

Results of the International Workshop:
Consequences of REACH
for other legal and administrative environmental instruments
Evaluating the Environmental Effectiveness of REACH (REACH:EEE)
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¹ With contributions by Dirk Bunke, Stefanie Merenyi, Antonia Reihlen and Martin Führ.

This document summarizes the overall results of the REACH:EEE² Workshop “Consequences of REACH for other legal and administrative environmental instruments” mainly by presenting the results of the five working groups. It is the intention to represent the general opinions and expectations of all participants concerning desirable or necessary consequences of REACH for other legal and administrative environmental instruments. However, not every opinion/statement is checked against the legislative framework in the Member States.

² Evaluating the Environmental Effectiveness of REACH. The workshop was organized jointly by Federal Environment Agency (UBA), Germany and The Ministry of Housing, Spatial Planning and the Environment (VROM), The Netherlands.

1

Aim of the Workshop

The aim of the workshop was to exchange information between the EU Member States on the practical consequences of REACH on other legal and administrative environmental instruments (e.g. environmental emission and quality standards, monitoring, licenses and permits),³ used to reduce the risks from chemical substances. Presentations, discussions and the collection of best practise examples as well as typical obstacles concentrated on the following topics:

- Consequences of REACH on the local situation in the Member States with respect to environmental licensing.
- Emission related strategic issues
- Immission-based strategic issues for monitoring
- Precaution and strategic points for an integrated monitoring of substances of very high concern (SVHC).
- Consequences of REACH for the Water Framework Directive (WFD)

The presentations given in the plenum and the working group were distributed – together with additional texts, such as articles published in scientific journals – among the participants on a CD-ROM.

2

Consequences with respect to environmental licensing in the Member States

As REACH is directly applicable in every Member State there will be no transposition into national regulatory systems. However, enforcement needs to be implemented in all Member States and is likely to be linked to other national environmental legislation. The impact of REACH on the implementation of the national environmental legislation may vary considerably, because every Member State has its own characteristics in the specific legal system and the procedures of environmental licensing. As REACH sets up a system which generates information and leads to the implementation of risk reduction measures by companies producing and using chemicals it is wise to get insight in the impact of REACH on the system of environmental licensing. Since every Member State has its own legal system, setting up a blueprint on how to deal with potential consequences is not possible. However, there are a lot of similarities due to the basic European legislation that call for mutual exchange of best practice and the establishment of a common learning process.

2.1

Agreement among participants

REACH generates lot of useful information/data that local authorities in the Member States are interested in using for their environmental licensing. However, generated data should be evaluated and reduced in its amount and complexity in order to be useful for local authorities. Yet, it is not quite clear, if and how the Competent Authorities for REACH will supply other authorities, especially local authorities, with information/data. One possibility could be to organize the support as a part of helpdesk activities.

Participants are consistently of the opinion that local authorities are not obliged to control whether activities described in the application of an environmental license are in line with restrictions, authorisations or risk reduction measures prescribed under REACH according to Art. 125 REACH. Nevertheless, licensing authorities should be obliged to control if authorisation or restrictions' conditions are followed. Depending on the national system other authorities

³ See the invitation to the workshop, documented under: <http://www.REACH-helpdesk.info/211.0.html>.

could be given the possibility to introduce conditions linked to REACH. Two possible types – already practiced or planned in some Member States – were described:

- The issuing of an environmental permit could need clearance of another authority, e.g. the competent authority for REACH.
- A modular environmental permit giving the competent authority for REACH the right to incorporate specific REACH topics in the environmental permit.

2.2

Unclear issues

No clear position was reached upon the topic, whether local authorities should refuse an environmental license if a company is not able to *provide enough information* on the substance it is using and emitting; this could be the case due to the eleven years transitional period for phase-in substance registration under REACH. There were mainly two opinions:

- “Pragmatic” opinion: an obligation for companies to provide a wide range of information should only be applied when a substance is registered/authorized under REACH or already regulated under sectoral law. This should be true unless existing information is intentionally hidden.
- “Strict” opinion: the applicant for an environmental permit should always be able to provide sufficient information on substances he is using and emitting, as industry is responsible to have enough information on the substance in question and has to implement Risk Management Measures. This is especially necessary when a substance is suspected to be hazardous.

