

DUCC Use & Exposure survey

RPA presentation

19th May 2022



Downstream Users of Chemicals Co-ordination group

Welcome, Intro, competition law	Led: DUCC	09:00 – 09:10
Expansion of downstream user reporting requirements	Led: RPA	09:10 – 09:25
Presentation of DUCC survey results + input from companies • Reformulation frequency and reasons • Tailormade products and year-on-year changes in substance use • Additional resources needed • Timing required to implement such obligatory requirements • Learnings from SCIP and CLP Annex VIII • Concerns with regards to the feasibility and appropriateness of this obligation • Focusing on all substances with a hazard classification • Supply chain actors that should supply information • Concerns over CBI protection	Presentation of the point by DUCC + additional information from DUCC members and companies	09:25 – 10:40
Q&A		10:40 – 11:00



COMPETITION LAW REMINDER

- ❖ Attendees shall refrain from discussing or exchanging sensitive competitive information, such as:
 - ❖ Information on price-related matters;
 - ❖ Production plans or production capacities;
 - ❖ Market procedures;
 - ❖ Market shares;
 - ❖ Blacklists or boycotts of customers, competitors or suppliers;
 - ❖ Branding strategies. (This is a non-exhaustive list)
- ❖ Discussions which appear to violate check list will be immediately stopped by the Secretariat.
- ❖ Every attendee agrees to abide by these rules.

The European commission is considering the expansion of downstream user reporting requirements under REACH. This would serve two purposes: 1) DUs would identify themselves to the authorities as users of a particular substance and 2) provide new (use pattern) data for a substances that can be used for authorisation and restrictions of specific substances.

This would apply for all substances with a hazard classification, and the following information would need to be reported:

- *Specification of the Product category the substances are included in (examples: PC9a: Coatings and paints, thinners, paint removers; PC39: Cosmetics, personal care products)*
- *specification of the sectors of end-use for the Product Category/Article Category produced*
- *concentration (range(s)) of the substance in the produced product*
- *the total tonnage used per Product/ article category*
- *total volume of PCs/ACs placed on the market*

As potential sub-options, the consultants are considering refining the scope as a) covering substances meeting the criteria for being classified hazardous for endpoints of (very high) concern and hence qualifying for EU regulatory risk management and b) only those substances that had been placed on the future list of candidates for regulatory risk management (i.e. substances intended to be addressed by restriction, authorisation or a combination of both).

This information would need to be provided regularly: annually, biannually or every five years.

To support a future regulatory framework and requirements that will be workable and not cause companies a lot of undue burden, we ask for input to the following short questions.

Timing

- Questionnaire published 1st April
 - Shared with: DUCC members, DUCC linkedin account, CheMI members, ECMA
- Deadline 19th April → 64 responses
- Results shared today.

Questions

General Questions:

- 1) Name
- 2) Company name
- 3) Location
- 4) Email for further contact
- 5) Company size:
 - a. Large > 250 Employees
 - b. Medium < 250
 - c. Small < 50

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- 6) Are you part of an industry association? Yes/No.

- a. If yes which one (s)?

- i. ~~A.I.S.E.~~
- ii. FEICA
- iii. IFRA
- iv. EFCC
- v. FECC
- vi. CEPE
- vii. FEA
- viii. ATIEL
- ix. Cosmetics Europe
- x. CropLife Europe
- xi. ~~I&P~~
- xii. Other

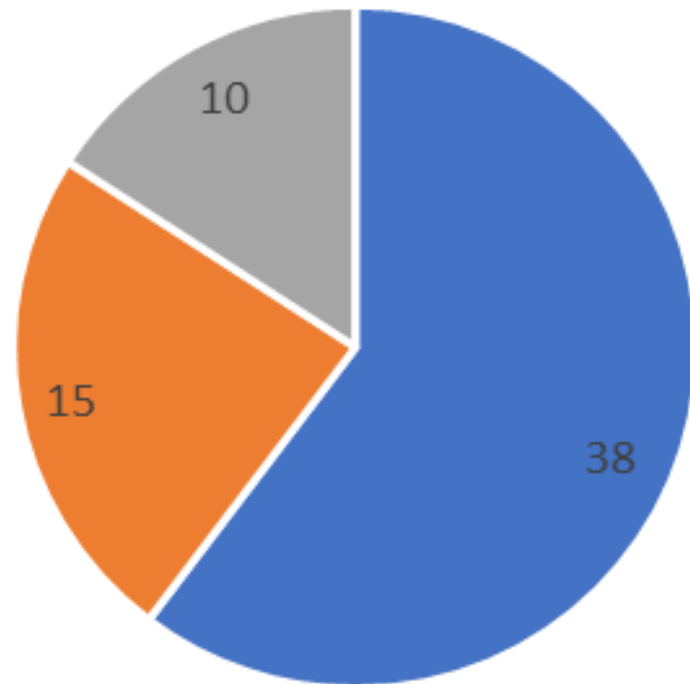
- 7) Would you be interested in participating to a DUCC working session with the Commission consultant working on this issue to provide your expertise on the topic or to be contacted for further input? Yes/ No

