REACH FORWARD
priorities for effective regulation

Discussion paper policy conference Brussels 1 June 2016 – final version

Content

1 INTRODUCTION

1.1 Purpose of this document

The Netherlands will host a policy conference on the 1st of June 2016 with the aim to build a common understanding among Member States of the desired further development of REACH. The results will be presented to the Commission as input for the 2017 REACH review. The implementation of the actions announced in the 7th Environment Action Programme will be at the heart of the meeting, complemented with opportunities to enhance competitiveness, innovation and green growth. This document serves to highlight possible discussion topics for the conference. The draft of this paper was compiled making use of 7th EAP and the reports of two earlier conferences (see section 1.3). This draft was circulated among the participants and the comments received were integrated in this final version.

1.2 Background: the 7th Environment Action Programme

The European institutions and Member States adopted the 7th Environment Action Programme in 2013, which includes actions in the field of chemicals with the aim of creating a non-toxic environment. These actions must be seen in the context of the goal of the World Summit on Sustainable Development in 2002, reaffirmed at Rio+20, and accepted also as the goal of the Strategic Approach to International Chemicals Management, namely to ensure 'the minimisation of significant adverse effects' of chemicals on human health and the environment by 2020.
These actions include the following:

- set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products;
- develop harmonised hazard-based criteria for the identification of endocrine disruptors and take horizontal measures to minimize exposure to such substances;
- ensure that, by 2020, all relevant substances of very high concern, including substances with endocrine-disrupting properties, are placed on the REACH candidate list;
- further develop and implement approaches to address combination effects of chemicals;
- ensure the safety and sustainable management of nanomaterials and materials with similar properties.

To date, none of these actions has sufficiently been implemented in EU policy and legislation, and the upcoming REACH review can be an important instrument for such implementation. The review is also an opportunity to identify possibilities to enhance innovation and green growth, and to strengthen connections and synergies with other policy areas and legislative frameworks, including the Circular Economy strategy. Administrative burdens, especially for small and medium-sized enterprises, could be reduced where this helps to achieve the objectives in a more effective and efficient way.

1.3 Building upon earlier meetings

The conference will also build upon the results of earlier meetings where many Member States were represented, in particular the REACH-up conference 'REACH and beyond' (20 October 2015)[1] and the ECHA-workshop 'REACH(ing) the WSSD 2020 Goals' (27 and 28 January 2016).[2]
The first meeting demonstrated considerable engagement from all participants in support of REACH while identifying a number of areas for improvement of implementation. Solutions were proposed to accelerate the work being done to make registration dossiers compliant, improve enforcement, support efforts to increase substitution, deal with the presence of problematic substances in articles, and increase legal certainty for companies.

[1] This event brought together high level representatives from EU Member States, the European Parliament, the European Commission, industry associations and consumer and environmental organisations. A detailed report can be found at http://conferencemanager.events/REACHandBeyond.
[2] The report of the workshop, organized by ECHA and attended by Member States, the European Commission and stakeholder organizations, can be found here: http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/workshop-on-reaching-the-wssd-2020-goals.

The second meeting confirmed the general support to the current initiatives on identifying and regulating those problematic substances that matter most, and many suggestions were made for improved implementation of the REACH and CLP processes. The conference on the first of June will focus on implications for the legal framework of REACH as a next step.

1.4 Structure of this document

The sections below will address:

- agreed actions by the European Union from the 7th Environment Action Programme;
- current initiatives, successes and shortcomings in implementation of REACH and suggestions for improvement, based on the two earlier conferences;
- additional issues raised by the prospective participants of the policy conference*;*
- summary of possible discussion topics.

2 ACTIONS IN THE 7TH ENVIRONMENT ACTION PROGRAMME

2.1 Introduction to the Union strategy for a non-toxic environment

The 7th Environment Action Programme specifies four elements of the 2018 Union strategy for a non-toxic environment (point 54): '*...(iv) continuing to implement REACH in order to ensure a high level of protection for human health and the environment as well as the free circulation of chemicals within the internal market while enhancing competitiveness and innovation, while being mindful of the specific needs of SMEs. Developing by 2018 a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on horizontal measures to be undertaken by 2015 to ensure: (1) the safety of manufactured nanomaterials and materials with similar properties; (2) the minimisation of exposure to endocrine disruptors; (3) appropriate regulatory approaches to address combination effects of chemicals and (4) the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances.'*

2.2 Comprehensive approach to minimise exposure, including from products

One of the elements of the EAP-7 is (point 50) that: '*the Union will also set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products.'* Exposure of vulnerable groups is an important aspect here (point 71): '*… In order to develop a comprehensive approach to minimising exposure to hazardous substances, in particular for vulnerable groups, including children and pregnant women, a chemical exposure and toxicity knowledge base will be established'.* The 7th EAP also mentions the importance of targeted human biomonitoring to obtain information about actual exposure.

