ECHA
EUROPEAN CHEMICALS AGENCY

Evaluation under REACH
Progress Report 2015

Recommendations to registrants

Disclaimer:

The report includes recommendations to potential registrants to improve the quality of future registrations. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not represent the position that the European Chemicals Agency may adopt in a particular case.

To correct any errors or inaccuracies that may appear in the text, the European Chemicals Agency is entitled to modify or revise the document at any time.

Evaluation under REACH: progress report 2015 – recommendations to registrants

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This summary focuses on the key recommendations to registrants. It is based on ECHA's annual evaluation report. The whole report is available in English under echa.europa.eu/evaluation

Overview: Key recommendations to registrants

ECHA's recommendations are relevant both to future registrants preparing their registration dossiers for the first time and to existing registrants who can identify potential shortcomings in their current dossiers and update them accordingly.

TESTING ON ANIMALS MUST ONLY BE UNDERTAKEN AS A LAST RESORT

- Actively explore all possibilities to use already existing information and alternative methods in meeting information requirements. Keep records to show your considerations.
- Remember that the REACH annexes are applied sequentially. Therefore, Annex VII requirements for *in vitro* irritation testing should be fulfilled before considering the Annex VIII *in vivo* test methods.
- The obligation to share data applies to any registrant under the REACH Regulation irrespective of the phase-in or non-phase-in status of their substance. Consequently, potential registrants of the same substance must collaborate to share the requested information and agree on the data to be submitted jointly.
- Testing proposal consultations provide an opportunity for submission of any valid information that may address the hazard endpoint(s) in question and may make animal testing unnecessary.

FAMILIARITY WITH THE READ-ACROSS ASSESSMENT FRAMEWORK (RAAF) IS ESSENTIAL FOR BUILDING A SUCCESSFUL READ-ACROSS CASE

- Adequately document the scientific reasoning for any read-across.
- Registrants can use the RAAF to identify the aspects of read-across justifications that ECHA considers to be crucial and can assess the robustness of read-across adaptations against these aspects.
- Structural similarity is needed for grouping and read-across approaches under REACH; however, it is not sufficient on its own to establish a basis for prediction of toxicological properties between substances.
- The hypothesis must address why structural differences between the substances do not affect the prediction of the property under consideration.
- Data on toxicokinetic properties of substances constitutes invaluable supporting information to justify a read-across hypothesis based on metabolic convergence.
- Supporting evidence must be included in the dossier, in the format of robust study summaries when possible.

MAINTAIN EFFICIENT COMMUNICATION AND PLANNING THROUGHOUT THE SUBSTANCE EVALUATION PROCESS

- Maintain good communication with the evaluating Member State competent authority during the substance evaluation process.
- Coordinate your comments with co-registrants during the relevant steps of the decision-making process and provide a single set of consolidated comments.
- Inform the evaluating Member State competent authority and ECHA of the relevant update whereby all requested information is submitted.

ACCURATE SUBSTANCE IDENTIFICATION IS VITAL

- The substance identity information in each registration dossier must be specific for a substance that is registered by a given Legal Entity.
- Substance identification is an obligation for each registrant and therefore it cannot be left to the lead of the substance information exchange forum (SIEF).
- The key elements of the substance identity information that must be included in the registration dossier consists of substance name and related identifiers, molecular and structural formulae (if applicable), composition, and the analytical data.
- Make use of support and services for improvement of the data quality, including substance identity information provided by ECHA. For example, ECHA developed the dossier quality assistant, which is a tool available for registrants to check their IUCLID substance datasets and dossiers for common shortcomings and inconsistencies before submitting their registration dossiers to ECHA.

1. Recommendations to registrants

In this section, ECHA provides (potential) registrants with advice on how to improve the quality of their registration dossiers. These recommendations contain technical and scientific information which are of most use when preparing or planning to update the technical dossier and/or chemical safety report. These recommendations are based on the most frequent shortcomings observed when evaluating dossiers.

In many cases, the shortcomings observed have already been highlighted in previous evaluation reports. These reports, available on the ECHA evaluation web section[1], give advice on how to avoid the shortcomings identified. They are still relevant, even though they are not repeated here. Instead, ECHA would like to emphasise the need to keep registrations consistent and up-to-date without undue delay, and how to use adaptation possibilities correctly.