Another controversial issue concerned substances which are placed on the candidate list for authorisation under REACH. It is questionable if local authorities should incorporate *extra severe demands* in environmental licenses for such candidate substance.

Basically two options were discussed:

- Information that a substance is SVHC should lead to more severe demands in the environmental license. But concrete measures should depend on the local environmental situation and be decided on a case-by-case basis. Moreover it should be possible to impose severe demands not only for substances on the candidate list but also for other substances of similar concern. The reasoning and legal basis to impose demands for substances of similar concern was not discussed.
- Once the substance is included in Annex XIV and an authorization is granted: As the authorisation for SVHC under REACH is quite demanding no additional benefit of more pressure on industry within an environmental license was recognized. However, the opinion was that from a legislative point of view local authorities have the right to impose severe demands.

The question whether local authorities can demand more far-reaching obligations than REACH for environmental licensing in a given specific situation was not discussed.

2.3

Approaches and first action

First of all, the “duties” arising from REACH for local authorities should be defined in order to make the data generated under REACH useful for the issuing of environmental licenses. Furthermore Guidance Documents could be elaborated – the Netherlands have already started work – and training for local authorities was identified as necessary. Helpdesks and internet-based support including links to other environmental legislation might play an important role but need to be developed. Finally, participants were of the opinion that information provided

for down-stream users (Safety Data Sheet and Exposure Scenarios) should be obligatory available for local authorities in Member States.

2.4

Cooperation needs

REACH creates no further legal cooperation needs for environmental authorities except the general duty to cooperate with the ECHA. Information management is one major challenge that needs to be developed by national authorities.

Data on the registration of a substance are to a certain extent publicly available in the ECHA database (Art. 119 (1) REACH). This will be the case for the testing results and the derived no-effect level (DNEL) or predicted no-effect concentration (PNEC). Concerning these types of data the challenge will be to provide an interpretation, e.g. for the local authorities in order to produce an added value of the data.

Other types of data, e.g. the whole background of the test and the margin of safety included in the PNEC, may not be available for the public. In a situation where authorities are taking decisions based on these data, e.g. issuing permits, it might be important to have access to the background information in order to justify a decision. Therefore the regional and local authorities need a reasonable way to get access to the data.

The national competent authorities for REACH can help to make the information generated under REACH accessible and useable for other national authorities responsible for environmental licensing can be compared with the role of formulators for the risk communication process up and down the supply chain.

3

Emission related issues for monitoring

REACH requires the development of exposure scenarios for certain classified substances. These are to describe the conditions under which a substance can be used safely, including the necessary risk management measures. Exposure scenarios cover all lifecycle stages and have to be communicated to and implemented by all users of the substances. How the emission related information generated in the chemical safety assessment under REACH interlinks with existing environmental and installation related information and practices was evaluated as following:

3.1

Agreement among participants

The participants agreed that the main benefit of REACH for the competent and enforcement authorities in the Member States is the increase of information on uses of substances. This could facilitate better, more targeted strategies for enforcement of environmental and installation-related legislation as well as permitting of installations. A better overall picture of emission sources of certain substances is expected.

Furthermore, information could be integrated in the BREF development.

There was also an agreement that the 'raw data' (original study results, e.g. the toxicity tests) in the data bases needs to be processed in order to be useful (cf. chapter 2.4).

3.2

Unclear issues

It is still unclear which information on substance uses will actually be available for inspections. Participants were of the opinion that managing the access and rights to the Agency data base are in the responsibility of the national competent authorities.

The status of exposure scenarios and how they could be enforced was not discussed in detail, partly due to the uncertainty how specific the information used in the exposure scenarios will be in practice.