Proposals for the comprehensive approach, with special emphasis on chemicals in products, although envisaged for 2015, still need to be put forward, and could be part of the REACH review. Minimising exposures recognises the limitations of carrying out risk assessments for all substances and uses. As set out in the 7th EAP, REACH offers a baseline of protection. REACH requires that all registrants of substances over 10 tonne per year prepare a chemical safety assessment and identify, implement and recommend to downstream users appropriate risk management measures to ensure adequate control of risks. As this does not function as expected, the REACH review could analyse whether specific requirements are necessary, similarly to those - for example - in the Directive on sustainable use of pesticides (with provisions about training, awareness raising, equipment etc.).[3] Another issue is that information about exposure in registration dossiers and (extended) Safety Data Sheets is often missing or incomplete. The REACH review could analyse whether information requirements regarding exposure are clear enough and how implementation can be improved.

2.3 Measures to minimise exposure to endocrine disruptors

The 7th EAP announces that the European Commission will develop harmonised hazard-based criteria for the identification of endocrine disruptors and take horizontal measures to minimise exposure to such substances. The 7th EAP mentions the following (points 50 and 54): '*Research indicates that some chemicals have endocrine-disrupting properties that may cause a number of adverse effects on health and the environment, including with regard to the development of children, potentially even at very low doses, and that such effects warrant consideration of precautionary action. … The Union will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation. In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors. … In order to safeguard the Union's citizens from environment-related pressures and risks to health and well-being, the 7th EAP shall ensure that by 2020: …(d) the … safety concerns related to endocrine disruptors are*

[3] Directive 2009/128/EC.

effectively addressed in all relevant Union legislation. … This requires, in particular: … (iv)(2) the minimisation of exposure to endocrine disruptors ….'

Minimising exposures to endocrine disruptors in chemical products covered by REACH and fulfilling the WHO/IPCS definition is achievable within the current REACH framework, if all potential endocrine disruptors are identified and efficiently controlled by industry and businesses and, as appropriate, are subject to authorisation or to restrictions. A major obstacle is however the Commission's delay in adopting scientific criteria within the context of the biocides and pesticides regulations respectively. Recently the European Court of Justice ruled that the Commission breached EU law by failing to publish the criteria for endocrine disruption due in 2013 in the context of the biocides regulation. The Commission plans to present criteria in the summer of 2016. The REACH text does not require criteria to put such substances on the candidate list and make them subject to authorisation, but horizontal criteria would make it possible to start identifying such substances systematically compared to the burdensome case-by-case identification today.
The introduction of testing guideline OECD443 at least provides for better information about reproductive toxicity that may be associated with endocrine disruption. However, modifications in the information and testing requirements for registration may be needed to obtain the necessary information such as including the results of other current OECD initiatives which may provide for information on some other endpoints relevant to endocrine disruption.

2.4 All SVHCs on the REACH candidate list

The 7th EAP (point 50) stresses that: '*... efforts need to be stepped up to ensure that, by 2020, all relevant substances of very high concern, including substances with endocrine-disrupting properties, are placed on the REACH candidate list.'* Recent years have shown progress towards this political objective in the context of the SVHC Roadmap. However, achieving the goal is at risk because Member States working on Risk Management Options Analysis (RMOA) encounter difficulties with obtaining information about hazards and exposure. This is one of the reasons why the number of concluded RMOAs is lower than expected (less than 50 per year) and the pool of potential SVHCs is becoming more and more limited. The REACH review could analyse the reasons for this decline in the number of SVHC dossiers and possible consequences for the conduction of RMOAs.

2.5 Combination effects

The 7th EAP mentions the following about combination effects, also referred to as mixture effects or cocktail effects: (points 50 and 54): '*In order to safeguard the Union's citizens from environment-related pressures and risks to health and well-being, the 7th EAP shall ensure that by 2020 … (d) the combination effects of chemicals … are effectively addressed in all relevant Union legislation… This requires, in particular: …(iv)(3) appropriate regulatory approaches to address combination effects of chemicals ….'*
As noted by the Commission in 2012[4], there currently is no mechanism for a systematic, comprehensive and integrated assessment of combination effects taking into account different routes of exposure. This is a particular concern for chemicals with common modes of action affecting human health, that may act jointly to produce combination effects that are larger than the effects of each of the mixture components applied singly. Although methodologies for the assessment of mixtures are available, extensive knowledge and data gaps limit their application. The Commission announced in 2012 to establish an ad hoc working group of relevant services and authorities to strengthen co-ordination across the different pieces of legislation and to promote the integrated assessment of priority mixtures. In addition, development of technical guidance to this purpose was announced, by June 2014. Other actions related to improved monitoring and research. A report on the assessment of chemical mixtures was due by the end of June 2015, reviewing the progress and experience associated with the actions.