Specific questions:

- 8) Do you have any concerns with regards to the feasibility and appropriateness of this obligation?
- 9) What is your opinion with regard to this initiative being focused on all substances with a hazard classification?
- 10) Please share any considerations with regards to the timing required to implement such obligatory downstream user notification requirements.
- 11) Based on your experience what additional resources will you need if you will have to report (use pattern) data for all substances with a hazard classification in your portfolio?
- 12) Do you manufacture products tailored for specific customers that it would be difficult to notify through such a system? Do you have significant changes in substance use and volumes year-on-year?
- 13) How often do products need to be reformulated in your industry? Please provide qualitative explanations as to why.
- 14) Such an obligation is likely to be more resource intensive than the CLP Art 45 Annex VIII reporting and/or the SCIP database. To avoid systems that are unworkable and to learn from past experience, can you share any information on your experience with these two systems (the UFI reporting and SCIP database).
 - a. What issues have you faced with these databases? Were there any situations where you had to provide information in a format that was difficult or counter intuitive?
 - b. Did you have any problems deciding on the product category applicable to your product?
 - c. Any information on additional costs? These include monetary burden or if you had to hire additional employees and/or contract an external consultant to meet these requirements.
- 15) At which stage along the supply chain should this reporting obligation be applied? Should your customers / further Downstream Users also be approached for this information?
- 16) Do you have concerns over how Confidential Business Information will be protected?

Count of Company name and location

Company size



Company Size ▼

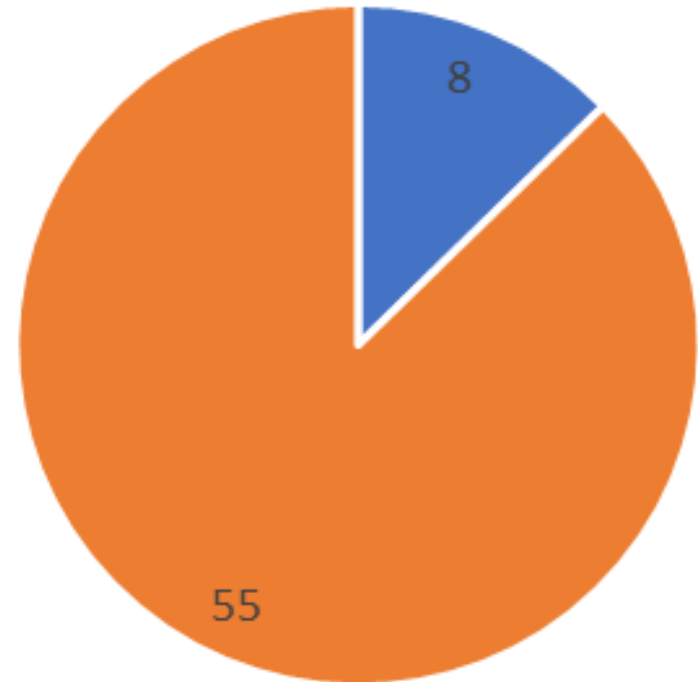
■ Large > 250 Employees

■ Medium < 250

■ Small < 50

Count of Company name and location

Part of industry association?



