forms covered by a registration / notification.

The table 'Test material identity' has been replaced with a link to a so-called *Test material information* (TMI) record. A test material record consists of a table in which to report the composition of the test material by using linked reference substances and concentration range fields. It also contains the existing fields to report the test material form, and the details on the test material.

Test material records are stored in an inventory, which can be reused in each record where the same test material was used. In this way, the test material information can be centrally prepared and managed, and linked to the relevant endpoint study records.

The former 'Test material identity' table allowed for the reporting of different identifiers, and multiple identifiers for the same test material. The updated composition table supports the same feature, but also allows the user to indicate whether the reported identifiers (linked reference substances) correspond to constituents, impurities or additives, and at what concentration they are present.

The test material should be reported to the level of detail available and relevant.

- For an experimental robust study summary, it is expected that compositional information on the test material exists and is provided, while for a study summary based on handbook information, less details on the test material may be available.
- When reporting the results for a QSAR study, the test material should correspond to the structure for which the prediction was made. In this case, instead of defining a theoretical concentration range, the registrant may indicate in the new field 'Composition / purity: other information' that the purity concept is not applicable for an *in silico* study.
- For a read-across *target* record (see item 14), the test material should refer to the target of the read-across approach. The experimentally tested material(s) should be identified in the *source* study summary record (analogue) or in the category member substance records (category).
- For a record corresponding to a testing proposal, the test material should be identified to the extent known.

Migration will create a test material information record in each endpoint study record which contains information on the test

material. The TMI record will contain the information on the test material form and details on the test material as provided in IUCLID 5. The 'Composition' table will be populated as follows:

- Each migrated entry in the table will be indicated as a constituent. No information on the concentration will be provided.
- If the picklist 'Identity of test material same as...' contained the selection 'yes', then the section 1.1 reference substance is linked in the 'Composition' table.
- If the previous 'Test material identity' table contained standard identifiers (EC, CAS, IUPAC), these will be mapped to existing reference substances in the dataset, and if no matches are found, new reference substances are created with these identifiers and linked.
- If provided identifiers are not of the type EC, CAS or IUPAC, new reference substances are created and the identifiers will be migrated to the IUPAC name fields, as well as the Synonyms table inside the reference substance.
- If no identifiers were provided in the table 'Test material identity', and no reference was made to the section 1 substance, but information was given in the field 'Details on test material', then a reference substance will be created as a placeholder, indicating that it was automatically created during migration.
- Duplicate reference substances will be removed from the table.

The completeness check will, as before, verify that information on the test material is provided for each endpoint study record indicated as a key study or weight of evidence. In the revised structure, the completeness check will require that a TMI record is linked, and that it contains at least one reference substance in the 'Composition' table. Each reference substance must have a standard identifier.

The above-described migration process will ensure that all existing key study and weight of evidence records that previously passed the completeness check will pass the check with the revised structure. It is, nevertheless, strongly recommended that registrants review the migration result and update their test material descriptions whenever unclear.

The completeness check will also verify endpoint study records indicated as testing proposals to contain information on the proposed test material.

As before, the test material information will be published unless the study or the IUPAC name has been claimed confidential. In addition, confidentiality can now also be indicated on a specific test material by setting confidentiality flags in the linked reference substance.

Relevance	All registration dossiers that contain endpoint study records in sections 4-7 (individual, JS lead, JS member)
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Action	To ensure a clean migration, you may wish to review the provided test material information in IUCLID 5 and verify that you have consistently reported the test material(s) used throughout the
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sections before migrating the information.

After migration, review the 'Test material information' records created in IUCLID 6 and make use of the Test material inventory feature. In particular, if you had not reported the test material in a consistent way before migration, you may wish to identify TMI records which contain almost identical information, choose one of them for future use / maintenance, remove the other ones, and link the remaining TMI record to all the endpoint study records where the same test material was used.

If you had in the past only described the test material with free text in the field 'Details on test material', you are advised to translate this information as far as possible into appropriate reference substances in the 'Composition' table.

14. Endpoint study record – reporting of read-across information (IUCLID sections 4-7)

Description

In connection with the launch of IUCLID 6, the approach for reporting read-across has been clarified.