[4] European Commission (2012). The combination effects of chemicals. COM(2012) 252 final.

The REACH review could analyse, given the fact that the above steps still await implementation, whether modifications of - for instance - information or testing requirements are necessary. Also options to limit the exposures to a proportion of the DNELs and PNECs could be explored. Obviously, actions to minimise chemical exposures (sections 2.1 and 2.2) will contribute to reducing concern for exposures to (unintentional) mixtures.

2.6 Safe use of nanomaterials

The 7th EAP proclaims that the Union will ensure the safety and sustainable management of nanomaterials and materials with similar properties, as part of the 2018 strategy for a non-toxic environment and horizontal measures in 2015 (see section 2.1). The Second Regulatory Review on Nanomaterials (2012)[5] reiterated concerns about certain nanomaterials, and also underlines their economic importance. It announced the definition of nanomaterials to be integrated in EU legislation where appropriate, and envisaged modifications in some of the REACH Annexes, since lack of (clarity on the) information requirements for nanomaterials is one of the barriers for their adequate control. The 7th EAP further notes (points 50 and 71): '*…There are also concerns about the potential impacts on the environment and human health of materials that contain particles of a size that falls outside the scope of the nanomaterials definition but which may have similar properties to nanomaterials. Such concerns should be examined further in the planned Commission review of the definition of nanomaterials in 2014 in the light of experience and of scientific and technological developments. … A Union-wide database should be considered, in order to increase the transparency and regulatory oversight of nanomaterials.'*

In the absence of these steps in the last years, national registration systems have evolved in some countries, confronting industry with a lack of EU-harmonisation. The Commission expects to finalise an Impact Assessment of regulatory options in 2016. Similarly to the situation with endocrine disruptors, clarifications in terms of definition, annexes and a system to increase transparency in the market will only take effect after companies have updated the dossiers accordingly, and EU authorities have assessed and used the updated information. Legal amendments will probably come too late for the 2018 deadline.

2.7 Related policy areas: Circular Economy

In addition to the actions in the area of chemicals, other EAP objectives and actions are relevant as well. An important policy domain is the circular economy, where the EAP states (point 40) *'Turning waste into a resource …. requires the full implementation of Union waste legislation throughout the Union, based on strict application of the waste hierarchy and covering different types of waste….. ensuring high quality recycling where the use of recycled material does not lead to overall adverse environmental or human health impacts, and developing markets for secondary raw materials are also necessary to achieve resource efficiency objectives.'* The interface with the Circular Economy will be discussed in section 3.3.

[5] European Commission (2012), Second Regulatory Review on Nanomaterials. COM(2012) 572 final.

3 DISCUSSION POINTS BASED ON EARLIER CONFERENCES

The importance of the actions in the 7th EAP was underlined by participants of the REACH-up conference. Furthermore, other pertinent issues that were not explicitly addressed in the 7th EAP have been discussed at the two previous conferences (REACH-up and WSSD). These issues, which are in many ways related to implementation of the actions in the 7th EAP, are reiterated here.

3.1 Improving data availability and use

Obtaining information about chemicals

REACH has generated and made publicly available information about more than 14,000 substances, and this amount will increase substantially with the next registration deadline in 2018. However, it has been acknowledged that information in registration dossiers is not always adequate or complete. Deficiencies in registration dossiers are diverse and may concern hazard information on certain endpoints, information about exposure, substance identity issues and substantiation of the use of non-test methods and waiving of information.

ECHA and the Commission already take several actions to improve compliance, and the REACH-up conference and the WSSD workshop yielded many suggestions to reinforce these efforts. The WSSD workshop highlighted that a mix of 'control' measures and 'soft' measures would be needed, and that it is important to look for (business) incentives that could encourage good quality information. In the short term, such measures are of a practical nature and do not require adaptation of REACH.

At a policy level, it will be important to evaluate progress after 2018, and to some extent already in the REACH review. It is important to remember that 2018 was not meant as an endpoint, but the end of a transitional period to address the lack of information about many chemicals on the market. Important aspects for the post-2018 stage are how to address remaining deficiencies, the role of ECHA after 2018 and the need for continued compliance checks, the question whether information requirements have proven sufficient given the experiences, and progress in the use of alternative test methods to avoid unnecessary animal testing. In a wider perspective, it is important to demonstrate the benefits of REACH and to see how these benefits could be enlarged, while reducing unnecessary costs.

Where Compliance Checks can be used to solve deficiencies in hazard information, the instrument of *substance evaluation* can be used to obtain information in addition to the regular REACH requirements about substances of potential concern, and to get monitoring data such as emission and exposure at the registrants' own sites. However, there are limits to possibilities to obtain additional information in substance evaluations. One of the reasons is that there are - legitimate - legal boundaries to information that can be asked from registrants, combined with the cautious approach of ECHA's Board of Appeal in the interpretation of those boundaries. Another issue is that registrants struggle to get exposure information from their downstream users and/or to determine whether assumptions on use conditions and exposure are realistic. The REACH review could analyse how to obtain extra information effectively. However, limitations will remain, particularly to obtain exposure information.

