REACHing the 2020 goals

Break-out group - 1

Data quality and availability

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Key areas

- **Data quality and availability;**

  → do we get the information we need?
- Supply-chain communication;

  → is this information being used?
- Regulatory Risk management;

  → do we address substances of concern quick enough?

Take stock on the current implementation and come up with tangible ideas for further improvement!

Topics for discussion …

1) **Dossier quality for the 2018 deadline**
2) **Compliance of existing dossiers**
3) Substance identity (SID)
4) Improving the impact of Compliance check (CCH)?
5) Tracking, communicating and considering the group of deprioritised substances
6) **Improving volume, use and exposure information**
7) Addressing specific types of substances (i.a. nanomaterials)
8) …

1) Dossier quality for the 2018 deadline

- 2018 Registration Roadmap: Series of actions that aim at better supporting registrants to prepare quality dossiers for 2018
- IUCLID format reviewed for better reporting of results of studies
- Completeness check process reviewed: automated rules and introduction of a manual check
- Support material and webpages simplified
- Practical guide on how to fulfil the data requirements for the 1-10 tonnes dossiers under preparation
- Communication campaigns coordinated with the MSCAs and other bodies

Which other actions should be taken for ensuring compliance and quality of (future?) registrations?

- How to ensure that companies make use of the available tools?
- How to improve the quality of the justifications where companies make use of Annex XI adaptation rules?
- Other issues?

1.1) Dossier quality for the 2018 deadline

Topic	Challenge	Recommendation
Language	Simple and own EU language necessary Go beyond what is on website	1. ECHA to make video tutorials that can be reused, translate if possible 2. MSs / Associations to make workshops, convey the tutorials / material from ECHA Train the trainers? (Example of French association)
Outreach	SMEs not in chemical associations that are dealing with REACH Many are not aware of their obligations	1. MSs to use national & local chambers of commerce 2. MSs to contact associations even outside the traditional ones, send them newsletters etc. 3. MSs to organise national workshops ECHA/MSs to collect and publish list of associations that can provide support or at least direct you towards right address

1.2) Dossier quality for the 2018 deadline

Topic	Challenge	Recommendation
IUCLID	Too complex for SMEs	1. ECHA to prepare a webinar/tutorial to make a demo, translated in all languages 2. Simple software such as Excel (but the harmonised templates are an obstacle for excel) – other solutions could be explored

1.3) Dossier quality for the 2018 deadline

Topic	Challenge	Recommendation
Support to SMEs	Dependant on consultants (cost issue) Timeline for registration MS helpdesks will be submerged by questions Economic crisis hampering MSs' capacity	1. ECHA to raise awareness on non ethical behaviour of some consultants/ORs 2. ECHA to encourage companies to start early as soon as IUCLID 6 is released (word of mouth – others will register) Commission to alert MSs ministries at the Council level of the importance of chemicals and resources needed at MS level Workshops organised by ECHA/MS with those preparing the dossiers incl. consultants to explain the quality expectations, especially on read-across/waiving

2) Compliance of existing dossiers

- Compliance check is an important instrument but taking into account the number of dossiers to be addressed and resources and timelines, what other actions can be recommended to address compliance? How to ensure commitment from sectors/registrants to update the dossiers?

Which other actions should be taken for improving compliance and quality of registrations?

- Informal communication with the registrant, on which aspects?
- More intensive dialogue between Industry – ECHA – MSCA?
- Communicate transparently on the dossier evaluation process?
- More “sticks “ for poor registration dossiers? Enforcement? Completeness check to be further refined? Revocation of registration decisions? Shame and blame?
- Promote good dossiers? How? Based on which criteria?

2.1) Compliance of existing dossiers

Topic	Challenge	Recommendations
1. Conflict between processes	2018 registration is a priority for many companies while at same time CCH & SEV,…	1. Process owners (Authorities) check that pre-conditions are in place e.g. registration exists (e.g. for CLH proposals). 2. Authorities to look better at the priority of the actions in light of the objectives (e.g. ECHA with the soft measures)
2. Update of existing dossiers	To reach the 2020 goal it is a continuous process to register and update the dossiers.	1. COM, MS and ECHA to prepare a joint letter to inform the CEOs of the needs to keep resources. Awareness if a continuous effort

2.2) Compliance of existing dossiers

Topic	Challenge	Recommendations
3. Outsiders, bad behaviours	Some ORs have taken the role of LR with poor quality dossiers – others do not want to join (IR force joint submission)	1. Registrants can use opt-out but then ECHA to consider action on those clear issues of data quality between existing registrants and newcomers 2. Also MS/industry associations can alert ECHA/authorities to act with precise cases and facts
4. Promote good dossiers & efforts done by industry	7 years of work and industry is always only hearing complaints. No recognition of good work.	1. ECHA to consider to use more real examples of good quality dossiers or good RSS/data packages. This option needs to be explored further with industry associations. 2. ECHA to consider a comparison of good dossier with bad dossier to illustrate the deficiencies

2.3) Compliance of existing dossiers

Topic	Challenge	Recommendations
Sticks	Not enough sticks when dossiers are not compliant, hence no consequences, hence no stimulation to update spontaneously	1. ECHA to explore further the possibility to use revocation and link it to the national enforcement authorities – in cooperation with MSs (ECHA Forum interlink procedures) 2. ECHA to continue to use this threat. Experience so far is that already the threat of revocation triggers updates which make actual revocation unnecessary
Promotion of data quality	Some data selected by the SIEfs – what if 3rd parties have relevant data? How to take into account data from newcomers in existing registrations?	1. ECHA to explore the possibility to enable registrants to contact 3rd parties e.g. via a forum on the ECHA website (as discussed for the new portal). However it is up to the registrants to decide whether they want to base their assessment on this new information (medium priority – timeline consideration)

