PEECL II – Practical Experience from Enforcement of Chemical Legislation

Comments to the Draft of the REACH Regulation

From 15th to 16th September 2003 the second PEECL meeting of experts from MSs, Norway and ACs experienced in enforcement of chemicals legislation took place in Graz/Austria. The working group was set up under the umbrella of **CLEEN**, which forms the **C**hemical **L**egislation **E**uropean **E**nforcement **N**etwork. Within this network all Member States excluding Luxembourg and including Norway participate voluntarily, covering the whole field of chemical substances legislation. CLEEN is basically a forum for information exchange. It sets - in collaboration with the Member States - priorities for enforcement projects in the EU.

The purpose of the meeting was to give advice how the draft of the forthcoming REACH Regulation could be improved in the light of better enforceability and to give recommendations to the Council and to the European Parliament for further treatment of the REACH Regulation.

Duty of Care

General remarks:

- It is welcomed that the principle of "Duty of care" has been taken up in the Regulation (Art. 1) and that also downstream users are considered under these provisions.
- "Duty of Care" in terms of information should be understood as both the generation and the communication of information.

Problems:

- The term "supplier" is used in the draft Regulation but no definition is given. It is further not clear how far it is covered by the definition of the "distributor".
- It is a continuous problem for enforcement authorities to receive the information on exact composition of a preparation.

Recommendations:

1. **Include a definition of the "supplier" in Article 3 or replace the term "supplier" in the text by "manufacturer, importer, distributor and downstream user".**
2. **The information systems and the information they have to hold, have to be well defined and regulated in the text, in particular the obligation to provide the information on exact composition of a preparation.**

Information through the Supply Chain

General remark:

- Data and information in the Chemical Safety Report (CSR) should be harmonised and standardised as far as possible to make it comparable and enforceable.
- The distributor of the preparation which is the first placing on the national market (responsible) could require a need for CSR

Problem:

- It is important for industry and also for inspectors to have the CSR available in the national official language.

Recommendations:

3. **Clarify the supply of the CSR down the supply chain: The minimum requirement should be, that CSR supply is mandatory as long as an actor still handles the substance as such (including the formulation into a preparation). For preparations the supply of the CSR could be on request dependent on use, provided that a SDS (Safety Data Sheet) is supplied which includes all necessary information on uses and recommended risk reduction measures.**
4. **Introduce the obligation of the supplier to deliver the CSR in the language of the actors down the supply chain (as it is stated for the SDS).**

Registration of substances

Problems:

- It has to be ensured that there are available instruments to check if a substance needs to be registered or not and if it has been registered already.
- Clear guidance should be given, which substances can be considered as registered by definition (e.g. active substances for biocidal products, plant protection products).
- While registration is a prerequisite for manufacturing and import of a substance, it seems from the draft Regulation that it is not the case for the use of such substance.
- The IT-System established under REACH will be an important tool for various user groups with different requirements. It has to be ensured that inspectorates will have full access also to confidential data.

Recommendations:

5. **Registration number has to be part of the CSR as well as of the safety data sheet.**
6. **All substances referred to in Article 8 need to be registered as far as they are not on an existing list of active substances.**
7. **The Agency should be obliged to take care that the information in the data base will be complete and valid. That must include a careful check of the substance identity and a procedure for a periodical checking of the data quality as an indicator of the "good health of the system".**
8. **Add under Article 20.1. the wording "or used" after "… or imported…".**

Downstream Users

General remarks:

- There seems to be an inconsistency in the definition of users: “downstream users” are defined under Article 3.11., however, also the wording “user further down the supply chain” is written in Annex XI. It should be clarified if the latter has the same duties?
- It is not clear if there is an obligation for the downstream users to confirm that their uses are completely covered by the CSR.
- Exact provisions are missing for how responsibilities shifted from one to another company (e.g. after merging, outsourcing of productions, etc.) should be dealt with.
- More detailed explanations are necessary on how to define “exposure scenarios” or certain “uses” of a substance in order to verify if the requirements of downstream users to report up the supply chain are met.

Recommendation:

9. **Oblige downstream users to confirm up the supply chain that their uses are completely covered by the CSR.**

Evaluation of Substances

General remark:

- No provision is given on how to proceed if the CSR is considered very poor by inspection and safe handling cannot be assured. It should be clarified how to follow the principle of “no data, no market” in cases where immediate action is necessary.