Dealing with limited data in regulatory risk management

Decision making under REACH is often hampered by deficiencies in the registration dossiers. This essentially moves back the burden of proof towards the public authorities and challenges them to find the balance between a precautionary approach on the one hand and refraining from measures that could be disproportionate on the other. This becomes apparent in different REACH processes.

At the stage of the voluntary *Risk Management Options Analysis* (RMOA), Member States often encounter difficulties with obtaining information about hazards as well as exposure, and try to

compensate for this with additional information sources and consultations with industry. Such additional work is useful in the short term, but it is important to remember that RMOAs were meant to establish the best possible measure on the basis of existing registration information.

Another bottleneck in REACH where the burden of proof is at stake is the substantial work load of preparing *restrictions*. The challenging information demands from the committees RAC and SEAC[6], which are not based on the REACH requirements for such dossiers, are often mentioned in this context. Because of these demands, Member States need to find alternative sources of information to demonstrate the risks and the need for European-wide measures, whereas REACH was actually designed to ensure action was taken when in doubt about industries demonstration of safety. Practical steps and working procedures to streamline the restriction process and increase clarity on the information demands have been implemented to a large extent. These steps are helpful, but do not fundamentally change the situation, since information demands have not decreased. Given that REACH was designed because risk assessments under the previous legislation were seen to be too burdensome, a significant change is needed to bring back the original intentions of the restrictions procedure towards targeted restrictions introduced in an improved and accelerated procedure. At the WSSD workshop, there was quite some support for the idea that regulatory processes, and in particular restrictions, could move on even without complete information. Participants suggested that restriction proposals could be based on less information and likewise for the opinions of the committees SEAC and RAC. Public consultations could be used to obtain additional information, especially so if the type of information was better specified. Another suggestion is that the committees could not only consider the strength of proof of the risk and the socio-economic benefit of a restriction, but also the strength of the evidence for the absence of risks.

The *application for authorisations* is a further area where limited data puts pressure on governments. RAC and SEAC sometimes have to deal with deficient and incomplete authorisation applications. Even though ECHA is very active in making the requirements for authorisations understandable, some applicants do not provide the necessary information. As it is the legal understanding of ECHA that when an applicant has paid the fee, an application conforms to the requirements, the consequence is that the committees come under significant pressure of either making an opinion based on insufficient information or investigating themselves actively missing information. Both of these cases are highly counter-productive and also in conflict with the principles of REACH. Furthermore, by issuing an opinion based on insufficient information, ECHA and its committees put the burden on the Commission and the Member States to take a decision on the application based on insufficient data.

Considering the above, it would be useful for the REACH review to analyse the degree to which problems with limited data, particularly in the context of restrictions, application for authorisation and substance evaluations, can and need to be solved with additional clarifications and/or implementing legislation. Such clarifications may concern the information that companies need to deliver (application for authorisation, substance evaluation) and/or the information that is sufficient to impose a restriction or to refuse an authorisation. This could be done in view of the REACH principles and the fact that the lack of exposure data was one of major shortcomings of the previous legislation which REACH was specifically designed to address.

3.2 Improving substitution and innovation

A central objective of REACH is the progressive substitution of substances of very high concern by suitable safer substances or technologies, thus contributing to innovation and a green economy. In practice, the Candidate List is a strong market signal that these substances should be replaced or avoided where possible. For many (uses of) substances on the authorisation list (Annex XIV) no

[6] RAC: Risk Assessment Committee. SEAC: Socio Economic Analysis Committee.

applications have been submitted, which seems to indicate that substitution takes place. However, a profound analysis of the substitution effects under REACH is still missing, and some Member States and the Commission are working on the necessary assessments. REACH and CLP also promote substitution through restrictions and harmonised/self-classification. Notwithstanding the - seemingly - positive experiences, several factors prevent REACH from working towards substitution in an optimal way.

Improvement of authorisation in view of substitution

Authorisation is often seen as the most important means to promote the substitution of SVHCs. Authorisation places the burden of proof with the companies that wish to continue to use SVHCs. Therefore, an assessment of alternatives is part of the application. At the REACH-up conference it was noted that the analysis of alternatives is often limited to drop-in substances directly available to the applicant. Applicants, especially those that manufacture or import the substance, usually have no incentive or knowledge to fully describe the benefits of alternatives, particularly when these involve changes in technologies, processes or business models outside his current practice or scope of use. For instance, a producer of styrene insulation material would not propose rock wool as an alternative, while such alternatives may be relevant for society at large. The public consultation could in theory serve as a showroom for alternative substances or technologies in a wider definition, but in practice such information is seldom submitted. Possible reasons are that companies are reluctant to interfere, use descriptions are not specific enough for the identification of alternatives, and/or public consultations may be too short for third parties. As RAC and SEAC have to base their opinions on the application and the input from the public consultation, it is of highest importance that all relevant information is available.