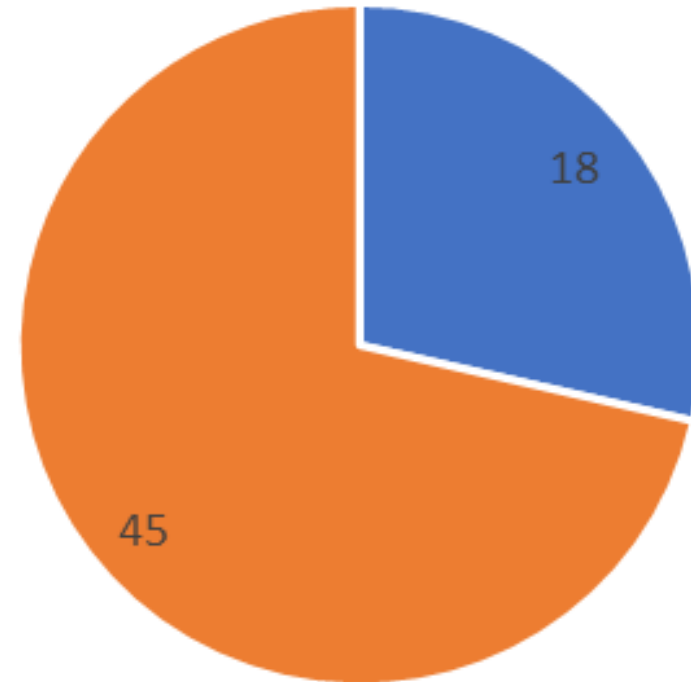
Are you part of an industry... ▼

■ No

■ Yes

Count of Company name and location

DUCC member ?