In brief, endpoint study records indicated with the 'Type of information' field to be 'read-across...' are considered to be *target* records. The target records document the outcome of reading across from the source substance(s) (analogue approach) or category (grouping approach). Both target and source information must be present in the dossier. When read-across is indicated to be based on a category approach, a category object, together with the relevant documentation on the category must be included in the dossier. When read-across follows an analogue approach, the dossier must include both the *source* study summary record and the *target* (read-across) record.

Following this clarification, the completeness check rules for read-across records were revised accordingly:

Read-across based on grouping of substances (category approach):

- Each endpoint study record indicated as category read-across in the registered substance dataset will be checked as a *target* record.
- At least one category object must exist in the dossier, and information must be provided in the field 'Category definition' or 'Report'.

Read-across from supporting substance (structural analogue or surrogate):

- Each endpoint study record indicated as analogue read-across in the registered substance dataset will be checked as a *target* record.
- In addition, the *source* record(s), i.e. the experimental

study summaries carried out with the source material of the read-across must be provided in the dossier, and must be linked in the *target* record field 'Cross-reference'. Source records will be checked according to the generic completeness check rules for experimental studies.

Target records:

- Target records are the endpoint study records with the 'Type of information' field set to 'read-across...'
- Target records are subject to a limited completeness check as it is not meaningful for the target record to contain information related to an experimental study, such as the guideline or reliability. They must contain information on the adequacy of the study, the target material of the read-across (indicated as test material), and the results.
- Target records must, additionally, contain an endpoint-specific documentation of the read-across approach, in the field 'Justification for type of information' (see also item #11).

As current reporting of read-across in IUCLID 5 has not strictly followed the analogue or category approach, and as analogue read-across has so far been reported with a mix of source and target information in the same record, a decision was taken to migrate existing read-across records with an indication in the 'Type of information' field of that the value was migrated from a previous version of IUCLID.

In line with the rationale behind the migration, existing read-across records will be checked according to general completeness check rules for endpoint study records, and will not trigger the revised checks on read-across records. However, if the migrated 'Type of information' value is set to the value 'read-across based on grouping of substances (category approach)' or 'read-across from supporting substance (structural analogue or surrogate)', this record will be considered a read-across *target* record, and the revised completeness check rules will apply.

It is advisable, for the sake of transparency and consistency, to adapt current read-across reporting to the clarified approach as soon as feasible. Further information on reporting of read-across in IUCLID 6 is provided in the dossier preparation manuals and in the practical guides on the topic.

Relevance	All registration dossiers that contain information in sections 4-7 of the type read-across (individual, JS lead, JS member)
Action	Revise the read-across approach applied in the dossier (category vs. analogue) and follow the new, clarified reporting approach when submitting an update in IUCLID 6 format.

15. Endpoint study record – physical hazards (IUCLID sections 4.11-4.15)

Description	<p>The OECD harmonised templates to report study summaries corresponding to physical hazards have been revised to support reporting of tests carried out with the UN test series* which underpins the classification for these hazards under GHS and CLP. The revision has resulted in certain re-structuring of results tables, mainly through the splitting of results for substances in different physical states, and different test types into separate tables. The most pronounced changes are in the sections on Flammability (4.13) and Explosiveness (4.14).</p> <p>Migration will, to the extent possible, populate the new structures based on the provided information. When corresponding fields are not available, information has been moved to the 'Remarks on result' field of the appropriate table. The completeness check has been adapted to the new structure; migration will ensure that dossiers which successfully passed the completeness check previously will pass the check with the revised structure. It is, nevertheless, recommended that registrants review the migration result to ensure that information has been reported in the appropriate locations.</p> <p>*Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria</p>
Relevance	<p>All registration dossiers that contain information in sections 4.11-4.15 (individual, JS lead, JS member)</p>
Action	<p>In IUCLID 6, revise the migration of study results reported for endpoint study records in section 4.11-4.15.</p>

