Comments by the Netherlands on European Commission public consultation on the targeted revision of the REACH Regulation ((EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals)

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This document contains comments by the Netherlands on the public consultation on the revision of the REACH Regulation. The document is an Annex to and hence should be read in conjunction with the answers provided to the survey questions raised in the public consultation. Comments are provided per section of the survey and a final section is added containing additional feedback.

SECTION I REGISTRATION

Headlines NL CA comments on the two registration-related topics: Increased information critical hazards and lowest tonnage level:

- Quality of information in REACH registration dossiers is a limiting factor. With respect to the quality of information REACH has not yet lived up to the expectations. Therefore, we support legal changes that strengthen and clarify the requirements of registrants and companies in the supply chain including on data requirements and obligations to update dossiers. Furthermore, we support introducing means to timely monitor the dossier quality and effectiveness of the registration and other REACH processes.
- The phase-in registration deadlines have all been passed. Therefore the bulk of REACH registrations is known and stable. Since REACH registration is a pre-marketing obligation we support strengthening the no data no market principle by accepting new registrations only if the dossiers are fully compliant.
- The requirements of article 22 are not specific enough and should be made more clear in terms of (minimum) update frequency. Companies should be required to at least (e.g. annually) update their dossiers for designated critical parts of the registration dossier for example volumes, classification and labelling, chemical safety report, uses and exposure (or indicate that there is no change in the information provided). There should be a clear legal deadline linked to the update requirement and the “no data no market” principle should be prevailing by giving ECHA enlarged mandate to revoke registration dossiers in certain cases when the registrant fails to fulfil the requirements of article 22.
- We propose consideration is given to further strengthening the public dissemination mandate of ECHA for animal test data in registration dossiers especially full study reports. Information submitted following compliance check, testing proposal or substance evaluation decisions should become publicly available without restrictions. It could be considered to introduce a transition period of a few years after which the data owner would be obliged to provide access to the full data for the interest of the EU public at large.
- Registration or notification of manufacture, import and uses of substances <1 ton per manufacturer/importer should be considered, as many uses remain under the radar. For some substances we see substantial numbers of notifications in the classification and labelling inventory. Such notifications are indications of marketing and use, whilst the substance is not REACH registered. At initial entry into force of REACH it was appropriate to first focus on the largest volumes in terms of registration duties and information generation. We are now 15 years further down the line and it therefore obvious to target lower

tonnages that first were not given priority. The 1 ton per year threshold is relatively high from a risk perspective as a limit for derogation from registration. The costs and benefits of reducing it to 100 kg per year should be assessed. Above this tonnage level, a base-set of information was required under the New Substances Notification scheme under the Dangerous Substances Directive (67/548/EEC) in place prior to REACH and a similar approach should be considered in our view.

- The information requirements set out in Annex VII are too limited for hazard and risk assessment purposes and require an upgrade. In the end a more pro-active information requirement policy will lead to benefits in terms of human health and environment. . This might also stimulate green and Safe and Sustainable by Design (SSbD) manufacturing and the development of safe alternatives for current and future SVHCs. Lowering the tonnage thresholds for information requirements will on a short notice result in additional investment needs but these need to be assessed vis-à-vis the returns on these investments in a broader socioeconomic context. It will also improve the knowledge on possible hazards for human health and the environment based on the intrinsic properties of chemicals. See also answer on socio-economic benefits above.
- For advanced materials and hazardous chemicals a lack of information and assessment of hazards and risks at lower tonnages is not in line with the zero pollution ambition. In particular, for certain types of substances (e.g. nanoforms, or more advanced materials that combine multiple chemicals – often at the nanoscale) production volumes are expected to remain below 1 ton per manufacturer/importer, while their (new) properties may challenge current risk assessment approaches (e.g. where other descriptors (like surface area) provide better explanations for differences in exposures or hazards). Also, the current REACH requirements regarding production volumes of nanoforms should be improved as to provide information for different forms (i.e. require production volumes for both the general and the nanoform).
- New Approach Methodologies (NAMs) do not by definition introduce more uncertainties in comparison with the use of existing animal models. For reasons of animal welfare we support the introduction of NAMs in regulatory schemes such as REACH registration. However, NAMs should be introduced only if sufficient scientific scrutiny is available, the robustness and transferability is proven and the method has been internationally accepted (e.g. OECD). As regards to impacts we do not see how proper implementation of NAMs could negatively affect competitiveness of EU businesses. On the contrary, a proper and timely introduction and use of NAMs may strengthen the level of competitiveness of EU companies as it would help to early adapt to new global standards related to alternatives for animal testing. However, introduction of obligations to use methods that are not internationally accepted will lead to additional costs as it will result in still having to use animal testing outside EU. Therefore incorporation of NAMs in regulatory schemes should be accompanied by creating international support with a solid scientific base and availability of datasets, supported/facilitated by ECHA/COM
- In general, all definitions in the Annexes are best moved to Article 3 of REACH. As an example, the definition for nanoforms is currently in Annex VI for practical reasons as this was the only possibility at the time the Annexes were updated for information requirements on nanoforms.
- The statements are in regards to the animal testing worded in such a way that the possibility of a win-win situation has not been taken into account. What might not be possible now, may be possible in the near future, as long as the non-animal methods are developed robustly enough and supported, both financially and scientifically.