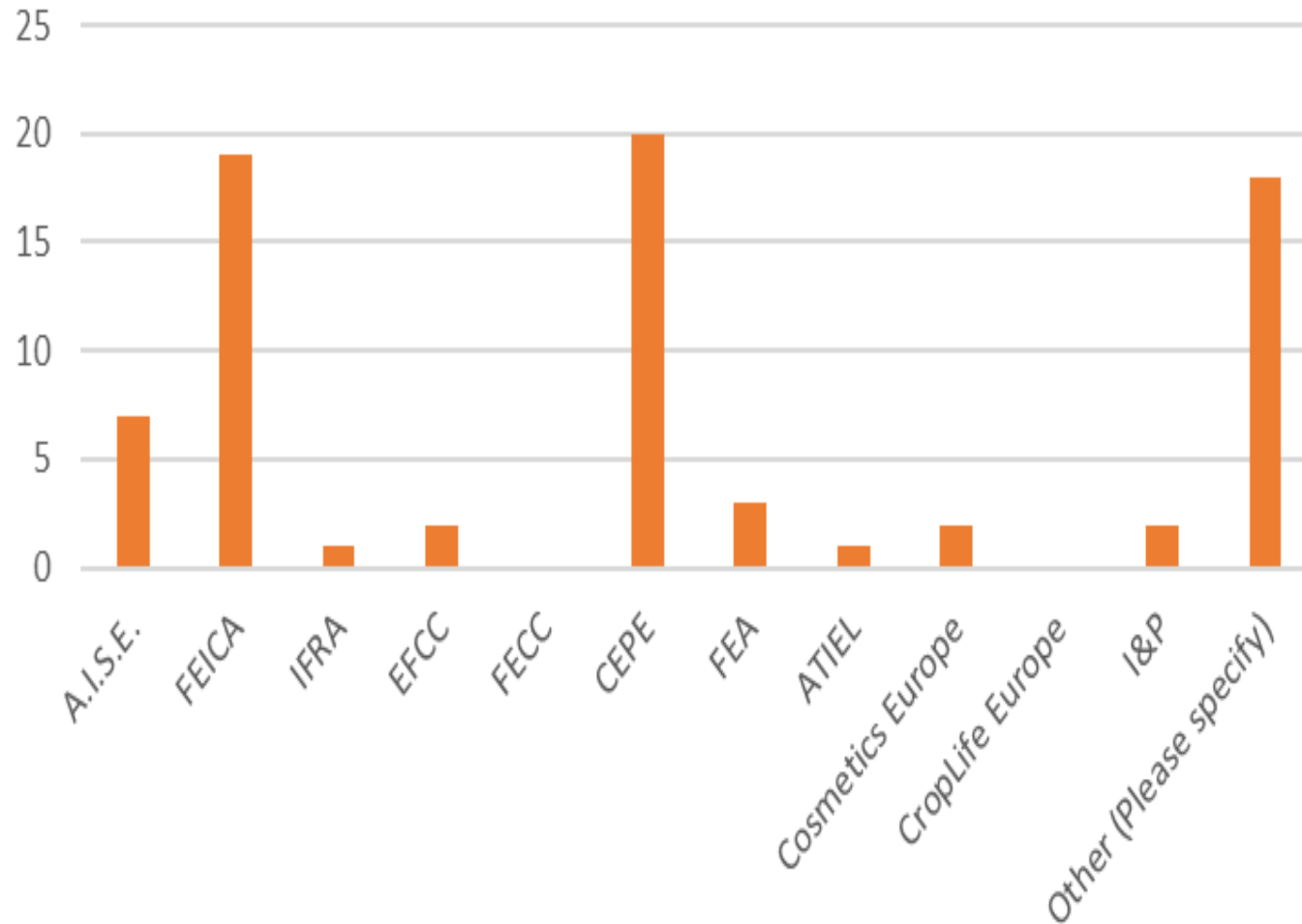


DUCC member (yes, no) ▼

■ No

■ Yes

Response by association



OTHERs

- BAMA
- BPHR (Swedish Detergent association)
- ECMA
- National associations in Norway, Sweden and Denmark
- SDAD
- SVEFF
- Verband der Nordwestdeutschen Textil- und Bekleidungsindustrie e.V., Münster

**Concerns with regards to the
feasibility and appropriateness
of this obligation**

Quantity of Data

"1000's of substances to report on, if there isn't a tonnage threshold"

"It will be very time and resources consuming if it affects all the substances with a hazard classification instead of the most hazardous ones such as CMR or SVHC."

"We question that the sheer volume of data that will be gathered can be easily processed by ECHA for a useful purpose."

"My personal feedback is that it depends a lot on what tier is actually implemented. No big deal to notify the hazardous substances that are used, especially if not all classifications are required and if there are volume thresholds. But if volumes are included, the effect could be massive. Most of our members are downstream users and purchase all or most of their supplies from EU suppliers. SVHC content of >0,1% is rather uncommon. So, they have (almost) no reporting obligations at the moment and do often not keep track of the volumes. The extra work would get considerable if the volume of the used classified substances had to be reported, or even the concentration ranges in the produced products."

Getting exact quantities

“Difficulty in some cases getting exact quantities from suppliers/ confidential supplier information. Difficulty controlling how end-users really use the products”

“Downstream users use mixtures, not substances. From the SDS it could be possible to identify the hazardous substances and the concentration band in the mixture. But if for each hazardous ingredient use information needs to be recorded and submitted to authorities, that would require a lot of resources and clear guidance and training. In case the composition changes, change of the volume or termination of the use, this would need to be repeated. There is a high likelihood that the data will not be kept up to date.”

“Concentration (range(s)) of the substance in the produced product concentration bands as given on the SDS is possible.”

“Estimated tonnages will be double-counted at several steps of the diverse supply-chain.”

“It is also not clear to us how to prevent the same substance from being reported several times. We, as a formulator, would report that we use X kg per year of substance A. Substance A may very well come from a raw material we in turn have purchased for another downstream user formulator, who have then already reported that they use Y kg of substance A. That would cause substance A to be reported in twice the volume it is actually being used. Even if by “downstream user” it is specified a formulator, which we don’t think we have seen anywhere that it will be, then how to separate between two different formulators in the same supply chain?”

Avoiding double counting

Comments on the Product Category requirement

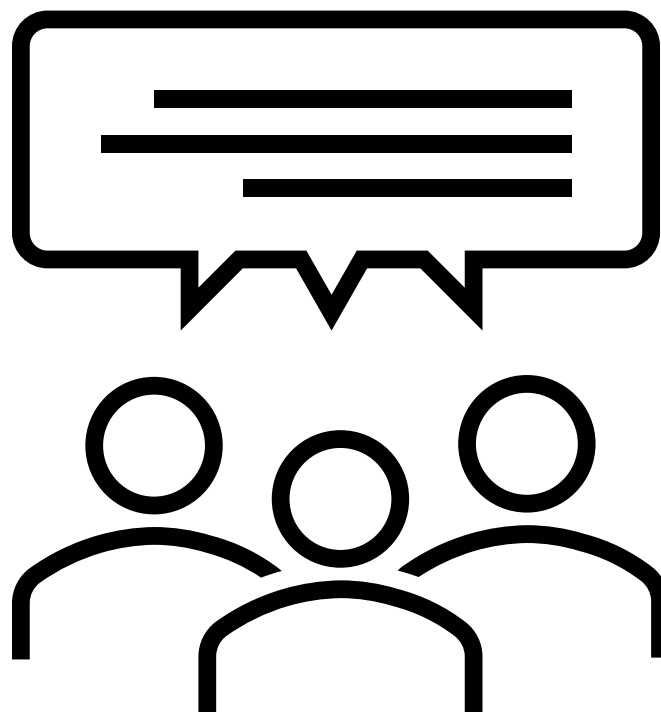
“Specification of the Product category the substances are included in (examples: PC9a: Coatings and paints, thinners, paint removers; PC39: Cosmetics, personal care products) not all products can be covered under a PC. This would result in reporting of PC0, which is rather useless.”