16. Overall results of study (IUCLID section 7.5, 7.8.1, 8.7.2)

Description	<p>The OECD harmonised templates to report study summaries on repeated dose toxicity, toxicity to reproduction and developmental toxicity studies have been enhanced with additional results tables, to summarise the overall effects relevant to the endpoint, in addition to the existing effect levels tables.</p> <p>For repeated dose toxicity, the new table 'Target system / organ toxicity' summarises whether critical effects were observed, the lowest effect level, the system and organ affected, and whether the effects are related to the treatment.</p> <p>For reproductive* and developmental toxicity, the new table 'Overall reproductive / developmental toxicity' summarises whether reproductive / developmental effects were observed, the lowest effect level, and whether the effects are related to other toxicity effects.</p> <p>The above-mentioned tables are subject to completeness check. To begin with, it must be indicated whether any critical effects were observed. In case such effects were observed, further information</p>
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	<p>on the nature of the effects must be provided. Migration will populate the indication of observed effects with the value 'not specified', thereby satisfying the completeness check. However, it is strongly recommended to revise these tables and provide the appropriate conclusions. The new tables will be published to the same level of detail as the results summarised in them.</p> <p>*Note that for the reproductive toxicity section, also the table 'Target system / organ toxicity' has been included. It is, however, not subject to completeness check.</p>
Relevance	All registration dossiers that contain information in sections 7.5, 7.8.1, 7.8.2 (individual, JS lead, JS member)
Action	In IUCLID 6, provide the appropriate overall result for each endpoint study record that corresponds to a study summary.

17. Endpoint summaries (IUCLID section 4-7)

Description	<p>In IUCLID 6, all endpoint summaries have been adapted to support linking to the endpoint study records which were used to derive the summary value for the chemical safety assessment.</p> <p>Endpoint summaries are not subject to completeness check. However, endpoint summaries are needed when generating the Chemical safety report using the IUCLID Report generator tool, and when exchanging information between IUCLID and the Chemical safety assessment tool Chesar.</p> <p>In addition, the Brief Profiles of substances published on the dissemination website will be updated in 2016 to display information from the endpoint summaries*. Until 2018, information on endpoint summaries will only be published from updated and new dossiers.</p> <p>IUCLID 6 also introduces the concept of Assessment entities (see item #18) which can be used to organise the information for more complex assessment cases, when multiple sets of data, and multiple endpoint summaries, have been generated for the same endpoint.</p> <p>*At present, the Brief Profiles only show range values compiled from the endpoint study records provided for the substance. With the publication of the endpoint summaries, registrants can make more transparent the values they consider relevant for the chemical safety assessment.</p>
Relevance	All registration dossiers that contain information in sections 4-7 (individual, JS lead, JS member)
Action	In IUCLID 6, revise and complete endpoint summary information, and consider including links to the endpoint study records behind the summary value, in case many records were provided.

18. Assessment entity (IUCLID section 0.4)

Description	<p>In some cases, the nature or scope of the registered substance is such that, for a meaningful hazard assessment, multiple sets of data need to be generated. This can, for example, be the case if the hazard profile of the substance changes during its life cycle because it transforms into another substance; the use of the substance leads to the generation of by-products with different hazardous properties from the substance itself; the hazardousness of the substance is driven by different (groups of) constituents in different environments; or if the registered substance covers compositions or forms that differ in their hazardous properties.</p> <p>IUCLID 6 introduces the new concept of <i>Assessment entities</i>. Assessment entities organise and explain existing hazard information. They are used to link hazard data, through endpoint summaries, to certain compositions or forms of the substance, together with an explanation of why the particular data set was generated.</p> <p>IUCLID 6 section 0.4 contains a main record to explain the behaviour of the substance during its life cycle, and the choice of assessment approach taken to cover this behaviour. In addition, under section 0.4, separate records can be created for different types of assessment entities (e.g. transformation product, specific groups of constituents...). The assessment entity records identify the type and composition of the assessment entity used, and stores the links between hazard information and section 1.2 compositions.</p> <p>The Assessment entity is a voluntary feature for users to organise the hazard information in their dossiers, and is not subject to completeness check. Information provided in the Assessment entities will be published, unless indicated as confidential, or unless there is a confidentiality claim on the IUPAC name of the substance. Information on specific Assessment entities is also not published if the compositions they relate to, have been indicated as confidential.</p> <p>Further information on the Assessment entity concept and its use can be found in the dossier preparation manuals and guidance.</p>
Relevance	Registration dossiers which contain a Chemical safety report involving multiple sets of hazard data and/or a "complex" assessment
Action	Explain the (complex) behaviour of the substance during its life cycle and document the type/choice of assessment approach followed in the IUCLID 6 section 0.4 main record. If you have gathered multiple sets of data on different materials / forms that are relevant for the assessment of the substance, it is recommended to create Assessment entity records under section 0.4 to organise these data, for increased transparency to the reader, and easier CSR generation and maintenance.