This leads to three questions:

- How to ensure that all relevant information on alternatives is brought into the process, possibly using additional sources of information next to public consultations?
- How to promote the use of alternatives and innovations even further (with authorisation or other instruments), considering the inherent limitations of a process based on information from applicants themselves?
- How to ensure decisions are made in accordance with intentions of the legislation in regard to substitution, respecting the burden of proof, if such information is not provided by the applicant or third parties?

The REACH review could assess whether procedural changes in the authorisation regime would be needed and appropriate.

Non-regulatory instruments to promote substitution and innovation

Non-regulatory instruments also contribute to substitution and innovation, and several ideas came up at the REACH-up conference. Member States and the European Commission can set up targeted R&D programmes in cooperation between governments, academia and companies. Another idea is a specific European research and training institute, following the example of the Toxics Use Reduction Institute (TURI) in the State of Massachusetts. In general, it was recognized that ECHA, as holder of the registration database, could play an important role in promoting substitution. Economic incentives for substitutes, such as taxes and green investments may be needed as well.

Some participants at the REACH-up conference highlighted the idea of a substitution platform, where ECHA could make information about alternatives accessible. Others pointed out that much information is already available, such as the SubsPort database and the OECD toolbox, and that awareness on these tools and databases should be increased. This is also important to avoid regrettable substitution. A suggestion at the WSSD workshop was for ECHA or Member State helpdesks to actively help downstream users to find alternatives for SVHCs.

Information about substances is obviously not enough for companies to make substitution work. Providers of alternatives should be matched with those asking for them. One of the challenges is to improve communication between chemicals producers and downstream-users.

There may be room for voluntary agreements (Green Deals) with industries to phase out hazardous substances, building on industry initiatives towards a greener chemical portfolio (such as the schemes of some producers of brominated flame retardants). Such Green Deals may under certain conditions (such as ambitious key actors that are able to influence other actors in supply chains) work faster than the authorisation process.

3.3 SVHCs in articles

Imported articles

As noted earlier, the 7th EAP (p. 54) aims at *'the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances'*. The issue is much wider than REACH and links to regulations for toys, food contact materials, cosmetics, medicinal devices, construction products etc. Hazardous chemicals in articles may bring about risks when they are unintentionally released by migration. There are also indirect exposure routes working in the long term that are not always sufficiently taken into account. Indications are, for example, that house dust is an important exposure route for plasticizers and some flame retardants.

When REACH is the adequate framework to regulate substances in articles, restriction is often the preferable instrument, since authorisation only applies to uses within the EU and does not cover imports of articles, and so puts home produce at a competitive disadvantage against imports. This disadvantage is at least partly mitigated by the provision in REACH (article 69.2) that after the sunset date has passed, ECHA considers whether the use in articles poses a risk that is not adequately controlled, and if so, proposals for restriction will be prepared. It would be beneficial for the competitive position of EU industries when restrictions for imported articles could be developed more easily; an additional argument in favour of reducing the burden to compile restriction dossiers.

A suggestion at the REACH-up conference was to have a simplified procedure for this specific type of restriction as drafted by ECHA. It is worthwhile to analyse the options for such simplification, taking into account the need for sufficient information showing there are risks that are not adequately controlled. More generally, the issue is how to address substances in (imported) articles, taking into account possible risks, competiveness for EU industries, global and WTO aspects, and the relation of REACH with more specific product legislation.

Articles 33 and 7 of REACH are intended to generate information on SVHCs in articles on the European market and will be discussed in section 3.4.

SVHCs and the Circular Economy

Recently the issue arose how to deal with SVHCs in articles on the market and at the end of their life cycle. Where the objectives of phasing out SVHCs and stimulating recycling are synergistic in the long term as both goals contribute to a green economy, in the short term they can be in conflict. The use and placing on the market of recycled materials containing SVHCs listed in Annex XIV requires authorisation, which can be a discouragement for recycling companies and their customers. It is also problematic that the recycling companies seldom have detailed information on the substances in the materials recycled. At a practical level, authorities could investigate possibilities to help recycling companies in fulfilling their obligations. One of the difficulties for this sector is that there are still diverging interpretations about the conditions under which recyclers or users of recycled materials

containing SVHCs fall under obligations of REACH. A more strategic question is how to deal with the substances already on the market that will become waste at some point in time.