1.1 Substance identity

Apply the 'one substance, one registration' principle
Manufacturers and importers of the same substance are obligated to submit their registration jointly. The identity of the jointly-registered substance must be unambiguous and reported transparently within the registration dossier. Transparency can be achieved by including the substance identity profile (SIP) in the registration dossier of the lead registrant.

Observation
The SIP sets the boundaries of the compositions registered collectively within a joint submission. It brings transparency regarding the compositions that were agreed to be addressed in the registration dataset.

Currently, the SIP can be inserted into the registration dossier as an attachment, however, a structured way of reporting this information will be provided in the next IUCLID release in 2016.

Be proactive in addressing potential shortcomings
For some EINECS entries, the substance description can be quite broad and may potentially be considered to cover more than one substance. Furthermore, some EC/CAS numbers used are not representative for the substances registered (such as where a substance includes specific stereoisomeric forms). Registrants should proactively adapt any identifier that they recognise as being inappropriate for the registered substance.

Complementary measures aimed at improving dossier quality, such as the IT-based screening on substance identity information[2], aim to help industry proactively improve the quality of their dossiers. Based on the screening results, registrants might receive an information letter from ECHA, providing advice on how to address their specific substance identification shortcomings. Failure to address any potential shortcomings may lead to follow-up actions from ECHA, therefore, registrants should update their dossiers whenever SID information is incomplete or inconsistent.

Use the available support and services to improve data quality
The Guidance for identification and naming of substances under REACH and CLP[3] is the key document to establish the identity of the registered substance. However, the sector-

[1] http://echa.europa.eu/regulations/reach/evaluation
[2] http://echa.europa.eu/support/how-to-improve-your-dossier/it-screening-campaigns-on-dossiers
[3] http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

specific documents prepared with the contribution of ECHA should also be taken into account[4].

ECHA developed the dossier quality assistant[5] (DQA), which is a tool available for registrants to check their IUCLID substance datasets and dossiers for common shortcomings and inconsistencies before submitting their registration to ECHA. The DQA incorporates a set of checks particulary dedicated to improving the quality of substance identity information. The DQA module is included in the IUCLID validation assistant plug-in[6], which also allows the user to verify business rules and completeness check rules that are checked during submission to ECHA.

1.2 Quantitative structure-activity relationships (QSARs)

Consider the type of assessment when building your case
The adaptation of REACH Annex XI, section 1.3 (QSARs) is based on the premise that the chemical structure determines the toxicological properties of substances. In this approach, the prediction should be adequate for the purposes of classification and labelling, and/or risk assessment to fulfil the requirements for replacement of standard information requirements alone.

Observation
It is understood that local QSARs developed for few analogues present a case of many-to-one read-across, and must be reported and justified as such. If a clear trend for many points is established (e.g. for acute aquatic toxicity), then it can be defined as QSAR and reported as such.

A pre-requisite for the use of QSARs is their accessibility, therefore, the advantages and disadvantages they offer with respect to reliability, handling complex evidence, and uncertainty must be well understood and handled carefully. Large aggregated models based on diverse data can be useful for screening but may not be suitable for addressing standard information requirements because they may fail the first OECD QSAR validation principle[7] (defined endpoint).

Ensure that all QSARs are properly documented
The QSAR prediction reporting format (QPRF) is needed in addition to the QSAR model reporting format (QMRF) to assess both prediction reliability and how the target is covered by the applicability domain, and to conclude on the adequacy of the prediction. The uncertainty associated with the prediction (e.g. the error of estimate) is an important component for assessing its reliability. However, the error of estimate alone is not sufficient to assess the reliability of the prediction. The REACH Guidance on information requirements and chemical safety assessment; Chapter R.6 on QSARs and grouping of chemicals (May 2008)[8] provides a detailed description of the information required in the reporting formats.

The adequacy of the prediction needs to be properly justified
If the tool does not offer all necessary information to justify the adequacy of the prediction, go outside the tool and try to compensate the missing piece of information. For example, several EpiSuite models provide training sets that can be taken out of the

[4] http://echa.europa.eu/view-article/-/journal_content/title/guidance-on-substance-identification-for-essential-oils-now-available
[5] http://echa.europa.eu/support/how-to-improve-your-dossier/dossier-quality-assistant
[6] http://echa.europa.eu/support/dossier-submission-tools/iuclid/validation-assistant
[7] http://www.oecd.org/env/ehs/risk-assessment/37849783.pdf
[8] http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf

tool and mined in software to assess the structural similarity of the target to the training set, and to individual chemicals in it.