Information requirements to provide information on endocrine disruption

Headlines NL CA comments on this topic:

- We consider it crucial to update the REACH information requirements on ED and to introduce horizontal criteria for ED across relevant legislation under CLP as soon as possible. This is essential in order to enable an effective identification of substances with ED properties for human health and the environment. The information gaps for ED identification need to be bridged urgently. To this end information requirements should be amended and aligned with the newly developed criteria under CLP.
- We support the development of ED hazard classes and categories in the scope of the CLP Regulation and the extension of the SVHC criteria under REACH to include endocrine disruptors. Testing in animals should in our view only be conducted if no appropriate alternatives are available and as a last resort. Under the current circumstances, we consider animal testing proportionate for the identification of EDs. Such testing should be done by means of a tiered approach. Depending on the substance, in vivo testing may be required to safeguard the environment and mammalian health (including wildlife). From an animal welfare perspective, it is of utmost importance to provide well-conducted (in vivo) studies performed according to OECD TGs and at appropriate dose-levels, in order to avoid inconclusive results that trigger a need for further testing. It is noted that waiving of the in vivo information requirements should be possible on the basis of e.g. reading across, exposure-based considerations.
- In a previous, targeted consultation on the update of the REACH Annexes for inclusion of data requirements on ED, we expressed our preference for an update with OECD GD 150 level 1 and 2 studies for EATS-modalities included on Annex VII, level 3 studies included on Annex VIII, and clear tiers for further testing with level 4 or 5 studies included on Annex IX-X based on the level 3 information on Annex VIII. We furthermore suggested to broaden the scope to also identify EDCs with non-EATS modalities in due time when test methods are available.
- Within the context of the CASG-ED, we have provided detailed commentary to the draft document CASG-ED/2022/02 on draft criteria for ED in CLP. We want to specifically highlight the importance of a category of suspected endocrine disruptors (category 2) when it is not possible to conclude convincingly on one or several of the three ED conditions included as criteria in category 1. For MOCS with ED properties, we consider that classification of MOCS should follow the mixture classification rules. On this aspect we would like to refer to our responses to the questions in a targeted consultation on the document CASG-ED/2022/03.

Information requirements for polymers

Headlines NL CA comments on this topic:

- We support extending the REACH registration requirements for substances to include polymers. Polymers are chemicals with special characteristics of which a relatively large molecular weight in general is a prominent feature affecting aspects like biodegradability and bioavailability. Adequate polymer identification and composition is a challenge. Such characteristics may distinguish polymers from other chemicals but should no longer be used to exempt polymers from REACH registration obligations. Polymers may be marketed and used in large volumes in many applications including consumer uses. To ensure uses of polymers in supply chains and all life cycle stages are safe, it is of utmost importance to start generating information on hazards and risks through introducing REACH registration obligation. Polymer manufacturers and importers active on the EU market should be offered a level playing field with manufacturers and importers of other chemicals.
- We propose to introduce a registration obligation for all high production volume polymers manufactured and imported at volumes >1000 tons per year. As regards the information required we are in favor of a tiered approach starting with mandatory basic information and additional requirements that should be at least partially concern-driven. The intention should be to move away from the paradox situation where a lack of basic (hazard) information does not trigger a need to know more.
- For lower tonnage polymers, we see a remit in a system defining Polymers Requiring Registration (PRR) rather than identifying Polymers of Low Concern (PLC) in combination with PRR. Whitelisting PLC will reverse the burden of proof and may potentially be a loophole circumventing registration for large groups of polymers of similar composition but for which evidence on hazards is largely lacking. Annex IV of REACH type registration exemption without limitation or back lock is a system we would not support. The denomination of “negligible risk based on intrinsic properties” will be hard to justify up-front without an adequate set of registered information. Past experience with the development of Annex IV of REACH has shown that such whitelisting should be limited to only very exceptional cases (carbon was removed from Annex IV after adverse properties of certain carbon nanotubes became clear as science progressed on this theme). For polymers it is in our view important to start generating information through a combination of notification and registration obligations instead of exempting (groups of) polymers based on PLC.
- Polyesters should not be exempted from registration even when this is the case in some international jurisdictions (e.g. US, Canada, Australia). The lists of accepted monomers used in these jurisdictions miss some relevant monomers, while some of the included monomers are hazardous, or are under scrutiny and may turn out to be hazardous. Furthermore, the assumption of full degradation to the monomers by hydrolysis may not always hold (e.g. in different environmental conditions). Overall, scientific evidence providing a rationale for exempting polyesters from REACH registration requirement is lacking. The necessity of including polymers is also reflected in recent research focusing on plastics (polymers) in the environment (oceans) and the presence in the human blood stream
- Sidechain fluorinated polymers, fluoropolymers and perfluoropolyethers should not be exempted from registration.
- We see a remit in a notification scheme for polymers that are not in scope for registration. The notification should provide clear substance ID, basic physicochemical properties, information supporting the conclusion of a polymer’s status, basic information on market,

use and volumes. To increase the predictability the notification purpose should be clarified upfront.

- The polymer substance ID rules should be amended taking into account the complexity of polymer chemistry providing information on polymer, monomers (reacted and unreacted), oligomers, other reactants that are part of the polymer, impurities and additives. The approach used for nanoforms may be referred to for inspiration here, although specific parameters to report are likely different.
- As regards to additives we consider only additives that are added during polymer manufacture with a stabilizer functionality are part of the REACH substance definition. Since many other types of additives may be used in the supply chain in all kinds of polymer blends we note REACH registration will probably not increase the knowledge on this important feature of polymers and polymer materials and articles placed on the EU market. In a recent report by Ramboll (March 2022) it is shown that over 350 additives are used in PVC with many different functionalities and hazardous properties. Therefore, we ask the Commission to consider legal measures to increase the information base on additives in polymers. A notification scheme under REACH could be helpful to this end if it would include obligations for downstream formulators and users of polymer mixtures.
- Registration of polymers will be beneficial as it will generate important information on the safe production, use and disposal of polymers in the EU. On the long-term the registration will also be beneficial for companies as a transition to SSbD polymers and materials in a non-toxic environment will provide innovative advantages for EU-based companies compared to non-EU competitors. A broader challenge in this respect is to link registration information to (research) strategies for alternatives development.
- Polymers with higher molecular weight (>1000 Da) can leach smaller constituents (e.g. unreacted monomers, oligomers, additives, impurities) or can degrade to smaller sized molecules that need to be assessed. This warrants to determine the extractability of such polymers under forcing conditions, as well as to determine their degradation potential. Polymers that are considered inert and that do not degrade at all, or just fragment to smaller sized particles, might lead to microplastics which can be hazardous to the environment and human health.
- For further details we refer to comments provided at various occasions in support of the work of the CARACAL subgroup on polymers (CASG-polymers).