“Specification of the sectors of end-use for the Product Category/Article Category produced assigning a life cycle stage (e.g. Industrial, professional or consumer use) might be possible, however, there are no clear cut criteria to distinguish between industrial uses and professional uses. The Sectors of Use as available in the guidance, is not sufficient, it would result in many uses assigned to the more generic SU’s.”

“In Sweden we already report similar information to the Swedish chemical agency, and the reporting is quite tedious and put a lot of requirements on the IT system. Avoid double reporting”

*“CBI of
formulations”*

- There are concerns on CBI, but use of adequate systems and tools could quell these concerns.
 - Sensitive information being disclosed includes but is not limited to: ingredients used in formulation and relative percentages, technical function, volumes, customers of individual companies, supply chains...
- Crucial to reassure companies on protection of their formulations from mis-management/ leaks/ hackers etc.



How often do products need to be reformulated in your industry? Please provide qualitative explanations as to why.

How often ? Why ?

- Reformulation periods may vary from several times per year to never, depending on technology, raw-material availability, customer needs etc.
- New products (with new materials) are launched annually. Existing products can be reformulated often due to materials availability, cost or legislative changes.
- Products are regularly reformulated (yearly/bi-yearly basis) mainly to mitigate regulatory measures, answer specific Customer/Consumer request ands, to certain extent, generate savings.

How often ? Why ?

- There is no defined answer to this. Depends on the substances in the product, regulations, supply of substances & company objectives
- With the supply chain in complete disarray, the re-formulation is a daily activity. In most of the cases, the re-formulation involves the use of technically equivalent raw materials with the same classification.
- We are spending a great deal of time sourcing and validating alternative materials to deal with the shortages of chemicals (COVID, supply factory shut-downs, transportation issues, global demand) just to keep factories operating and customers supplied. In addition, we have been experiencing a large number of classification changes, which themselves can result in a need to use alternative substances. There are other drivers, including cost reduction, and sustainability, which mean that our product formulations change frequently. 100 - 200 reformulations per month would be a ballpark figure.

How often ? Why ?

- Last years it has been frequent reformulations, a couple of time a year. Due to raw material shortages, price increases, re-classifications of substances that trigger exclusion of these from our mixtures.
- For our **tailormade products**, there is **constant reformulation** going on. In addition, each **new ATP** can bring a risk that reformulations are needed. We also have an **internal list of substances we are looking to substitute** so there are always reformulations ongoing. **ECHA's Green Deal** will also increase the reformulation work taking place. In addition, the **shortage of raw materials we have experienced in the last few years** makes urgent reformulations a necessity. Unless the raw material shortage ends, this is something we will have to learn to live with.
- **Every month**. Every **changing of raw material, dye, scent, additive and internal change composition of single component change material composition of final product**.

Summary

yearly bi-yearly basis
tailor made products
never
several times per year
daily annually every month
a couple times a year
100 - 200 per month

- Technology
- Raw-material availability
- Changing of raw material, dye, scent, additive
- Customer needs
- Cost
- Legislative changes (e.g. new ATPs)
- Company objectives (internal list of substances companies look to substitute)
- Tailormade products
- Sourcing and validating alternative materials to deal with the shortages of chemicals (COVID, supply factory shut-downs, transportation issues, global demand)
- Green Deal will also increase the reformulation work taking place.

Based on your experience what additional resources will you need if you will have to report (use pattern) data for all substances with a hazard classification in your portfolio?