Observation
For large training sets, the proximity of the target to a well predicted molecule from the training set, provides additional assurance that the model works for the particular type of chemistry.

Consider the specific chemistry of the substance to highlight whether it can be difficult to predict. For example, information on reactivity or specific modes of action can highlight structures where excess toxicity would be expected, and predictions may be potentially less accurate. There are statistical techniques that need to be applied only for models where statistical pitfalls are expected. However, this test cannot make the prediction acceptable, if the endpoint is unclear, or is a broad compilation of all available data for a given endpoint.

1.3 Read-across

ECHA has developed the RAAF[9] to provide experts with a transparent and structured methodology to assess read-across approaches. Applying the RAAF results in a structured assessment of the case, identifying strengths and weaknesses of a read-across approach.

Observation
Registrants are encouraged to familiarise themselves with the RAAF since this framework may be used to identify the critical weaknesses of their read-across adaptations and to further improve on these aspects.

Structural similarity is required for grouping and read-across approaches under REACH, however it is not sufficient on its own to establish a basis for prediction of toxicological properties between substances. The role of the structural similarities and the impact of the structural differences between the substances on the possibility to predict properties need to be established.

Observation
Registrants should ensure that each read-across hypothesis establishes why the structural similarities and differences between the source substances and the target substance allow for a possibility to predict properties of the target substance.

Supporting information constitute an essential part of a read-across justification. Adequate and reliable supporting evidence is necessary to verify the read-across hypothesis. However, even though read-across hypotheses are frequently based on toxicokinetic arguments, these arguments are often supported only by general considerations on toxicokinetics rather than information on toxicokinetic properties specific to the substance under consideration.

Observation
Providing adequate and relevant supporting information increases the robustness of the read-across approach. This information should be reported as (robust) study summaries allowing an independent scientific assessment.

[9] http://echa.europa.eu/documents/10162/13628/raaf_en.pdf

1.4 Substance evaluation

Plan dossier updates effectively

When a substance is listed within the second or third year of the CoRAP[10], registrants should take the opportunity to update their dossiers for that substance. This is particularly important for information that may fall within the scope of the initial concerns, defined in the justification document.

In contrast, if the substance is listed within the first year of the CoRAP, where the eMSCA will begin their evaluation once the CoRAP is published, registrants should avoid submitting new dossier updates for that substance. Instead, any planned dossier update should be communicated and agreed with the eMSCA beforehand, to prevent delays in the evaluation process.

Observation

By default, dossier updates received after the day on which the draft decision was notified to the registrants will only be considered if agreed in advance with the eMSCA. Dossier updates received after the deadline agreed with the eMSCA will not be taken into account.

Communicate clearly and with a 'single voice'

It is highly recommended that registrants maintain good communication with the eMSCA during the substance evaluation process so that there is an opportunity to explain and understand the scientific issues arising from the risk assessment. In particular, registrants may provide valuable insight into any exposure-related issues.

Observation

Registrants should coordinate their commenting during the relevant steps of the decision-making process and provide a single set of consolidated comments. A good approach is to select a single representative who will submit comments on behalf of the whole group.

Within 90 days of receipt of the adopted substance evaluation decision, registrants should inform ECHA regarding which registrants will perform the requested experimental studies. If the decision contains requests for multiple experimental studies, registrants may nominate different registrants to be responsible for the performance of each test. If no agreement can be reached regarding who will perform each experimental study requested, ECHA will designate the responsibility of performing the tests to one of the registrants, regardless of the number of experimental studies requested in the decision.

Registrants should use the available webform[11], to notify ECHA and the eMSCA once all information requested in the decision has been delivered by dossier update. This is important since it will trigger the 12-month period for the follow up assessment.

1.5 PBT/vPvB assessment

Substances that persist for long periods of time in the environment and have a high potential to accumulate are of specific concern since their long-term effects are rarely predictable.

[10] http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances

[11] https://comments.echa.europa.eu/comments_cms/Sedraftdecisioncomments.aspx

PBT substances are persistent, bioaccumulative and toxic, while vPvB substances are characterised by a very high persistence in combination with a very high tendency to bioaccumulate.