2.4) Compliance of existing dossiers

Topic	Challenge	Recommendations
Transparency/ dialogue	Not always possible to have a dialogue with ECHA/MS before regulatory process – differences of behaviours across MSs	1. Based on good experience in certain MS, MSs are encouraged to organise informal dialogues /consultation with registrants before starting a SEV, RMOA 2. MS with good experience can share this with other MS 3. 3. Authorities to announce specific interest for certain sectors

2.6) Compliance of existing dossiers

Topic	Challenge	Recommendations
Promotion of data quality Confidence in the data	Not sufficiently clear on the website whether the data has been "validated" by ECHA/MS – where there is a dossier evaluation? If data are "validated" they could be used for other legislation	1. ECHA to work further on making clear which dossiers went through compliance check, and with what outcome on the website 2. Use of the data, taking into account of the process / legislation that uses it.
Promotion of data quality		1. Industry is committed to proactive improvement of certain dossiers on a voluntary basis

6) Improving volume, use and exposure information

Lack of sufficient volume, use and exposure information hampers the identification and prioritisation of substances of concern

- What use and exposure information is needed for which decision-making step/process?
- Are there new ways for obtaining this information? E.g.:

  1) More extensive use of Article 36 to obtain existing exposure information from registrants and downstream users

  2) Stimulate DUs to provide their use information

  3) Companies volunteering to provide the information - they should do it mostly for their own benefit and not only upon request of the authorities

  4) Further develop the approach by sector of use, based on their potential for exposure to humans and/or the environment, supplementary to the more hazard based starting point currently used in common screening

  5) Use external sources of information (not based on information provided by EU industry)

6) Improving volume, use and exposure information

Topic	Challenge	Recommendation
Getting info on use/volume	Mostly difficult with non members of consortia or ORs and importers Difficult to motivate the DUs as they do not see how REACH impacts them	1. Industry associations or sectors should get organised to clarify the downstream uses, e.g. sector-specific workshops 2. They should promote the tools already developed by ENES 3. Link to restrictions
		1. MSs/ECHA to use proactively Art 36 for getting information from both M/I and DUs

6) Improving volume, use and exposure information

Topic	Challenge	Recommendation
	DUs do not want to provide their uses to the manufacturer	1. Registrants should confront their customers with the consequences of not providing their uses incl. advise against such uses (DU would need to do a DU report – Art 38) 2. Registrants should communicate clearly what uses are supported by the registration 3. The Forum to explore the feasibility of a pilot project on DUs respecting the compliance with the registered users 4. Consider DCG outcome
	Reach out DUs	1. ECHA's campaigns to increase the visibility of DUs obligations. MS can be multipliers

3) Substance identity (SID)

- SID is essential information for all REACH/CLP processes and needs to be correct at the beginning of the process, i.e. in the SIEFs. However many deficiencies observed that prevented authorities to evaluate the registration or the best prioritise the substances

- How to ensure that registrants construct a hazard dataset that takes account of the variability in the compositions covered by the (joint) registration?
  - Is the substance identity profile (SIP) available in IUCLID 6 sufficient?
  - Further transparency on the scientific rationale on how the dataset was constructed?
- What is the most impactful action? At which point in time (before the common screening?)
- How to ensure that registrants reconsider their hazard datasets when the identity of their substance is not sufficiently known (e.g. further to a screening letter or a targeted SID decision?)

3) Substance identity (SID)

Topic	Challenge	Recommendation
UVCB	By their nature it may not be possible to fully describe the substance Uncertainty to relate the SID information with the hazard data set Test is done on a sample and difficult to understand whether the results are representative for all compositions covered by the registration	1. Registrants are responsible for ensuring that the SID information provided can be linked to the data and fit for purpose 2. Registrants to make use of IUCLID 6 to revaluate the data. 3. Registrants to make use of the Substance Identity Profile for ensuring transparency (explain that the boundaries are fit for purpose) and the information on the tested substance 4. ECHA to use soft measures to the extent possible if authorities need to take action.

Topics post plenary (1)

General

- More precision – to whom the recommendation is directed
- Many recommendations – prioritisation needed

SID

- UVCB: there are now technics / analytical methods to better characterise the substance to a certain degree
- When variable part in a substance, it is important to be able to link the SID to the right hazard data
- Important that SID is clarified for 2018 substances
- Is it realistic to validate the data? Should we focus on priority substances?
- It is difficult to ask right information in Sev, when there is no understanding of the substance identity, e.g. when there are several forms, several grades

Topics post plenary (2)

Existing dossiers / Dossier updates

- What are the incentives for making industry update their dossiers?
- “Clean” the database: For which purpose? If there is a concern for the substance, it is important. But other cases?
- Timeline: by 2020 we need to have a transparent equal level playing field for all substances. (No substitution for an unknown substance). To be considered in our discussion
- A lot of exercises done by ECHA/MS (screening). Is there any shortcuts? Only improve part of the dossiers needed for Risk management measure? Dialogue with industry?
- Maximise the learnings of what has been done with the existing dossiers to educate
- Poor quality dossiers must not get rewarded

Topics post plenary (3)

Full study report

- Industry must understand that Authorities need the full study report for certain processes. However REACH is based on the concept of the Robust study summary (RSS). Criteria when RSS is needed?

CSR

- Many efforts done by industry to prepare their CSRs. However little use of them so far.

Article 36

- Can be used by MS also – for getting targeted info e.g. for a restriction