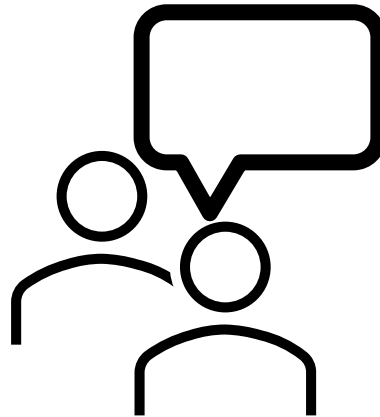
Generating the data regular (including updating, verifying, etc.) 2-3 FTE

For the implementation phase 7-8 FTE and for the maintenance 3-5 FTE based on the UFI notification

One SME said: "We will need at least 1 FTE (= 50% extra resources for this kind of work."

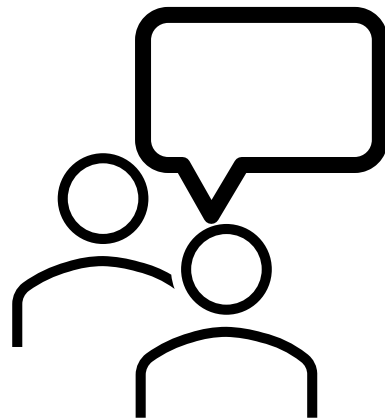
1-2 people

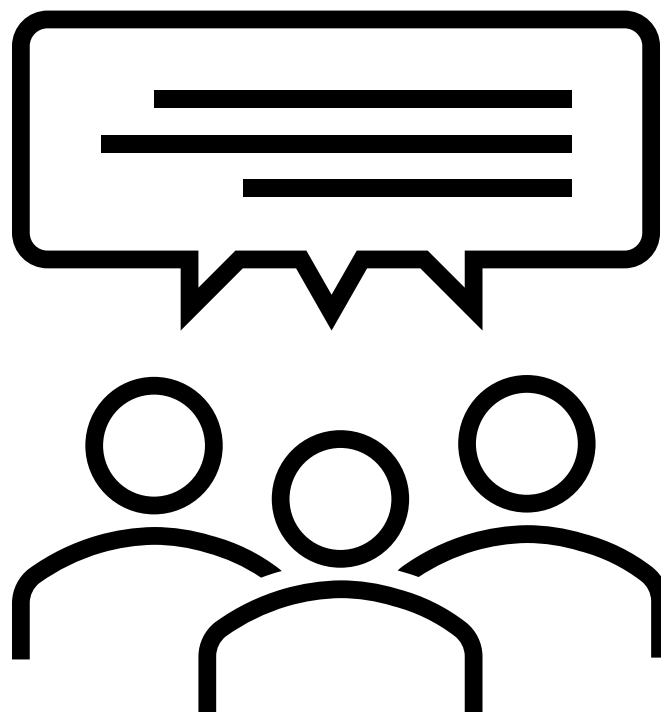
"We use about 15000 raw materials, comprising about 4000 substances in 0.5 million products...However, the actual resource required will depend very much on the hazard categories included in the scope of the legislation.



We would also need to hire new staff. The data listed above would need to initially be manually entered into this IT system that so far does not exist and it would also take time in the future to maintain it. In addition, we would need staff to do the annual data compilation and submission. With the experience we have from submitting data to the EU Poison Centre, just the actual submission would take considerable manhours. Even with a fully automated system, quality control would take time.

As we already are reporting similar data to the National product registers in the Nordic countries, we are aware that this is an extremely time-consuming task. As we use several hundreds of classified substances it is easy to understand that even if only one hour is required per substance, the total extra administrative burden will be a number of many-months.





Focussing on all substances with a hazard classification



While focussing “only on hazardous substances” sounds good – in reality this would mean almost all our products. Even our non-hazardous products do contain small amounts of biocides.



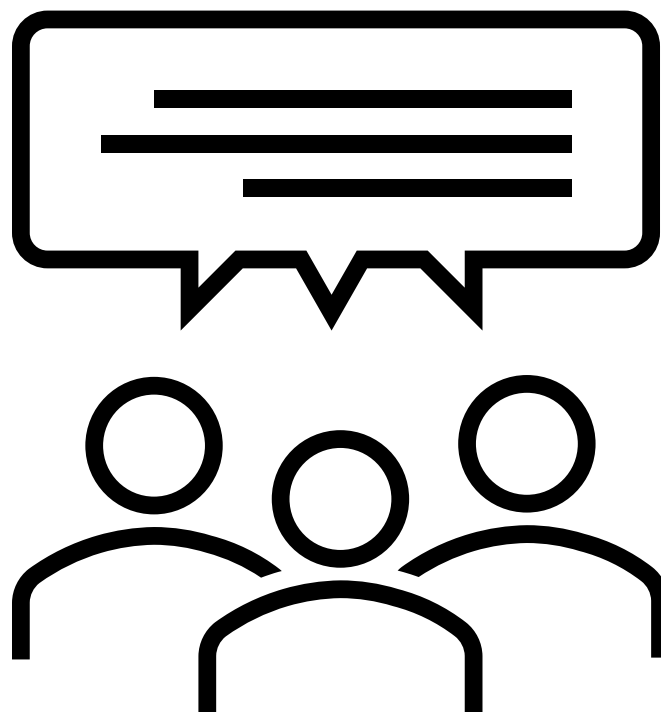
It would be difficult or even impossible to get access to deeper information of the substances up streams apart from what can be read from a MSDS. It would also mean that we have to give an account for all our products.