Information on environmental footprint

Headlines NL CA comments on this topic:

- In REACH 1.0 sustainability considerations are limited to some considerations in its recitals not translated into legal requirements. For the zero pollution, energy, circular economy and climate transitions the EU needs to make in the next decades it is crucial that also chemicals manufactured and imported, placed on the market and used in the EU are marketed with clarity about their environmental footprint. The CSS puts safe and sustainable chemicals, products, and production forward as its main goal. This needs to be addressed from a lifecycle perspective, thereby demanding that also the environmental footprint of the substances needs to be included. Both impacts on climate parameters as well as environment and safety should be considered. This could include information whether the inclusion of certain substances could limit the potential for safe recovery (incineration) or recycling of materials at the end-of-life.
- We support to add information about the environmental impact of chemicals to the registration requirements under REACH. This however changes the functioning of REACH which was to get information about hazards and risks of substances.
- It will be challenging to provide such information for the lifecycle, especially for basic chemicals that are used in a wide range of products.
- EU-wide harmonization of the format of the environmental footprint will be needed to avoid differences in in the presented information.
- We propose to introduce an assessment of information on the environmental footprint of chemical uses in restriction and authorization decisions. In addition to technical and economic feasibility, availability and safety considerations, information on the sustainability characteristics of alternatives to substances of very high concern that are targeted by regulatory management under REACH should in our view play a key role in the consideration of the scope of Restrictions proposals (including derogations) and in granting authorisations. As an example, circularity and recyclability may play a prominent role in some restriction cases. A framework for considering recycling derogations has been presented in a 2019 study by RIVM and Ramboll for the Commission (Clean material Recycling project): https://op.europa.eu/en/publication-detail/-/publication/26e22c04-5b62-11e9-9c52-01aa75ed71a1/language-en/format-PDF).
- The questions 8a and 8b need clarification. We have interpreted 8a and 8b as a choice in scoping. However, they can also be approached differently in terms of instruments. Of course, the purpose is to cover the whole life cycle as much as possible. But since this ambition will face similar problems as encountered for information requirements on use and exposure (next question), a possible strategy could be to focus on health and environmental burden (including remediation costs) when ending up in air, soil, water or sediment.
- The challenge behind every information requirement is to balance negative drivers (changing behavior for avoiding regulatory requirements) and positive drivers (engaging in finding the best solutions). The latter can be improved by linking registration information to (research) strategies for sustainable development, including other statutory instruments, notably the Sustainable Products Initiative.
- Information generated on the environmental footprint of a chemical and chemicals in product formulations should in our view be made available in the supply chain through the SDS enabling downstream users to make sustainable and safe choices.

- We prefer a whole life cycle approach for environmental foot printing of chemicals since manufacture, formulation, the use stages and disposal all contribute to an overall environmental footprint. However, we question whether the required information for foot printing will be available for registrants on top of (complex) supply chains. Therefore, we question the feasibility of this option especially for complex supply chains. A solution might be to introduce such increased information requirements in a step-wise manner (progressively including registrant groups for which the task is deemed to be(come) feasible).

Information requirements on use and exposure

Headlines NL CA comments on this topic:

- There are three major areas that are vital for a meaningful registration dossier and related regulatory activities regarding the topic of use and exposure information. 1) correct and detailed information on use; 2) the exposure assessments related to real-life uses (including product repair, dismantling and recycling) and 3) proper communication up and downstream on use and exposure and concrete measures. So in principle on all three areas improvements can be made by setting higher legal requirements that entail more detailed descriptions of use, fulfil set standards for exposure assessment which allow the downstream user (DU) to use this data for the workplace risk assessment under OSH and in some cases obligating DU's to provide feedback to registrants regarding their use or providing information to ECHA directly if that is preferred.
- The use information is mainly provided via the use descriptor system which lacks a certain level of granularity. The codes themselves do not provide sufficient detail and uses are not being described in a harmonized way, unless sector organisations have worked on it (e.g. AISE). Having a better and harmonized way of describing uses would really help registrants and completing the registration dossier and downstream users recognizing their use and possibly improve its description. Moreover it would aid authorities understand better what uses are involved.
- Information on tonnage levels and technical function should be provided per use in order to make this kind of information meaningful for authorities to make better informed decisions. That would also benefit industry parties.
- Exposure assessment criteria are described rather vaguely in REACH legal text and more elaborate in ECHA guidance documents, but still lack clear instructions as to what standards the exposure assessment should adhere to. There is much room for interpretation and freedom to decide on how to perform the exposure assessment. For various reasons, overall quality of exposure information has been low, models have been erroneously applied or estimates are lacking altogether. A quality improvement could be achieved by introducing fixed fields in IUCLID similar to use information, where elements of the exposure assessment need to be filled in. The benefit would also be that from that information the conditions of use (as a text box) are easily distilled and shared and can be used for the workplace risk assessment.
- Detailed information is generally lacking or missing regarding OC/RMM in all life cycle stages and perhaps most prominent in environmental assessments where information on environmental fate, substance behavior, transformation of substance is poorly described. More information is however available in other legal settings (environmental permits, OSH, GPSD) but are not being pulled into registration dossiers. More transparency is needed when compliance with other legislation is sufficient (for instance if a workplace is compliant with OSH).
- Having better information in registration dossiers will be transferred down the supply chain (including waste operators/handlers) enabling especially the SMEs to benefit from proper exposure scenarios to show they work safely as they themselves often do not have the knowledge or capacity to perform the exposure and risk assessment for their substance/mixture.
- Some but not all end-users in our view should be made responsible for providing use and exposure information. It would be sensible to distinguish large industrial end-users from

smaller users such as professional users, many of which are SMEs or even self-employed. For the latter categories we question the practical feasibility of such requirement. If the DU can demonstrate compliance with OSH, he does not have to provide information to ECHA. In other cases there should be an obligation to provide feedback to registrants (if that is through organized sector branch organisations or directly from the DU) and a legal way to approach DU for requesting information.