3.3

Approaches and first action

Attendees agreed that the implementation of measures in the exposure scenario is seen as a requirement under REACH that should be enforced by the local authorities. Two approaches were introduced:

- Phase-in of the installations which are checked → starting with the bigger installations (which also require permits) and widening the scope of enforcement activities to smaller installations over time and
- Developing inspection approaches that focus on the methods and instruments by which companies integrate exposure scenarios in their EHS management system

3.4

Cooperation needs

In most EU Member States the enforcement of occupational, environmental, consumer and product legislation as well as for transport falls within the responsibility of different authorities. Therefore the authorities within the Member States need to cooperate in order to ensure the enforcement of REACH and in order to benefit from the information generated under REACH. In order to harmonise enforcement activities, experience exchange at EU level was seen as crucial.

4

Immission-based strategic issues for monitoring

At present, several types of limit values exist for the risk characterisation of substances: REACH requires the derivation of specific “reference values” such as PNECs and DNELs for the risk characterisation – indicating whether the intended uses of the substance is safe or not. Until November 2010 these values will be available at least for all high production volume chemicals classified as dangerous or characterized as PBT or vPvB substances.

The Workshop delivered results concerning a common understanding on:

- specific “reference values” generated by REACH for the description of the safe use of chemicals;
- the relation between these values and existing environmental reference values;
- possibilities for enterprises and authorities to use this information for the monitoring of risk reduction measurements;

Further positions were drawn up on:

- the implementation of an immission-based monitoring;
- the cooperation between authorities on the European level and
- the cooperation between authorities and enterprises.

4.1

Agreement among participants

There are specific links between PNECS (which exist already for some “existing substances”⁴, but will in future be generated for a much higher number of substances due to REACH) and environmental quality standards developed for IPPC/WFD. Exceeding the PNEC limits may automatically indicate the presence of “significant” pollution (in accordance with IPPC Directive (Article 13(2) second indent) and may indicate that point source pollution reduction measures are to be realized pursuant to Article 10(3) of the WFD.

4.2

Unclear issues and open questions

A scaling for the extent of exceedances should be developed. It was not completely clear in which aspects differences exist between the methodology of PNEC development and derivation of environmental quality standards, e.g. in the field of air quality.

The following problems have been identified:

- REACH is based on a single substance approach. There are no parameters regarding the total emission of a set of substances (sectoral environmental law uses sum parameters in addition to single-substance parameters)
- Many CMR-substances can not be addressed by PNEC values if there are no thresholds for the chronic action of these substances
- Different PNECs in different dossiers require an efficient quality management and quality control
- Legal status of the “PNECs”: Does a situation where the immission values exceed the PNEC ask for immediate action by local authorities or should PNECs be interpreted as “soft links” to sectoral environmental legislation? Questions regarding the relationship between PNECS and existing limit values in different sectoral environmental laws are still unanswered. Primarily, in the framework of REACH PNECs will be the reference points for the registrant as well as for downstream users in order to decide whether the use of a substance is safe. For the sectoral environmental law they can become important substance-related information indicating whether there is a need for additional risk reduction measures.

The Commission and/or Member States should provide answers to the following questions:

- How can an influence of the testing strategy on the result of the PNEC derivation be restricted?
- Does the low number of organisms involved in the tests ensure a sufficient degree of safety of the derived PNEC values?
- What sort of standard do we need in the context of licenses?
 - o local scale
 - o regional scale
- What is monitored?
 - o surveillance (species + substances)
 - o operational risk based: point sources
 - o investigative monitoring: one situation
 - o compliance monitoring: industry + spot checks

⁴ The legislation on Existing Substances (Regulations 793/93 and 1488/94) is valid until June 1, 2008 according to Art. 141 (2) REACH.

4.3

Approaches and first action

Policy in the Netherlands uses a PNEC equivalent for the definition of a first threshold (exceeding triggers action of national government) and a second threshold (PEC/PNEC \leq 0,01 equals a negligible risk level).

The German state North-Rhine-Westphalia considers the use of PNEC values in the framework of new licenses in order to check whether risk management measures are sufficient.