As announced in the Circular Economy Action Plan, the Commission highlights that *'The promotion of non-toxic material cycles and better tracking of chemicals of concern in products will facilitate recycling and improve the uptake of secondary raw materials. The interaction of legislations on waste, products and chemicals must be assessed in the context of a circular economy in order to decide the right course of action at EU level to address the presence of substances of concern, limit unnecessary burden for recyclers and facilitate the traceability and risk management of chemicals in the recycling process. The Commission will therefore develop its analysis and propose options for action to overcome unnecessary barriers while preserving the high level of protection of human health and the environment.'* [7]

Some participants at the REACH-up conference were of the view that safety standards should not be lowered for recycled material compared to the original virgin material, and that recycled materials must be of a high quality to make them an attractive alternative. The need to find the right balance between the two policy goals was recognised. It can be noted that the risks depend on the specific waste stream and its options for recycling, and that risks and environmental effects of recycling, incineration or landfill should be taken into account in a balanced way. Further innovation and development of technology, for instance techniques to extract SVHCs from recycling streams, will be crucial in this regard. Useful approaches for solving these issues could be taken from the POP-Regulation, in particular Annex I (restriction of POP) and Annex VI (recycling of materials with POP), provided that there is a balanced and preferably integrated process of setting limit values, taking the risks into account. In the long run, phasing out substances of very high concern will prevent the presence of these substances in waste and recycled materials.

3.4 Communication in supply chains

Efficient communication about safe use of chemicals

The system of compiling and applying Safety Data Sheets often receives less attention than registration and regulatory issues, since it already existed before REACH. The only addition of REACH is the inclusion of exposure scenarios. However, compiling, distributing and applying safety data sheets amounts to 50% of total REACH compliance costs for SMEs, because of their large number.[8] Furthermore, the SDS could play an important role in view of the approach envisaged in the 7th EAP to minimise exposure.

Indications are that REACH information has started to improve risk management in supply chains. This includes workers understanding of the chemical portfolio and the risk management needs , changes in safety instructions, application of additional personal protective equipment, or reformulation of mixtures due to new hazard information becoming available.[9]
Still, several bottlenecks in the system of SDSs remain. Studies show that risk management measures are often described in too general terms, measures are not always consistent with the substance classification, probable exposure routes are missing and DNELs are often lacking.[10] Other studies highlight unclear descriptions of prescribed measures, as well as inconsistencies between the SDS and the exposure scenario, and lack of standardisation.
End users often find SDSs too technical and voluminous, and claim to lack time and expertise to use the information in the workplace. Here different information needs are apparent: companies in the

[7] European Commission (2015), Closing the loop – an EU action plan for the circular economy. COM (2015) 614 final. P. 12.
[8] Ministerie van Infrastructuur en Milieu (2015); Aanpak kosten REACH voor het MKB. Eindrapport (with executive summary in English).
[9] ECHA (2016), Draft five year report on REACH and CLP. Draft version.
[10] RIVM (2014), Quality and usefulness of (extended) Safety Data Sheets. Research carried out by TNO Triskelion BV.

formulating sectors need technical information about the substances they use to make the SDSs for their mixtures, but end users 'only' need specific and simple working instructions. For companies that sell many mixtures (such as paints), the distribution of SDSs can be quite a burden as well. These firms have to keep records which customers received which SDS and whether these are up to date.

The Exchange Network on Exposure Scenarios (ENES) brings together authorities, registrants, downstream users and other stakeholders to develop templates that enable clear and simplified information flows down the supply chain. ENES also developed a better readable uniform electronic format for exposure scenarios. For communication from downstream users to registrants, the instrument of use maps has been developed as a means to inform registrants on common uses and conditions of use. This enables registrants to base their chemical safety assessments and exposure scenarios on realistic conditions of use and practices of risk management. Use maps are developed by sector associations of downstream users using a standardised format.
Other promising developments are SDSCom XML and ESCom XML, electronic standards for compiling, sending and reading (e)SDSs. The use of standardised phrases in (e)SDSs makes it possible to directly process the information in different IT systems, instead of manual processing. ENES does not develop systems for electronic distribution of the SDSs themselves, and this is left to (mostly national) initiatives of sector organisations; only few of such systems have evolved until now.

The WSSD workshop agreed that the ENES-tools should be applied as widely as possible, and that trade associations play a major role here. The above solutions can be implemented within the existing legal framework of REACH. That said, it is worth considering whether legal requirements on the format of exposure scenarios will further improve clear communication in the supply chain. This is a case where enforceable requirements could actually reduce burdens for the supply chain by the mechanism of standardisation and routinisation.

Relevant to the REACH review is also that the usability of Safety Data Sheets would benefit from more alignment of REACH and Occupational Safety and Health legislation. Recent Commission initiatives aimed to improve alignment of both frameworks from the viewpoint of consistency of regulatory measures, and to determine which framework is better suited to regulate a substance in a specific situation of work related concern. One of the initiatives is the request to RAC and SCOEL[11] to look at possible harmonisation in the setting of safe limit values. Alignment of REACH and OSH is also important for SMEs that need to apply the REACH information in (e)SDSs, and may encounter discrepancies between provisions based on REACH and OSH, for instance regarding the risk management measures. This particular angle of the REACH/OSH interface (usability of the SDS for SMEs) has received less attention thus far.