- For further details we refer to comments provided on CARACAL document CA/12/2022 on the Use and Exposure information.

Derived Minimal Effect Level for non-threshold substances

Headlines NL CA comments on this topic:

- A quantitative approach (DMEL) will help users and authorities to assess the actual risk of the use, and prioritise risks of non-threshold chemical uses in the workplace and for consumers. The use of DMEL should be made mandatory for assessment of non-threshold risks in the Chemical Safety Assessment such as carcinogenicity. The use of DMEL should be default in case a DNEL cannot be derived.
- On the other hand, when the risk level corresponding to the DMEL is too high, the DMEL may give a false sense of security (exposure under DMEL is acceptable under REACH so no further action necessary, while there still is a relatively high risk). Therefore a DMEL should always be accompanied with an explanation on how it should be interpreted.
- A traffic light model with acceptable and tolerable risk levels should be considered.
- Question Q9h: In the Netherlands we use the following acceptable risk limits: Acceptable cancer risk for workers under OSH is $1 \cdot 10^{-6}$ per year or $4 \cdot 10^{-5}$ after 40 years of exposure, and prohibitive risk level is $1 \cdot 10^{-4}$ per year or $4 \cdot 10^{-3}$ after 40 years of exposure. For the general population these risk levels are $1 \cdot 10^{-8}$ per year and $1 \cdot 10^{-6}$ per year. We propose these limits are also used at EU-level.
- Trying to reach consensus on European acceptable risk levels should in our view be pursued acknowledging the challenges ahead. Striving for unified acceptable risk levels is a high target providing many benefits such as a common approach towards safe use, legal clarity for companies and enforceability benefits. The challenges should be faced as it is not acceptable that in one European market of supply and use acceptable risk levels of non-threshold hazards are explained differently for workers as well as the general public.
- Acceptable risk level should not concern REACH only, but also other types of legislation (e.g. OSH). It may help to make a better connection between REACH and other legislation (one substance one assessment principle laid down in the Chemicals Strategy on Sustainability (CSS)).
- OSH and other legislation may still require minimization of exposure, even when there is a DMEL. The practical effects of a DMEL may in those cases be limited.
- Robust data sets are necessary to derive a dose response relationship and a DMEL. For many substances, data are currently insufficient and current data requirements will not lead to better data.
- The future use of NAMs rather than in vivo studies will further complicate the derivation of dose response relationships.
- For other effects than carcinogenicity there is even less experience on the derivation of dose response relationships and acceptable risk levels.

Introduction of a Mixture Assessment Factor

Headlines NL CA comments on this topic:

- We support the introduction of a mixture assessment factor in the REACH regulation based on existing scientific evidence pointing towards negative effects of combined exposure to chemicals both for human health and the environment.
- MAF should be a concept applicable to all registrants being conscious not to negatively affect the level playing field of registrants and downstream users of chemicals on the EU market.
- Introducing a MAF is also necessary because tox studies with mixtures are almost never performed (and at the best acute studies). There are many different situations possible where exposure to a mixture is possible. For instance a worker can be exposed to a mixture or on a workplace exposed to 3 different substances. In real life, the number of different mixtures and the exposure routes to different chemicals with comparable impacts is unlimited. It should be clear introducing a MAF should apply in all these situations.
- A MAF approach under REACH in our view should be a correct balance between sufficient scientific justification and generally applicable rather than specific for each substance, registrant or user as such an approach would be impossible to implement.
- Ideally a single MAF addressing both human health and the environment would suffice. However combined unintentional exposure to chemicals will differ between humans and the environment. Hence, separate MAFs might be needed to ensure safe exposure for both. However, currently data is lacking to motivate a specific MAF for human health so practically one single MAF for both human health and the environment would be the most logical option.
- MAF should not distinguish between substances with different effects/hazards, as it is not necessarily the most hazardous chemicals that contribute most to the potential mixture effect. Also differentiating between uses does not seem useful as the generic MAF is thought to address exposure in general to multiple chemicals, and specifically the exposures which are unknown/unforeseen/unavoidable. Only 'intermediate use in closed systems' could possibly be excluded from a MAF, but transported or on-site isolated intermediate REACH dossiers already have a status that limits the information requirements and risk assessment.
- Under OSH there exists a general obligation to take into account risks of a combination of substances to which the worker is exposed (article 4.4 98/24/EC). But this obligation is not very concrete. It might be an option to make clear to the employer that the MAF (provided by REACH for a certain substance) doesn't have to be used at the workplace if the employer can show that the risk assessment (workplace-) takes into account all possible combination effects of the substances by dermal and inhalatory route.
- For further details we refer to comments provided in the separate survey on the implementation of a MAF under REACH.