19. Characterisation of nanomaterials (IUCLID sections 1.2, 4.28)

Description	<p>When the registered substance covers nanoforms, IUCLID 6 offers the possibility to provide additional characteristics relevant for the nanomaterial in the section 1.2 composition record. Composition-level information on the nanomaterials can be reported under a new heading 'Characterisation of nanomaterials' at the bottom of the composition document.</p> <p>The new sub-section offers range fields for the key properties shape, particle size range, specific surface area and surface treatment. As the composition section is included in the registration dossiers of all types of registrants, also member registrants can report information on nanoforms of the substance they manufacture / import. The fields for reporting characteristics of nanomaterials are not subject to completeness check.</p> <p>IUCLID 6 also includes in the REACH dossier the set of OECD harmonised templates to report study summaries of physicochemical properties of nanomaterials, under section 4.28. These templates are not subject to completeness check but will be published along the same principles as other endpoint study records.</p>
Relevance	All registration dossiers for substances with nanoforms
Action	<p>To provide information on nanoforms of the registered substance in IUCLID 6, select 'solid: nanomaterial' in the field 'State / form' at the top of the relevant section 1.2 composition record and provide the information under the heading 'Characterisation of nanomaterials' at the bottom of the section.</p> <p>When reporting study summaries on physicochemical properties of nanomaterials, fill in all the relevant fields in the appropriate section 4.28 documents. In addition, when reporting results on environmental fate, ecotoxicological and toxicological tests that were carried out on a nanomaterial, indicate this in the 'Test material form' field of the test material information record, and provide further information on the characteristics of the nanomaterial in the field 'Details on test material'.</p>

20. Opt-out of information (IUCLID section 14)

Description	<p>In accordance with Articles 11(3) and 19(2), registrants may opt-out for certain information that is foreseen to be jointly submitted, and provide this information in their own dossier. The opt-out information must be accompanied by an explanation. In the past, the opt-out information was selected, and the justification provided during dossier creation. The consequence of this was that when submitting an update and wishing to keep the same opt-out approach, registrants had to repeat the selection and justification of the opt-out information, leading to potential mistakes.</p>
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	<p>In IUCLID 6, the selection and justification of opt-out information has been moved to section 14 within the substance dataset, where it can be maintained to be reused for subsequent submissions. During dossier creation, section 14 and all documents listed inside it are automatically included in the dossier.</p> <p>Opt-out information provided in IUCLID 5 dossier headers cannot be automatically migrated to the new section 14 (this would mean that information would be migrated from one or several dossiers to their one, corresponding dataset).</p>
Relevance	All registration dossiers with opt-out information
Action	To opt-out for information, first provide this information in the relevant sections in IUCLID 6. Next, create a new record in section 14, create a block under 'Data selected for opt-out' and link those documents you want to opt-out for, which have a common justification, in the table 'Documents' of the first block. Enter the explanation for the opt-out in the field 'Justification'. For each set of opt-out documents that rely on a different justification, create a new repeatable block in the section 14 record and repeat the above.

21. Legal entity (IUCLID section 1.1, IUCLID working legal entity, submitting legal entity in REACH-IT)

Description	<p>In IUCLID 5 and the previous version of REACH-IT, three types of electronic legal entity objects were necessary for submitting a registration dossier. These included the IUCLID section 1.1 legal entity for the substance; the working legal entity of the user creating the registration dossier; and the legal entity of the REACH-IT account submitting the dossier.</p> <p>During submission of the registration dossier, it was verified that the three legal entities were synchronised, i.e. the objects had the same electronic identifier (UUID). This was done to prevent mistakes, whereby a party preparing dossiers for several legal entities would submit the wrong file for the wrong legal entity, leading potentially to incorrect fees being issued and information being disclosed to the wrong company.</p> <p>However, for users who prepare dossiers for a single legal entity, this "legal entity synchronisation" has proven to be less relevant and, particularly for small companies with less dedicated staff, quite complicated to understand. Therefore, the requirement on legal entity synchronisation has been dropped in IUCLID 6 and the new REACH-IT.</p> <p>When creating a dossier in IUCLID 6, by default, the legal entity object will not be included in the dossier. If the user wishes to include a legal entity in the dossier, this can be indicated during the dossier creation in the dossier creation wizard.</p> <p>For users that do include a legal entity in the IUCLID dossier, REACH-IT will inform the user, during the submission, as to</p>
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	<p>whether the legal entity of the REACH-IT account is the same as the one(s) included in the IUCLID dossier. The user can choose to ignore this warning and proceed with submission. For those users who need to keep track of different legal entities, this will serve as an opportunity to check the submission details and correct the mistake if any.</p> <p>The REACH-IT account legal entity will be considered as the one submitting the dossier and will be the one used in further communication/processing. Legal entity information specified in the IUCLID dossier will be disregarded.</p>
Relevance	All registrants
Action	By default, the legal entity is not included when creating a dossier in IUCLID 6. If you wish to include it, you should indicate this during dossier creation. To synchronise legal entities, compare their 'UUID' codes in IUCLID (available in the Information panel at the bottom of the window, when opening a legal entity object) with the one shown in REACH-IT. Before submitting a dossier, check that your legal entity details in REACH-IT are up to date.