4.4

Cooperation needs

Authorities of the EU Member States need to cooperate in order to be able to use the new information given by REACH for an immission-based monitoring strategy. The monitoring can be part of the environmental policy of the enterprises as well as part of the regional/national regulatory systems. Discussion of experiences with existing systems of quality standards for an immission-based monitoring have been an important issue of the working group on immission related issues and should be continued.

5

Precaution and strategic points for an integrated monitoring of Substances of very high concern (SVHC)

Substances of very high concern may be included in Annex XIV of REACH and thereby become subject to the complete new authorisation system.

The system starts from the identification of a substance as a SVHC based on the screening criteria of Annex XIII and continues with listing on the candidate list up to the final inclusion in Annex XIV. Annex XV includes the dossiers for authorisation and restriction.

Against the background of a proposal for a draft version for a new "Annex XVa REACH" the group discussed details concerning the content and process of the authorisation procedure of SVHCs. The following results address especially the distribution of duties and responsibilities between the competent authorities and the applicant in the authorisation process plus the necessary information to be included in the application (estimation of emissions from point and diffuse sources, options to measure and minimize emissions and exposure, duties and coverage related to the monitoring of SVHCs):

5.1

Agreement among participants

The authorisation of a certain use of a SVHC concludes an iterative legislative process. Decision making starts with the establishment of a candidate list up to the setting up of an Annex XIV followed inter alia with considerations whether an authorisation is the most appropriate instrument to control risks for a special SVHC. Nevertheless, the need for structured monitoring efforts regarding SVHCs was acknowledged, because of the specific risks of SVHC.

First of all a clear definition of monitoring and distribution of responsibilities was seen as important:

- "Compliance-Monitoring" in order to control the compliance of the applicants behaviour with authorisation conditions (also regarding Art. 60 (10) REACH); this would cover emission-control and eventually regional ambient monitoring (depending on substance and authorised use). Compliance-Monitoring was seen in the responsibility of the holder of an authorisation (self-responsibility of industry).
- "Ambient monitoring" being in the responsibility of the competent national authority

Finally participants were of the opinion that if a holder of an authorisation is under duty to monitor a SVHC this does not mean an obligation of national competent authorities to establish an ambient monitoring for that specific SVHC.

5.2

Unclear issues and open questions

Several participants raised general concerns on obstacles for the implementation and effectiveness of an ambient monitoring:

It is unclear who will finance the costs for ambient monitoring, e.g. will the authorisation fee include the costs? However, the application of the “polluter-pays principle” was favoured.

Different level of the enforcement of Monitoring in the Member States could lead to competitive disadvantages for companies in different Member States.

It is expected that there are only limited laboratory capacities in the Member States.

Regarding new substances the availability of enough information, e.g. on appropriate risk management measures or on admissible emission levels, was seen as a restriction for monitoring.

There were different opinions on the consequences of ineffective Risk Management Measures (RMM), i.e. if they do not comply with the conditions set out in the authorization. In that case attendees proposed either to revoke the authorisation according to Art. 61 REACH or check, if restriction of the substance may be the better alternative. Further proposals were submitted that either the Commission or the applicant has to propose effective RMM.

5.3

Approaches and first action

The content of the presented draft proposal for an additional Annex XVa to REACH describing the elements of a monitoring concept for SVHC (i.e. monitoring requirements for emissions and immissions, unforeseen effects of SVHC and their degradation products) were considered to be a possible focus by the majority of participants. However, rather a minimum standard of monitoring duties on the level of the RIPs or Technical Guidance Documents than a new Annex XVa REACH seemed to be the appropriate form.

In order to set up ambient monitoring for SVHC in the Member States it should be checked whether the monitoring requirements could be established in the context of EPER and IPPC.

5.4

Cooperation needs

A strong need for better exchange of information between national competent authorities (horizontal) and MS and Commission/ECHA (vertical) concerning especially BAT (best available technologies) and Risk Management Measures was identified.