*Positive if it replaces the Product Register in Sweden, Norway, Denmark and Finland.
Negative if it does not replace already existing registers*

We believe that this initiative should be focusing to the most severely classified substances in formulations when they are present in such concentrations that they cause a classification to the product. Or alternatively to the most severely classified substances

- Some proposals made in the survey
 - CMR, STOT
 - Substances above a certain cut off and can be enforced (aligned with CLP cut-offs)
 - Substances that are widely used and in high volumes
 - SVHC, CMR Cat. 1, PBT
 - CMR, PBT, vPvB, equivalent concern
 - CMR, SVHC, Tox 1
 - Limit to substances that needs to be mentioned in section 3 in a product's SDS
 - Limit to SVHC-substances $\geq 0.1\%$
 - Substances identified by the GRA



Learnings from issues faced by SCIP database and CLP Annex VIII

Lengthy, time consuming system

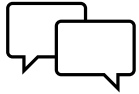
1. *UFI: very time consuming, many clicks. It would be easier with more fields on the same page, now you have to click many times just to enter one info.*
2. *Often takes long time to log on to the data base. Repetitive input of data.*
3. *The need to input substances- there should be a database already available in the system- eg. you input CAS number and you have already all the information about substance and you can edit it- for example by adding the additional hazards.*
4. *Some data had to be entered manually even if it made no sense, e.g. harmonized classifications had to be entered in IUCLID6 even though it should be able to have that data drawn automatically from the CL inventory based on CAS/EC-number. It is sometime difficult to get data for raw materials where 100% of the composition was not known.*
5. *Issues with the UFI-reporting: system needed updating, interpretation of requirements caused delays. Integration and automation of regulatory and the ERP systems is extremely difficult and very expensive. System not flexible enough to be able to reflect all business operations and product scenarios. Data gathering was difficult as we had to collect new information that was previously not held in systems that is required for the notification.*

Sector, company or country specific issues

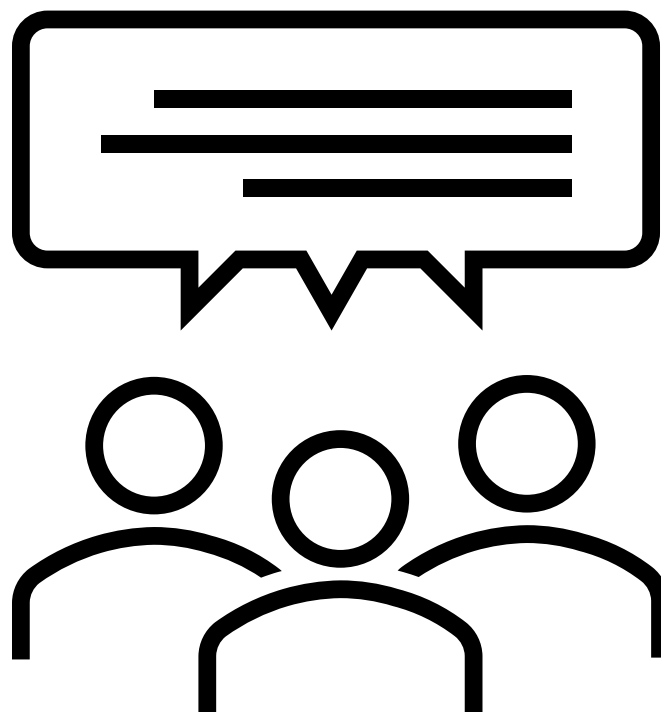
1. *The UFI reporting was mainly how to create an automatic reporting system, we have to many articles to do it manually in IUCLID. We don't have a business system like SAP that included a program, so we had to build our own. So far it seems to work. For this we had to hire a person with this kind of expertise, it was hard to find information on how to create the program and I know my colleague had to call ECHA many times for help.*
2. *Bespoke paints are an example of a system that had to be invented to solve concept issues in CLP Art 45 Annex VIII reporting. Having 7 UFIs on one bespoke paint means 112 figures to be read in an emergency.*
3. *In some countries (e.g. Denmark) there is a need to notify products both in PCN and in local systems. It is a huge burden to follow all local requirement, it's double work. It should be consistent throughout the whole EU.*