Authorisation

General remarks:

- In cases where authorisation is granted for specific uses, use and conditions should be very clearly defined for these uses to ensure enforceability.
- The Authorisation number for an authorized substance should be required on the label and in the safety data sheets for substances and preparations as well as the customs code numbers if available.
- The three months period for downstream users to notify the Agency of the first supply of substance seems to be too long.

Restrictions on the manufacturing, marketing and use of certain dangerous substances and preparations

General remarks:

- It is appreciated to have a faster procedure for the uptake of new substances than it is now with the co-decision procedure. It is further welcomed to have the provisions for restrictions included in a regulation instead of a Directive as it is today. With respect to enforcement care has to be taken that the

provisions (e.g. on certain specified uses, etc.) are clear enough to be directly enforceable.

Recommendations:

10. **Delete the following part of the sentence under Article 65.2. "and for which restrictions to consumer use are proposed by the Commission".**
11. **Without delaying the uptake of certain substances to Annex XVI efforts should be made by the Agency to develop harmonised analytical methods.**
12. **Restriction of substances in articles should be bound to the amount and the inherent properties of these substances.**

Agency

General remarks:

- The establishment of the Forum and its future tasks are highly welcomed.

Problem:

- Due to the need that a regulation should be clear and detailed enough to ensure enforceability the enforcement experience should be taken into account during the preparation of each substance restriction.

Recommendation:

13. **Foresee procedures to consult the Forum in parallel to the Committees under Articles 67 and 68 in order to highlight enforceability.**

Classification and Labelling (C&L) Inventory

General remarks:

- A mandatory and harmonised list of substance classifications has proven to be a very helpful tool for enforcement and for industry to achieve accurate and harmonised classification of substances and also of preparations.
- Existing Annex I of DSD needs clarification about the incomplete character of some entries (outdated entries as well as future entries acc. Article 112.
- It is recognised that there is a need to focus on CMR and R42 substances. However, use should be made of the full information from the chemical safety reports. C&L documentation in the CSR referring to all endpoints will be available and should be included into Annex I to keep it as complete as possible following the precautionary principle.
- Many different formats are required per substance: C&L Inventory, pre-registration and registration dossier.
- The wording of transitional periods in Article 113 is unclear.

Recommendations:

14. **Ensure that the Agency makes effort to develop fast and effective procedure to harmonise different C&L proposals for the same substance in the Industry-Inventory. The harmonised entry should be specified by the Agency.**

15. **An explanation is needed for the future Annex I regarding the substances contained with incomplete C&L. The legal requirements for their C&L should be clear.**
16. **Article 112: Harmonised classification should not be reduced to substances classified as C/M/R and respiratory sensitisers but take into account all other dangerous properties.**
17. **The same formats should be used by companies for pre-registration and notification to the C&L – Inventory list.**

Enforcement

General remark:

- An approach in the direction of harmonised sanctions – as far as within the possibilities of the respective national legal systems - is welcomed.
- The sanction system should not only be bound on fines.
- The involvement of other Commission services should be considered (eg. DG TAXUD and DG SANCO)

Recommendations:

18. **Extend the last sentence in Art. 123 to "The Agency shall make these reports available to the Commission and to the Member States."**
19. **Replace the expression "fines set" by "sanctions initiated" (Art. 123).**

Other legal instruments

Recommendations:

20. **Directive 67/548/EEC: Definitions should be checked if they are still in conformity with the definitions used under REACH (e.g.: definition "offering")**
21. **Directive 1999/45/EC: New provisions to include the registration number on the label as well as other possible obligations regarding information systems require an amendment as it is foreseen in Volume VII for Directive 67/548/EEC. Therefore an amendment should be considered also for the Dangerous Preparations Directive.**

Concluding Remark

Under the proposed REACH-Regulation the establishment of a "Forum for Exchange of Information on Enforcement" is foreseen, which shall co-ordinate a network of Member States authorities responsible for enforcement of this regulation.

The European Commission is urgently requested to set up a working group as early as possible within the interim period in order to get prepared for the tasks of the Forum in time. Thereby maximum use should be made of the expertise and resources of the already existing CLEEN network.