For recognised PBT/vPvB substances, an assessment containing a demonstration that emissions are minimised must be provided.

The properties of the PBT/vPvB substances lead to a high uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies. For PBT and vPvB substances, a 'safe' concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way. Therefore, a separate PBT/vPvB assessment is required to take these specific concerns into account. Registrants are required to perform this specific PBT/vPvB assessment in the context of their chemical safety assessment (CSA).

A PBT/vPvB assessment is required for all substances for which a CSA must be conducted and reported in the chemical safety report (CSR). In general, these are all substances that are manufactured or imported in amounts of 10 or more tonnes per year that are not exempted from the registration requirement under the regulation.

Observation
Following the identification of substances as PBT/vPvB, in some cases the requirement for an exposure assessment (corresponding to emission characterisation) and risk characterisation (corresponding to demonstration of minimisation of exposure) has not been met.

PBT properties of constituents of UVCB substances are generally not properly addressed in the registration dossiers.

The constituents of UVCB substances need to be considered in the PBT/vPvB assessment. The assessment does not mean that all constituents must be identified by their chemical structure, but the identity needs to be sufficiently analysed to enable the PBT/vPvB assessment to be concluded. Only in cases where the constituents are similar with regard to fate properties, may it be sufficient to provide only data on the whole substance. In most cases, however, the constituents need to be assessed either one-by-one or fraction wise.

Registrants should characterise and know their UVCB substance, including the 'unknown' constituents to such a level that they can conclude whether the substance contains PBT/vPvB constituents or not. A CSA can only contain negative or positive conclusions on PBT/vPvB properties of a UVCB substance and its constituents, or testing proposals. A CSA on a UVCB substance cannot conclude that there is insufficient information on PBT/vPvB properties of some constituents, if no testing proposals are submitted.

Observation
PBT properties of constituents of UVCB substances should be properly addressed in the registration dossiers. The characterisation and assessment of properties of UVCB constituents need to be carried out to such a level of detail that allows an unequivocal conclusion to be derived on the PBT-properties for all constituents of the substance.

1.6 Chemical safety report (CSR)

Use the available tools to make a transparent and consistent safety assessment
In response to experience gained in generating and using exposure scenario information under REACH, ECHA together with industry and Member States launched an action

programme called the CSR/ES Roadmap[12] in 2013. This programme defines the areas of improvement on CSA/ES and the corresponding actions until 2018.

In 2016, several actions under the Roadmap[13] will deliver products that will increase the efficiency, transparency, consistency and usefulness of the chemical safety assessment (CSA) under REACH. The products include:

- **IUCLID 6** which provides extended options to document and link different information elements on use and exposure within a registration dossier, in a transparent, consistent and structured way. This allows authorities to process information from REACH registrations efficiently and enhance understanding of the case.

- **Chesar 3** which supports a systematic safety assessment based on i) information on substance properties documented in IUCLID and ii) the use information of substances collected from the supply chain. Chesar[14] also enables the generation of the CSR and exposure scenarios for communication, and export of the CSA results into the corresponding IUCLID sections.

- **EScom standard**[15] was developed by industry to support efficient communication on the conditions of safe use down the supply chains. It consists of a library of standard phrases to express the conditions of safe use in a standardised way and an xml exchange format for exposure scenario information.

- **Sector use-map formats** allow sectors to provide a description of the typical activities performed with chemicals in a sector and the typical conditions under which these occur. The conditions are expressed in a way that allows the information to be easily fed into the registrant's safety assessment. There are standard formats/templates to provide information on the description of uses and conditions of use to be used as input to the exposure assessment of workers (specific workers exposure determinants, SWEDs), consumers (specific consumer exposure determinants, SCEDs) and environment (specific environmental release categories, SpERCs). Downstream user sectors are encouraged to use these templates to make the relevant information available to registrants.

- **ECHA Guidance documents on chemical safety assessment (CSA)** have been updated to include the practices and principles that have emerged over recent years. These principles will be complemented by further practical advice in the help-systems of the tools and by examples published by ECHA.

All the products are aligned with each other and support an efficient exchange and update of information, as well as consistency during the information flow within the supply chain.