Question 10a: We support the introduction in REACH of a MAF to account for risks caused by combined exposure/combined toxic stress. The most prominent and well developed scientific knowledge base is in place for the freshwater aquatic compartment. For the CSA for risks for freshwater ecosystems several studies (published and ongoing) provide a basis for the establishment of a MAF that is sufficiently protective ensuring every single registrant for all uses in its supply chain accounts for presence of other xenobiotic aquatic pollutants in a scientifically robust and fair way. In our view it would be extremely burdensome and time consuming to perform a similar analyses for the sediment, soil and marine compartments of for secondary

poisoning and the outcome is not expected to be drastically different. The overall toxic pressures may differ and also the typical contaminants driving the toxic pressure. The principle of an overall increased toxic pressure to which a single chemical emitted to the environment by a single user contributes stays the same. Therefore, for the environment there is a remit in using the information base for a MAF for the risk assessment for the freshwater aquatic compartment as a model for all other parts of the environmental risk assessment. Hence, most likely a single MAF applicable to all environmental compartments would be a defendable solution. An option for a higher Tier refinement of MAF may be offered for specific emission situations.

With regards the MAF for the human health risk assessment we are in favor of a scientifically underpinned but relatively simple solution as the REACH requirements for risk assessment apply equally to all registrants and users. It will remain impossible to qualify and quantify exposure of individuals to a typical cocktail of chemicals. Workers are also general public outside working hours. And no human is the same in who we are, what we eat, breathe, drink and do in our lives. Therefore, humans will have greatly varying exposure patterns. For registrants it is therefore not possible to do a case by case risk assessment based on solid (measured or modelled) exposure data. Introduction of a MAF for human health risk assessment in REACH is a first Tier solution for a very complex risk assessment question. We think there could be a remit in separate MAFs for workers and the general public (both consumers and humans exposed via environment accounted for) as workers using specific chemicals in industrial or professional settings may have a more predictable exposure pattern to a small or rather specific group of chemicals.

Simplifying communication in the supply chain (options for improving SDS, including harmonised electronic formats)

Headlines NL CA comments on this topic:

- Different actors in the supply chain have different information needs. The information in the SDS (and eSDS) should help downstream users to fulfil their duties according to REACH and other legislation (e.g. workplace exposure or emissions). Receiving SDS with many exposure scenario's (which are perhaps not necessary for this SME) can be overwhelming for SME companies.
- Harmonized electronic formats would allow the selection of information aimed at the specific user category, and allow to make workplace instruction cards.
- The requirements for an exposure scenario should be based on the information that is necessary to fulfil the duties from REACH and other legislation (so it is necessary to coordinate with this other legislation).
- Information from exposure scenarios is often not sufficiently specific to be used in a workplace assessment. Refinement of the use descriptor system may help but might still not be sufficient. In addition, a better coordination between REACH and OSH legislation is needed.
- Exposure scenario information in the SDS for the mixture or of some components can be missing or can be unrecognizable or hard to interpret for downstream users. As a result it is not clear which downstream user obligations are triggered. Hence, better specified and more stringent requirements should be introduced for formulators responsible to make clearer and better understandable mixture SDS for the products they supply to customers..
- Upstream communication could further improve the quality and usability of exposure scenario information, however, it may not be feasible to make this a legal obligation.
- To ensure SDS are up to date we propose to introduce an obligation to update the SDS with a minimum frequency (e.g. 3 years).
- Digitalisation is an opportunity in a (complex) supply chain to disseminate the correct and up to date information about safe use in the supply chain. This could be further facilitated by introducing an EU SDS database. Such database would increase the accessibility and would also allow NEAs and member state authorities to review the quality if appropriate.

SECTION II EVALUATION

Headlines NL CA comments on this topic:

- We agree to make legal changes to strengthen the common expectation of dossiers 'compliant at all times'. Compliance of dossiers is important for both safety and environment and for the proper functioning of the internal market. The dossier update obligation laid down in article 22 should be an important instrument to keep dossiers up to date and compliant but has proven insufficient and poorly manageable and enforceable. This article should be amended to increase clarity and enforceability including setting timelines how often and how fast after new relevant information becomes available a dossier should be updated (or notify no changes were required after scrutiny of the dossier update needs). We agree to make a legal instrument to withdraw a registration number for companies that persistently do not meet the registration requirements.
- We recognise the importance of assessing the waivers to ensure that they are sufficiently justified and if not that further data need to be generated to substantiate that substances can be used safely. For this purpose it would useful to develop criteria to comply with to make a waiver justified and to investigate what this means for registrants and authorities with respect to responsibility and burden of proof.
- We agree to make legal changes to empower ECHA to consider a dossier to be incomplete not only when required information is missing but also when it shows manifest errors, as it would take too much effort to repair them during TCC.
- We agree to clarify the interpretation of article 50(3), to make clear what are consequences to the decision-making process as well as to the obligation of the registrant declaring cease of manufacture at specific points in time during CCH procedure. As mentioned above we recognise the importance for registrants to keep their dossiers updated and that it should have consequences if this is not the case. In that respect we agree that during CCH decision-making process registrants cannot modify the scope of the information requirements and can only comment on the assessment of ECHA of the information in the dossier at the time.
- We agree to replace CoRAP with a lightweight and dynamic registry. Experience has taught that there is hardly any disagreement among MSCAs on the proposed CoRAP updates. This would allow for more flexible approach by giving MSCAs the possibility to include a substance on CoRAP as soon as they are ready to start a SEv instead of making use of cycle or batch approaches. We are open for any improvement to make the MSC procedures more efficient, but has reservations to the proposal that TCC and TPE decisions are taken by ECHA alone. We recognise that several data requirements and testing strategies have been discussed at length and will no longer necessitate an amendment to the draft decision. Nevertheless, there are still remaining issues and new methodologies and data requirements to be expected (as proposed by the commission) for which involvement and utilization of expertise and experience from the MSCAs/MSC is valuable and important to ensure that the data requested as a result of the TCC and TPE are widely supported.
- We agree to make changes to the requirements for Testing Proposal Examination (TPE) to increase efficiency and the availability of data. We could support the proposal to limit the requirement for test proposals for vertebrate animal tests only (for all tonnage bands), although aspect of costs, test duration and availability of alternative test methods could be considered to restrict the obligation for submitting a test proposal to certain type of tests.
- As regards Q12b our view is that the >100 ton testing proposal system should be retained only for vertebrate animal tests as testing proposal evaluation by authorities in the Member

State Committee has proven to be a powerful tool to prevent unnecessary or ineffective animal testing. The experience with higher Tier toxicology study protocols is extensive and for proper use in further evaluation processes it is important studies are performed correctly at the appropriate dose levels and waiving options are assessed up-front prior to developing the study protocol.