Communication about substances in articles

Articles 33 covers communication in supply chains about substances in articles. Article 33.1 requires a supplier of an article containing an SVHC to inform the recipient of the article – with information available to him – about the safe use of the article; as a minimum, this is the name of the substance. This obligation exists when the concentration of the substance exceeds 0,1% by weight. The information should also be given, freely and within 45 days, at a consumers' request (article 33.2). The producer or importer of such articles must also notify ECHA in case of quantities of the substance of 1 tonne per year or more (article 7.2).

Current compliance with these requirements is low, because of low awareness of the obligations, difficulties in the implementation, and (until recently) different interpretations on the 0,1% threshold. For downstream users, it is difficult to find out whether their product contains SVHCs or not. Their suppliers often do not (or only late) respond to requests for information, and their

[11] SCOEL: Scientific Committee on Occupational Exposure Limits.

statements that a product is ‘REACH compliant’ are not always trustworthy. To test the products themselves is often expensive for downstream users.
Suggestions at the REACH-up conference to improve the situation were to strengthen enforcement, testing of SVHCs in articles by authorities, and improved guidance and training for companies. Other ideas pointed at the potential for voluntary initiatives, such as tools for communication in the supply chain, voluntary labels, and the use of other voluntary lists of hazardous substances. Variations to these ideas are the establishment of an industry database on articles containing candidate list substances, or to request the reporting to a database hosted by ECHA. In the current situation, ECHA is already working on improvements on its website by making information about substances in articles more easily available, and further improvements may be possible.

The REACH review provides an opportunity to evaluate article 33, from the perspectives of effectiveness, efficiency and overlap with other (product) legislation. When evaluating this provision, it is important to look back to the objectives of this article and to see to what extent these objectives are met and also whether there might be more effective or more efficient ways to meet the objectives. The review should also consider feasibility and proportionality. Finally, the review could take into account the need highlighted by the Circular Economy Action Plan to facilitate the traceability of chemicals of concern in products.

4. OTHER ISSUES OF CONCERN

Several participants to this policy conference have indicated during the preparation that other issues of concern regarding the functioning of REACH remain. These are addressed in this section.

4.1 Application of the precautionary principle

Under the previous legislation a number of decisions were made under the auspices of the precautionary principle. These decisions were submitted from the European Chemicals Bureau to the Competent Authorities for a policy decision. The decisions balanced the time needed to generate information needed in order to take a decision of 'normal' certainty against the consequences on human health and the environment of that delay in decision making should the data confirm the concern. Under REACH such approaches have not been applied yet, despite REACH being legally underpinned by the precautionary principle. This potential for taking similar approaches should be assessed and procedures should be developed to enable the application of the precautionary principle to evaluations, restrictions and authorizations.

4.2 REACH and Green Chemistry

REACH responds to the risks posed by chemicals which are on the market or which are in the due process of being marketed. On a long term perspective, a more pro-active approach should be considered which takes the development of new chemicals, the resources which are used and the waste which will be generated into a wider perspective. In the last years, green chemistry has become an integral part of chemical research and planning. Sustainability principles have been proposed (e.g. those of Anastas and Warner) which assess different aspects of a chemical all through its life-cycle-stages: product planning and prevention of hazards, process optimization, use of renewable resources and recyclability of products and wastes. On a long-term perspective REACH could be adapted such as to integrate different aspects of sustainable production. Green chemistry is an approach which embraces the concept of substitution, so substitution policy may be one possible element where green chemistry can well be integrated. Since research and development are normally the place where sustainability is considered by industry, R&D could be another element for integrating green chemistry into REACH.

4.3 Consistency REACH-CLP in CMR information requirements

In view of standard information requirements in REACH and the experience of the last years with evaluations under REACH, it is becoming clear that REACH will hardly provide information that will result in CMR classification. With the current requirements for all tonnage bands, harmonized classification for carcinogenicity is for example not possible, because CLP indicates that information on two species is needed for this conclusion, where no study is required by REACH. In principle this information could be retrieved through the substance evaluation process. Experience of the last years shows that substance evaluation is a lengthy and costly process and it could take up to 15 years to classify the unknown new substances as CMR ,taking into account all necessary steps (placing on the CoRAP, substance evaluation, discussion in MSC, possible appeal cases, carrying out the study, evaluation by MS, drafting CLH dossier by MS, discussion in RAC, comitology). In view of the important role the CMR classification plays in REACH it is important to start the discussion how to solve this problem, whether adaptation of REACH and/or CLP is required or whether RAC should be requested to start employing the ‘weight-of-evidence’ principles provided for in CLP, article 9(3) in their assessment of proposals for harmonized classification, taking into account testing costs and animal welfare.