6

Consequences of REACH for the Water Framework Directive (WFD)

Under the scope of the Water Framework Directive 2000/60/EC (WFD) Member States are asked to set up a system for regulation and protection of the aquatic environment in Europe. Primary goals of the WFD are to achieve the desired quality of the water resources to ensure that there is enough clean water for different uses. In order to reach those goals Member States need to establish risk reduction measures for hazardous substances, specifically for priority substances. They shall particularly focus on the control of emission of contaminants from industries, households, and agriculture to the aquatic environment. The WFD prescribes that “good

ecological quality” and/or “good chemical quality” should be reached in the water bodies no later than 2015.

6.1

Agreement among participants

It was the overall result that REACH provides massive opportunities for the enforcement of the WFD. Authorities dealing with obligations of the WFD can benefit from the risk management measures recommended under REACH, although the information cannot be used directly. For example competent authorities for WFD can use information generated under REACH for point source permits or they can benefit from CSR (Chemical Safety Report) information indicating the appropriate type of technology to protect water bodies and the possible level of emission to be achievable. However, those opportunities may mainly be true for large authorities as smaller authorities are less aware of the consequences of REACH. Therefore competent authorities for REACH in each Member State should have a specific helpdesk in order to support all kind of authorities with screened data and offering limited access to that data.

If a substance in question is subject to authorization this should lead to restricted water permits, e.g. limited period and only for a specific (authorized) use.

It was consensus that competent authorities granting permits under the WFD take into account the risk assessment and control measures recommended under REACH. Environmental quality standards (EQS) are the objective according to the WFD and strict legislation applies to that. However, members of the group argued that the competent authorities can go beyond the EQS and ask for stricter conditions in the WFD-permit, not only if new information on uses or new PNECs justifies this but also because of the single substance-approach of REACH in contrast to the holistic approach of the WFD.

Another point of discussion was if permits granted to installations carrying out activities with SVHC should be reviewed after authorization of a substance-use under REACH and with view to new information generated. Here the attendees identified a conflict between “phasing-out”-policy and the authorization of SVHC calling for a harmonization of policies. Furthermore SVHC listed in Annex XIV should also be listed in Annex X of the WFD and the listing in Annex XIV REACH should be seen as “new data” that triggers the review of Annex X of the WFD.

6.2

Unclear issues and open questions

Authorities granting permits under the WFD shall respect the risk assessment performed and control measures recommended under REACH. Attendees questioned who will have to take the burden of proof: the companies or the competent authority (e.g. the local authority responsible for protecting local environment?).

No conclusion was reached upon the exact timing for the review of a water permit including the use of a SVHC, which was granted based on limited data that has been authorized meanwhile. Should the review start when the substance:

- is listed on the candidate list,
- listed in Annex XIV or
- after sunset date?

In that context it was discussed what happens if a company having an authorization for a SVHC under REACH refuses to comply with stricter regulations set out in the water permit.⁵

⁵ Cf. Art. 2 (4) REACH which states that REACH “shall apply without prejudice to: (a) Community workplace and environmental legislation”.

Different opinions existed on the question whether permits granted on basis of the WFD should be taken into account for the evaluation of an authorization under REACH. Opinions arguing that this should not be the case stressed

- that permits under the WFD must not be overruled by the authorization under REACH,
- that the authorization rules would only set minimum standards and finally
- that the down-stream user needs clarity about the legal situation.

One member of the group was in favour of taking into account the water permits in the evaluation of an authorization. He argued that this would not automatically mean that the Commission would call for an authorization of the substance in question. Moreover Art.60 (10) REACH calls for a continuous improvement for minimising emissions. It was regarded sensible that the competent authorities under the WFD authorities can give input in authorization process.

6.3

Approaches and first action

Local authorities need guidance regarding the European and national objectives in the Water Framework Directive and their relationship towards the PNECs of the REACH system.

6.4

Cooperation needs

The communication between local and central authorities is necessary, especially regarding the cooperation between the competent authorities for REACH and those responsible for the implementation of the Water Framework Directive. Both must exchange their information needs⁶ and analyse points of cooperation to reach more efficiency in their work.

⁶ See also chapter 2.4, page 5.