[12] http://echa.europa.eu/en/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap
[13] http://echa.europa.eu/documents/10162/15669641/csr_es_roadmap_en.pdf
[14] https://chesar.echa.europa.eu/
[15] http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

The dossier should be transparent, consistent and up-to-date.
The new IUCLID and Chesar versions support registrants in enhancing the transparency by facilitating the reference between the compositions of the substance, the related hazard profiles and the use patterns that the different compositions may have.

Transparency is also supported for cases where more than one set of data is relevant for the assessment, for example, when substances form reaction products, or when constituents in a substance are very different in terms of their hazard or their exposure behaviour.

The tool package generally facilitates consistency between the conclusions from the hazard assessment, the descriptions of use, exposure assessment and the risk characterisation. The tool package also supports IT-based updates of the CSA/CSR information.

The use description and the exposure assessment should reflect the actual uses and conditions of use in companies.
This is essential for generating useful information for authorities and for downstream users. Roadmap products support industry sectors by providing formats that enhance communication up the supply chain. This will contribute to making realistic assumptions for the exposure scenarios, including the operational conditions and the effectiveness of risk management.

It will also help registrants to provide customers with exposure scenarios matching the reality of their operations and products. Registration dossiers (including CSRs) are the main information source for authorities when prioritising substances for post-registration REACH processes. Registrants may wish to demonstrate that their substances are not a priority concern for substance evaluation, classification, authorisation or restrictions. For example, the substance only enters into wide dispersive use to a very minor extent, or is only used under strictly controlled conditions. The new IUCLID 6 will allow more transparent presentation of the case in the registration dossier.

Use the exposure assessment tools within their domain of applicability and justify all deviations from defaults.
For exposure tools integrated into Chesar, users receive some warnings when using the tool in a way that may conflict with the applicability domain.

Improve the information on personal protective equipment
Despite the recommendations presented in previous evaluation reports, the available information on personal protective equipment (PPE) continues to present problems during the CCh process.

Dermal protection requires information to be provided on the material, breakthrough time and thickness (where appropriate) of gloves, which should ideally be reported within both the CSR and Section 11 of the IUCLID dossier. The best approach is to also provide information on gloves that should not be used as this information can be very important. Predictions of skin exposure from tier 1 models can be misleading as dermal contamination is often highly variable and workers must be protected against unexpected events leading to high exposures.

Some registrants have indicated that they consider that dermal predictions from the ECETOC TRA can be estimates for the whole body. If so, information on the appropriate protection to stop splashes and wetting events reaching the skin should be provided. Such information often requires proposing advice on the provision of chemical protective work wear. Some appropriate European Standards are:

EN 13034:2005 (Type 6), limited protection against liquid aerosol.

EN 13982-1:2004 (Type 5), protection against airborne dry particulate chemicals.
EN 14605:2005 (Type 4) protection against liquid chemical splash.

Observation
In general, normal work wear coveralls cannot be regarded as offering any reliable protection against chemical exposure as they are not tested for permeation and penetration.

Respiratory protection: exposure scenarios may appear to place a heavy reliance on the long-term performance of respiratory protective equipment (RPE). Generally, RPE is intended to address residual risk after other risk management measures have been applied. An exposure scenario can appear unrealistic when a quick calculation indicates the actual predicted external concentration (outside of the RPE) of a highly noxious or obnoxious substance is considerably above the DNEL.

In these cases, exposure scenarios that predict exposures just below the DNEL when expecting workers to wear RPE all day are not compatible with the concepts within the Chemical Agents Directive (Directive 98/24/EC). In practice, RPE may not always be entirely reliable and high workplace protection factors may not be readily achieved by an untrained workforce, which leads to a potentially unacceptable high indication of risk. RPE is usually intended for cases where the RCR is only marginally above 1 and high exposure tasks may be intermittent, so that application of RPE reduces the RCR to well below the critical long-term DNEL level.

Observation
Registrants suggest 8h RPE to get an RCR just below 1, without suggesting technical measures to reduce exposure. This is against key principles and would only be acceptable with an explicit justification that technical measures are not possible under the conditions of use. If >4h RPE is needed to control risks, then the type of RPE and the management system supporting proper use needs to be described in the exposure scenarios. In some cases, RPE is the primary risk management measure. For example, during car respraying operations where special arrangements are needed to ensure long-term worker protection and to avoid consequences such as occupational asthma when spraying certain formulations creating a high risk environment.