- For further details we refer to comments provided on CARACAL document CA/08/2022 on the reform of evaluation processes.

SECTION III AUTHORISATION AND RESTRICTION

Headlines NL CA comments on this topic:

General comments on the Authorisation and Restriction reform

We support the need for reform of the current Authorisation and Restriction system in REACH. Main comments are included below. For further details we refer to comments provided on CARACAL document CA/03/2022 on the reform of authorization and restriction. Focus should be on the following topics:

Reform options

- The three options addressed for reform of the A&R system (1 - simplified authorisation; 2 – merged authorisation and restriction; 3 – deleting authorisation from title) all consist of building blocks. In our opinion the optimal building blocks have to be selected to form the optimal (effective and efficient) new authorisation and restriction system. This could also mean a hybrid form of the options (elements from options combined).
- The 2018 REACH evaluation already suggested to complement each authorisation proposal with an assessment to determine if a restriction would be needed as well. Combining these should reduce the administrative costs on the side of ECHA and the Member States.
- We do not support deleting Authorisation from the title of REACH, as authorisation is one of the few tools to get specific exposure and emission information on specific uses (and hence, which OCs and RMMs are necessary to adequately control risks). Furthermore, authorisation encourages the search for less harmful alternatives and provides the opportunity for a more sectorial approach in the search for alternatives.
- More information is needed on the Generic Approach to Risk management (GRA) and the Essential Use concept including how both concepts could be implemented, as these two building blocks are still in development, but have a prominent place in the A&R reform plans.
- Streamlining processes and decreasing the administrative burden are part of increasing effectiveness and efficiency, but should never have a negative impact on the main objectives of authorisation and restriction system to maintain a high level of protection for human health and the environment. Also, the net administrative burden should be decreased and not shifted to another place or point in time.

Candidate List

- The Candidate List should in our view be retained, and in addition, information requirements for substances on the Candidate List should be extended (at least to exposure information (human and environment) for specific uses). This would help in getting access to essential information for prioritization of SVHCs and for possible restrictions early in the process.
- Dynamic link CLP classification and CL: we see benefits in automatic Candidate Listing of substances included in CLP Annex VI. This dynamic link between CLP classification (CLP Annex VI) and automatic uptake of substances on the CL helps in making the system predictable for companies and in getting valuable information for authorities to help prioritize the most relevant groups of substances to further regulate.

- SMEs should not have reduced information requirements on uses and exposures, as these are mainly linked to the least adequately controllable uses.

Extended Generic Risk Management Approach (GRA) under article 68(2)

- We support the idea of extending the GRA under article 68(2), as this makes addressing relevant concerns for human health and environment more efficient for authorities, whilst making it more predictable for companies what to expect when developing/manufacturing/importing substances with hazard properties falling under the extended GRA.
- We support extending with priority the scope of GRA for CMR in consumer mixtures to include also the other SVHC hazard classes endocrine disruption and PBT/vPvB and as laid down in the CSS. We also support addition of PMT and vPvM as SVHC hazard classes in this respect although not included in the CSS. Addition of immunotoxicity, neurotoxicity, respiratory sensitisation and target organ toxicity can also be supported to be generally banned in consumer formulations. As regards consumer mixtures, the scope for derogations should be limited to exceptional cases or none at all. Limit values should follow CLP generic or specific concentration limits. In some cases the 0,1% level should be applied (PBT/vPvB substances). The scope of the GRA for mixtures can be extended to professional uses, however, the options for conditional derogations should be introduced, either using the essential use concept or using SEA.
- An extension of the GRA mandate to regulate all targeted SVHCs in articles for consumers and professionals as well should be properly investigated. A simple hazard-based approach is clearly too generic as articles vary tremendously in their composition, complexity, use and disposal. The “presence equals exposure equals risk” paradigm that is central to GRA does not hold for articles in general. Hence, some kind of exposure- or risk appreciation will be needed to be able to ban SVHCs that are of concern and exempt those that are used safely in articles and cannot be replaced. The latter in our view should not fall under automatic GRA-based restrictions as such measures would be disproportionate and disrupting.
- To ensure maximum efforts by authorities for swift phasing out relevant uses of the most hazardous SVHCs in line with the CSS we are in favour of legal changes providing a mandate under article 68(1) to Member State competent authorities to propose Restrictions following the Generic Risk Management Approach principle.
- Joint derogations under the extended GRA should be scrutinized by scientific (a) committee(s).
- We do see the advantage in a dynamic link between CLP Annex VI and the Candidate List, but for Annex XVII proportionality should be a part of this process as well.
- The mandate for restrictions under article 68(2) should remain with COM, but a work plan with (yearly) reporting obligations on restrictions under article 68(2) should be implemented with a legal basis. The GRA intentions should be made transparent.

Essential use concept

- The current system of risk and socio-economic assessment can result in a positive opinion to authorise substances, even if has very negative impacts on health or environment.