5 SUMMARY OF POSSIBLE DISCUSSION TOPICS

Based on the above sections, the following issues can be mentioned for consideration in the REACH review (or earlier as appropriate), and for discussion at the 1 June conference. Since there is no time to discuss all the items at the conference, the Dutch presidency suggests to discuss only the first four clusters of issues. Separate initiatives could then be taken to discuss the other items.

(to be discussed at the conference)

Political commitments in the 7th Environment Action Programme

The 7th EAP mentions the following actions in the area of chemicals:

- set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products;
- develop harmonised hazard-based criteria for the identification of endocrine disruptors and take horizontal measures to minimize exposure to such substances;
- ensure that, by 2020, all relevant substances of very high concern, including substances with endocrine-disrupting properties, are placed on the REACH candidate list;
- further develop and implement approaches to address combination effects of chemicals;
- ensure the safety and sustainable management of nanomaterials and materials with similar properties.

These commitments should be the point of departure for the REACH review and analysis of possible modifications of REACH. Discussion could focus on the question how these action points can be implemented in REACH and what would thus be the points of attention for the REACH review.

Improving data availability and use

There are information deficiencies in the registration dossiers, and this sometimes prevents governments from taking regulatory action or to assess whether this is necessary. There are two aspects to this item: obtaining information (data availability) and decision-making in case of incomplete information (use of data).

- The first aspects relates to registration, which is the main process to obtain information. After 2018, and to some degree also in the REACH review, progress with the registration process can be evaluated, given the intentions with REACH to acquire sufficient information about chemicals on the market both as regards their hazards, but also use and exposure data. Important aspects are how to address remaining deficiencies, the role of ECHA after 2018 and the need for continued compliance checks, the question whether information requirements have proven sufficient given the experiences, and progress in the use of alternative test methods to avoid unnecessary animal testing. For the 1 June conference, discussion could focus on the question: do participants at this stage see possible implications for the REACH legal framework, based on the experiences with *registration*? Since modifications of data requirements will come too late for the 2018 deadline, the answer to this question relates to the ambitions for dossier quality and the registration process in the longer term.
  Another question is whether any improvements are needed regarding *substance evaluations*, being a supplementary mechanism to obtain information for substances of concern.
- The question relating to the second aspect is: can problems with limited data, particularly in the context of *restrictions* and *application for authorisation*, be solved with additional clarifications and/or implementing legislation? Such clarifications may concern the information that companies need to deliver (application for authorisation) and/or the information that is sufficient to impose a restriction or to refuse an authorisation. This could be done in view of the REACH principles (burden of proof with industry, precautionary principle) and the fact that the lack of exposure data was one of major shortcomings of the previous legislation which REACH was specifically designed to address.

Improving substitution and innovation

- How can incentives in REACH be strengthened towards substitution and innovation, in a wider sense than drop-in chemicals that are relatively easy available? Could improvements in the authorisation process (ensure that all alternatives are brought into the process, possibly using additional sources of information) be helpful? How to ensure decisions are made in accordance with intentions of the legislation, respecting the burden of proof, if information about alternatives is not provided by the applicant or third parties?
- Is there a need for extra incentives from non-regulatory instruments (technology pull) to promote substitution and innovation, and which instruments could be used?

Communication in supply chains about substances and mixtures

- Would adaptations in REACH be needed or helpful to secure wider application of the ENES-tools (such as a standardised format for exposure scenarios), to reduce burdens for companies and to improve communication about chemicals and mixtures in supply chains?
- Would alignment of REACH and Occupational Safety and Health be beneficial for the usability of Safety Data Sheets for SMEs that need to apply the REACH information in (e)SDSs?

(next issues not to be discussed as separate agenda items at the conference)

SVHC in (imported) articles

- How to address substances in imported articles, taking into account possible risks, competiveness for EU industries, global and WTO aspects, and the relation of REACH with more specific product legislation? Would a simplified procedure for restrictions based on article 69.2 covering imported articles be needed or helpful?
- What is the right balance between different policy objectives regarding the legacy of SVHCs in recycling streams?
- To what extent do we meet the objectives of article 33 about substances in articles? Could there be more effective or more efficient ways to meet the objectives, considering also feasibility, proportionality and the need to improve the traceability of chemicals of concern in products?

Other issues

- Is there a need to reinforce the implementation of the precautionary principle to evaluation, restrictions and authorization?
- Further discussion on whether on a long-term perspective key elements of Green Chemistry could be integrated into the framework of REACH by adequate adaptations
- Could consistency between REACH and CLP be improved in terms of the information requirements for CMRs and carcinogens in particular, given the experience that REACH will hardly provide information that will result in CMR classification? Are there other REACH-CLP consistency issues that warrant attention?

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