22. One substance one registration (REACH-IT)

Description	<p>Following the entry into force of the 'Commission Implementing Regulation (EU) 2016/9 on Joint Submission of Data and Data Sharing', new checks have been put in place to ensure that submissions are in line with the 'One Substance, One Registration' (OSOR) principle.</p> <p>OSOR clarifies that there can only be one joint registration per substance and per registration type (full or intermediate). Subsequently, the creation of a Joint Submission (JS) in REACH-IT will not be allowed if another JS for the same substance and registration type already exists in the system.</p> <p>Furthermore, different scenarios apply to different submission contexts in REACH-IT.</p> <ol style="list-style-type: none"> 1) Initial individual submissions will not be allowed if the following are available in the system: <ol style="list-style-type: none"> a. an active JS (for which the lead registrant has successfully submitted the lead dossier) for the same substance and registration type; b. one or more individual submissions for the same substance and registration type. 2) The scenarios for submitting an update in REACH-IT are: <ol style="list-style-type: none"> a. A JS exists for the same substance and same registration type and the registrant already has a successful registration outside of this (i.e. individual): The registration cannot be updated until the registrant joins the JS. The only exception are
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	<p>requested updates following a technical completeness check (TCC) which can still be submitted.</p> <p>b. A JS exists for the same substance and registration type and the registration is part of the JS: The registration dossier can be updated without any limitation, as long as the update is covered by the JS registration type.</p> <p>c. No JS exist for the same substance and registration type (full or intermediate) but other individual registrations have been submitted: The registration(s) outside the joint submission can be updated without any limitation, as long as there is no change in the type of registration and no JS is created. For intermediate registrations, the update to a full tonnage band is only possible if no other individual registration with a full tonnage band exists.</p> <p>Any potential or existing registrant can create and submit a joint registration. Existing individual registrants of the same substance and registration type will need to submit a spontaneous update in REACH-IT in order to join the JS as a lead or a member. The justification 'change from individual to joint submission' needs to be indicated in the dossier header of their IUCLID 6 dossier (previously, registrants were required to indicate 'change of tonnage band' in order to perform this action in IUCLID 5 and REACH-IT).</p>
Relevance	All registration dossiers (individual, JS lead, JS member)
Action	Review your submitted registrations and make sure that you take the appropriate action in case your registration falls under any of the scenarios above.

23. Contact and third party representative (REACH-IT)

Description	<p>In IUCLID 5 and the previous version of REACH-IT, the contact person and the Third Party Representative (TPR) assigned to the dossier, were indicated in section 1.1 of IUCLID. This information was then extracted and stored in REACH-IT.</p> <p>In the new REACH-IT, contact and TPR will be specified directly in REACH-IT at the time of submission. Any TPR, or contact (other than SDS contact), indicated in IUCLID 6 will be disregarded by REACH-IT.</p> <p>The new REACH-IT will offer also a central management of the contact(s) and TPR. This means that companies can view and update the contact and TPR information associated to a dossier without having to resubmit a IUCLID dossier.</p>
Relevance	All dossiers types

Action

When submitting your dossier in REACH-IT, indicate in the submission wizard the contact and / or the TPR that will be responsible to represent your company in discussions with other companies (e.g. data sharing in case of an inquiry submission) and ECHA (e.g. request for further information) for the specific submission/substance.

You can also change the assignment of contact and TPR for a dossier already submitted directly in REACH-IT. This can be done from the reference number history pages.

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