- To prevent such ''regrettable'' authorisationt, an additional layer of essential use would be welcome.
- Derogations or exemptions based on essential uses should be addressed. For this, more information is needed on the definitions within the essential use concept to be able to assess the impact.
- Clarity on the conceptual framing of the essential use concept is important both from the perspective of authorities and companies. Companies should be obliged to motivate/explain with solid argumentation why a use of an Annex XIV substance can be considered essential.
- Clarification is required on whether the concept is intended to be applied in specific cases only with the clear preference it should be part of the current risk assessment and SEA.
- Within the essential use concept, scientific scrutiny should be guaranteed, especially since 'essential use' is subject to change (e.g., availability of alternatives, moment in time, but also because it is a value-based principle).
- This could best be realised by maintaining the role of the RAC and SEAC and giving time limited indications of "essentiality".

Role of enforcement and scientific committees

- Forum should be involved in an early stage of opinion development of AfAs and restrictions (or derogations in a merged system) to advise on enforceability issues (mainly related to OCs and RMMs). The role of National Enforcement Authorities (NEAs) is still important, but by addressing it in Forum on an EU scale and incorporating this into its mandate, we can better safeguard uniformity. Forum should have the opportunity to judge the enforceability of authorizations (option 1), just as it has now for the enforceability of restrictions, or in case of option 2, the opportunity to judge the enforceability of a merged restriction/authorization. This also means that more time is needed to coordinate nationally with all relevant inspectorates. Furthermore, the costs and capacity for enforcing new restrictions/authorizations should be far more than up to now and automatically result in more NEA capacities in Member States.
- We oppose national authorisations. This is not in line with the goals of REACH of uniformity and in guaranteeing a level playing field in the EU.
- The role of RAC and SEAC should not be downsized to gain efficiency. They should be supported in getting the right information at the right time to increase efficiency instead. The role of these commissions in the scientific scrutiny in the whole authorisation and restriction system should not be underestimated. The insights gained dealing with A&R (like weighing alternatives) should be incorporated in the mandate of RAC and SEAC and necessary resources made available.

Other issues in A&R reform

- Level playing field EU/non-EU companies: consider restrictions for imported substances, mixtures and articles for which Annex XIV substances have been used in the production process.
- Clear and limited definition of the SR&D exemption to allow for a level playing field on an EU level. Especially the controlled conditions
- Transferring present responsibilities from REACH to OSH is not a good idea in our opinion, as authorization and restriction under REACH gives more concrete form ((compared to OSH) to measures to control the risks for workers.

- Manufacture for export: as risk for workers and environment is still relevant in manufacturing for export, we would like to see the exemption for manufacturing for export cancelled.
- Requesting information on the waste phase of substances in Annex XIV and XVII should be made easier to complement the assessment for which the burden of proof lies with authorities. The waste stage is addressed in the CSR, but in practice information is very limited.
- Need for a quick fix mechanism for existing Annex XVII Restriction entries to repair issues emerging from enforcement such as unforeseen misinterpretations or unwanted loopholes offered by specific wordings in the entry.

SECTION IV ENFORCEMENT

Headlines NL CA comments on this topic:

It is currently unclear what the role of the European Audit Capacity (EAC) will be and how the EAC will be implemented. It is therefore difficult to estimate the effect of the EAC on the capacity and skills of the enforcement of Member States. We propose to include these points of interest in the Impact Assessment. Another requirement for good and efficient enforcement is clear regulation and well-coordinated with other legislation on chemicals (e.g. OSH). Points of improvement in this area have already been identified in the REACH-OSH survey (survey on OSH-REACH enforcement interactions (europa.eu)). The opinion of the Netherlands is that enforcement of REACH is very important to guarantee a high level of compliance and to protect man and environment against adverse risks of chemicals.

Additional comments related to questions:

Q14c:In case the Member States have raised their level of enforcement and regulations are made more enforceable, European audits may be beneficial and lead to suggestions to improve further the level of enforcement and lead to comparison of the level of enforcement between Member States through benchmarks, best practices, uniform level of enforcement at the borders of the EU, level playing field, etc. In that case minimum criteria for enforcement may be formulated and audited too. Guidance from the Commission could help to improve the level of enforcement based on the results of an audit. Forum will discuss the results of the COM inquiry about the EAC under Member States in the course of 2022 and this will/should be of influence too for the way an EAC will be implemented.

Q14e: Not only the REACH, CLP, POP and PIC regulations are of importance, but also the OSH regulations. It should be investigated whether an EAC may also audit the OSH-regulation, especially where there is an interface between REACH, CLP and OSH (for example in the case of restricted substances).

Q14j: Giving customs more possibilities to enhance their information position (for example by having access to REACH-IT data) may raise the effectiveness of cooperation between customs and inspectorates and so the level of enforcement, but this is highly dependent whether there will capacity and knowledge building at customs. More manual measuring equipment for customs or NEAs will be of help in specific cases, but in the light of so many REACH regulated chemicals and mixtures this will be of limited importance.

Q14k: Forum is an example of a project group for REACH issues already in place. Harmonised risk profiles and harmonized operations may be very useful but normally in the specific cases temporarily valuable, so they have to be updated regularly.

Q14l: More portable measuring equipment for customs or NEAs will be of help in specific cases, but in the light of so many REACH regulated chemicals and mixtures this will be of limited importance.