Clearly justify the use of SpERCs for environmental exposure assessment
The reliability of the CSA highly depends on the reliability of the input parameters used in the hazard and exposure assessments. One of the main parameters affecting the outcome of the environmental exposure assessment are the release factors to the environment. ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012)[16] suggests generic worst case release factors for each environmental release category (ERC) that registrants can use without further justification. If safe use cannot be demonstrated on this basis (because of substance hazard profile or the amounts used), registrants need to determine more appropriate release factors and the corresponding conditions of use.

It has been proposed by industry to use sector specific environmental release categories (SpERCs) as a key means to arrive at refined release estimates for the environmental assessments. The concept of SpERC is accepted in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012), provided that the operational conditions and risk

[16] http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf. Please note that at the time of publication of this report, this Guidance document is under review. Drafts are available at: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach

management measures leading to the refined release factors are sufficiently documented.

In general, SpERCs include a definition of scope (applicability domain), information on conditions of use leading to a certain expected release factor, expected release factors, and an explanation of how the release factors were derived.

SpERC developers and users should ensure that the description provided in the SpERC factsheet is detailed in a clear and accurate manner with sufficient justification, and covers all relevant activities/processes, operational conditions, and risk management measures claimed.

If environmental release factors are set lower than the defaults suggested for ERCs in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation (version 2.1, October 2012), a proper justification for those is expected. As a minimum, this should cover:

i) the description of conditions of use under which the release factor occurs, and

ii) a description on how the release factor was derived (with underpinning data reported and explained).

Registrants often refer to SpERCs as a source of the applied release factors, however, many SpERCs do not contain sufficient background information on the release factor proposed. As a consequence, the registrant's CSR may not be convincing in demonstrating the control of risk.

Registrants using available SpERCs for their CSA must ensure that the substance and the use described in a particular dossier are in the domain of applicability of the SpERC used.

1.7 ECHA's guidance and tools

Consult the guidance material on the ECHA website when preparing and maintaining your registration

The Data Submission Manuals (DSMs)[17] and the REACH-IT Industry User Manuals (IUMs)[18] give definitive instructions for preparing and submitting dossiers. These manuals will be reviewed and integrated in the tools in the context of the release of the next versions of IUCLID and REACH-IT.

ECHA has continued to develop REACH guidance in 2015. The following updated guidance documents, particularly relevant to evaluation, were published on the ECHA website during the year (see ECHA website for all publications):

- An update of the Guidance on information requirements and chemical safety assessment; Chapter R.7a: Endpoint specific guidance, Section R.7.6 related to reproductive toxicity and Section R.7.2 related to skin and eye irritation/corrosion (October 2015)[19].

[17] http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-manuals
[18] http://echa.europa.eu/support/dossier-submission-tools/reach-it/industry-user-manuals
http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

- An update of the Guidance on information requirements and chemical safety assessment; Chapter R.12 on Use description (December 2015).

- An update of the Guidance on the compilation of safety data sheets (August 2015)[20].

- A corrigendum to the Guidance on the Application of the CLP Criteria - Part 2 Physical Hazards and Part 3: Health Hazards (June 2015)[21].

- An update of the Introductory Guidance on the CLP Regulation (July 2015)[22].

A number of Guidance documents are still under review, notably those dealing with chemical safety assessment. Final versions are expected to be published throughout 2016. Drafts and consultation processes can be followed here: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach

ECHA invites you to take note of these new/updated resources and to update the relevant parts of your dossiers, where appropriate. ECHA will consider the new approaches described in the guidance in on-going and future dossier evaluations.

Use the validation assistant plugin for IUCLID when preparing your registration

In addition to verifying business rules and completeness check rules, the plugin hosts the dossier quality assistant module that warns the user of deficiencies and inconsistencies found within their dossier. It is strongly encouraged that registrants run the plugin on their substance datasets and dossiers and correct all reported issues before submitting them to ECHA.

[20] http://echa.europa.eu/documents/10162/13643/sds_en.pdf
[21] http://echa.europa.eu/documents/10162/13562/clp_en.pdf
[22] http://echa.europa.eu/documents/10162/13562/clp_introductory_en.pdf

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