Selecting product category

- 1. Three respondents expressed that they faced no issues selecting product category.*
- 2. One comment was that some products can be used for multiple purposes and therefore difficult to assign to one product category.*



“Our general impression is that CLP Art 45 Annex VIII reporting database is not intuitive, and not user-friendly. It takes a lot of time before you understand how the system works, and our impression is that it is far more complicated than it need to be. As our products are rather simple everyday products, we do not experience any problems in deciding product categories, but it is easy to imagine borderline cases where the choice of category is not obvious. Furthermore, we cannot find all our packagings in the scroll-down list (e.g. cartons for detergent products).The additional cost for reporting to the CLP Art 45 Annex VIII reporting database for us is about 3-4 man-weeks annually, based on approx. 300 products. We see the reporting requirements far too detailed, and a need to update every time that there is a small change in the formulation, such as a change of fragrance due to legal requirements or changes in the requirements for environmental labelling. Also, there is no possibility so register alternative raw materials, that is sometimes necessary to use due to shortages and other delivery problems. This kind of details creates excessive extra work but could hardly be seen as adding any benefits to anyone.”



Please share any considerations with regards to the timing required to implement such obligatory downstream user notification requirements.

- *It will take some time to set up systems to extract the relevant data. At least 12 months, and preferably 18-24 months in advance of notification would be required. In addition, there is the problem about flow of compositional information downstream and CBI, which may require a significant amount of time to solve (potentially involving many secrecy agreements). As regards the frequency of notifications, due to the magnitude of the exercise, it should be only required at infrequent intervals, e.g. every 3 – 5 years.*
- *Based on the recent CLP Art. 45 Annex VIII experience, we would say that Industry would need to have at least 5 years to implement new/additional requirements. In addition, Industry would need to be made in the position to comply with the requirements by being given the necessary guidelines on the related new provisions well in advance.*
- *The scope is very large and the burden to be put onto the companies is likely to be very high. If the initiative is pursued, it must be preceded by a proof of concept and pilot exercises. Sufficient time (matter of years) would be needed to develop and then to implement in companies the necessary IT infrastructure and software.*

At which stage along the supply chain should this reporting obligation be applied? Should your customers / further Downstream Users also be approached for this information?

- It is difficult to identify a trend from the responses
- Every actor in the supply chain should have the possibility to provide information on uses as relevant and depending on the situation different actors may be more appropriately placed to provide information.
- There are large variations between downstream users regarding what information they have access to and what they can report. A downstream user that is a formulator has access to more information than the downstream user that is a car painting facility or a carpenter
- For every step down the supply chain the number of actors involved increases drastically

SMEs

- 10 SME responses
- Small companies are all-ready very occupied with reporting on national level, community-level, client, level. Adding more reporting → many small companies will suffer severely and might be out of business.
- Already need to notify to the Nordic product registers. If it does not replace already existing registers this will take a lot of extra time each year.
- One SME response: “We will need at least 1 FTE (= 50% extra resources for this kind of work.)”

Conclusions

- DU companies are concerned with the proposal for DU notification requirements for all hazardous substances
- Reformulation of mixtures is an ongoing process – daily to yearly timeframe.
 - Various demands. Recently including: sourcing and validating alternative materials to deal with the shortages of chemicals (COVID, supply factory shut-downs, transportation issues, global demand)
- Place large burden on companies
- Concerns for getting exact quantities of substances, CBI, overlaps with other existing databases



Asks

Downstream Users of Chemicals Co-ordination group

- More information can be provided by DU, but the level of detail to be provided for any screening process should be case specific, depending on the level of concern, available data etc. to ensure a workable system
- **A more targeted approach.** Not workable to target all hazardous substances
- Consider overlaps with other existing systems (e.g. Product Register in Sweden, Norway, Denmark and Finland)