FINAL (ADDITIONAL) FEEDBACK ON THE REACH REGULATION REVIEW:

- We see a need for a review of REACH article 33 and its alignment with the SCIP notifications under the Waste Framework Directive. Article 33 has the intention to provide information on the presence of SVHC's in articles in the supply chain and to consumers. However, it is not clear this article fulfills its purpose, to help consumers making informed decisions. It should therefore be assessed how the functioning of this article can be improved. Moreover, adequate surveillance by authorities on compliance with article 33 is an infeasible task. Article 33 paragraph 1 could be limited to supply chains for which the need and feasibility of transfer of information on SVHC presence is clear. These supply chains are likely to be those for which the upcoming Eco design Regulation will set requirements regarding SVHC presence in product passports. Therefore, coupling article 33(1) to the related provisions under the Eco design Regulation seems to us an appropriate solution. Since the Waste Framework Directive (WFD) refers to this article, the consequences of possible amendments to the REACH text for the WFD should be taken into account.
- In addition to the environmental footprint, it is essential to create a clear link between the chemicals policy and the pollution reduction policies as well as the policies promoting the transition towards a toxic-free environment, and, as in achieving the zero pollution objective, a circular economy. As to the link between chemicals and pollution, if a substance is identified as a substance of very high concern, in the Netherlands this automatically results in additional legal obligations for large companies and SMEs using the substance to minimise emissions of this substance to the environment. The introduction of such obligation at EU level would help to reduce emissions of harmful substances as one of the important elements towards the zero pollution ambition. The transition to a circular economy provides good perspectives for reducing the harm done by hazardous chemicals to human health and the environment. A circular economy implies that producers must arrange the safe recycling of the products they place on the market. This would provide a strong incentive for avoiding the use hazardous chemicals, because they make future recycling more complicated and expensive. On the other hand, in case of essential use of hazardous substances, circular economic business models ensure that the respective products remain traceable, and remain under the control of production chain actors, which gives the possibility to prevent release of the hazardous substances.
- We note that the registration exemption for substances recovered in the EU (article 2(7)(d)) is potentially creating problems as the requirements for recovery operators are minimal and as a consequence limited information may be available for some (very) hazardous substances that may be recovered in high volumes whereas only low volume registrations may exist and can be simply referred to in the presence of a safety datasheet. This could be regarded as an unwanted 'escape' route to bring large volumes on the market without any risk assessment which would normally be required above 10 tonnes per year.
- We see a need to update some definitions in REACH article 3:
    - The definition of nano materials should be moved from the Annex to article 3;
    - A definition for polymers is lacking, currently only available in ECHA guidance. We see a need to clarify whether a polymer falls under the "substance" definition or whether additional criteria are applicable;
    - The definitions of on-site and transported isolated intermediates need to be updated to clarify "strictly controlled" conditions are an integral part of their definition rather than part of the additional criterium for an articles 17 and 18 limited registration obligation. We think it is crucial to add this as the authorisation

exemption for intermediates refers to intermediates as defined in article 3 and not to intermediates that are strictly controlled. As a consequence, currently intermediate uses of Annex XIV SVHCs that are not used under strictly controlled conditions may continue to be used after the Sunset Date without any additional control on exposure and risk. This to us is not acceptable;

- The definition of 'controlled conditions' for SR&D exemptions should be made more specific to decrease the grey area that enforcement experiences currently (e.g., in-situ use of substances in routine quality control --> is SR&D exemption valid? What if tests are performed outside a laboratory ? How controlled are the conditions in such a case?).

- We have concerns about the readiness of REACH for chemical and material innovations and specifically as regards the information requirements The case of nanoforms (and subsequently more "advanced (nano)materials") highlights that physical properties become more important in identifying and characterizing substances, which leads to a more diffuse difference between chemicals, mixtures and materials/articles. The engineering of complex materials, often at the nanoscale, leads to so-called 'advanced materials' that can distribute relatively easy within organisms and the environment (similar to nanoforms) and end up in unexpected places. This clearly has consequences for sustainability and life-cycle assessments. Will the update of REACH be flexible enough to be ready to handle such 'new' materials, or do we run the risk of going through a similar lengthy trajectory to update REACH similar to that for nanoforms each and every time?
- Recent studies (e.g. by Forum) have shown REACH (and CLP) obligations are not complied with in e commerce. Hence, we care legal measures are taken in REACH or through other EU legislation to ensure chemicals in formulations and professional and consumer products (articles) can be used safely also in case these are bought online. We favor strengthening the focus on enforcement and border control (import from outside EU) enabling national enforcement authorities to act upon identified incompliances.
- Currently SVHC identification is applied on a per substance basis not allowing for a group approach whereas such group approaches do exist in REACH restrictions and in harmonized classifications under the CLP Regulation. To prevent regrettable substitution and speed up the regulatory management of SVHCs we consider there is a need to investigate legal options to use grouping in the process of SVHC identification. E.g. all Cr^{6+} compounds including the non-registered ones which still may be marketed and used as alternatives.
- The role of Only Representatives should be clarified, e.g. with regards to updating the SDS
- There should be an option for authorisation holders to make minor changes to the CSR, provided that the exposure and emissions don't increase and the new RMMs are in line with the hierarchy of control under the CAD
- There is a need for an urgent clarification about the REACH and EU OSH legislation interface. Specific clarifications are needed with respect to authorization, restrictions and the setting of occupational limit values. This theme has already been included in the 2018 REACH review.
- Under the current authorisation system only the Annex XIV properties are assessed in applications for authorisation whereas we would expect the applicant to be responsible for assessing any human health and environmental risk associated with the used applied for. Under the authorization permit it would not be acceptable to prevent workers from reproductive effects whilst serious effects on target organs would not be prevented (e.g kidney effects). The European Court decided a narrow approach focusing only on the Annex

XIV property should be applied. We consider an update of REACH should tackle this pressing issue.

- As regards enforcement we note that additional requirements that are considered for low tonnage substances, endocrine disrupters, polymers, environmental footprint, MAF and evaluation will inevitably lead to more work for national enforcement bodies due to more compliance checks of registrations, more specific measures (for example restrictions), possible increase in administrative burden and enforcement costs. Failures to respond or will need to have a proper follow-up at national level. This factor should be accounted for in the impact assessment.