PEECL III – Practical Experience from Enforcement of Chemical Legislation

Comments to the Political Agreement on the REACH Regulation

From 16th to 17th May 2006 the third meeting under the umbrella of CLEEN focussing on practical experiences from the enforcement of chemicals legislation, PEECL III, took place in Linz/Austria. Participants experienced in enforcement of chemicals legislation discussed the draft text of the REACH Regulation published by the Council 9th March 2006. The present text politically agreed by the Competitiveness Council at its meeting on 13 December 2005, was considered in relation to its enforceability.

Experts from the following countries attended the meeting: Austria (AT), Belgium (BE), Denmark (DK), The Netherlands (NL), Latvia (LV), Slovakia (SK), Slovenia (SI), Spain (ES) and the United Kingdom (UK) besides Switzerland (CH) and Bulgaria (BG) and Romania (RO).

The purpose of this meeting was to give recommendations to the European Council, the European Parliament, the European Commission and the Member States (MSs) for further treatment of the REACH Regulation. Furthermore, the common agreed recommendations will be presented at the 7th CLEEN Conference in June 2006.

The recommendations will be sent to different addressees as indicated in the Annex.

The following problems were detected and recommendations were compiled:

Title II Registration

- Under REACH there will be a shift of responsibility away from authorities to Industry. There was general concern over the lack of awareness for this new arrangement. An atmosphere should be created to prepare industry better for their responsibilities.
- General enforcement concerns over the registration requirements: how to ensure that M/I (Manufacturer/Importer) fulfil their obligations?
    - Will a substance have more than one registration number?
    - There are no clear explanation for the calculation of tonnages Will an importer, who has partners or departments in more than one MS, who also are importers, be considered as one registrant or will each department be regarded as one registrant? And do the tonnage limits then apply to the aggregated tonnage for all partners in EU or to the imported tonnage by each partner/importer? Who is responsible for that the aggregation?
    - There will be some special problems in case of building of consortia:
      Who is responsible for registration dossiers and authorisation for that substance?

Problems expected in identifying violations if registrants are unknown (e.g. in case of 2 importers/manufacturers: 1 or 2 registration numbers?)

- Problems are expected concerning the enforcement of substances in articles. As there is no concrete concept for articles following questions will arise:
    - How to identify if the release is intended or not? How to ensure health protection in case of unintended release?
    - Imported articles: Importers will have to know the composition of the article otherwise they can not meet their obligations for notification/registration
    - Enforceability of Art.6, 2: how to prove if substances are of high concern? What to do if inspectors establish that a substance in an article has not been notified?

Recommendations:

1. Develop guidance (probably introduction into RIP, REACH Implementation Project) that covers the regulatory steps of registration; consortia formation (identifying a company, what happens with responsibility of registration dossiers and authorisation); aggregation of tonnages where companies have subsidiaries in other MSs and identifying violations.
2. Clear definition and descriptions of articles is needed for a proper enforcement of the legal provisions. Descriptions should cover an intended/unintended release and when an article contains substances that are subject to registration/notification.
3. Launch CLEEN campaign (until FORUM is established) to raise awareness in MSs inspectorates concerning the responsibility of industry about content of the imported articles.

Title IV Information through the supply chain

Problems:

- No clear description concerning the supply of safety data sheets (SDS) (when, how, etc.), especially for the first time, description only concerning changes of an existing SDS. Art 29 (1) seems not to be sufficient in this regard due to lack of clear provisions about further supply
- New tasks for inspectors to follow substances down the supply chain
- Often no assessment of SDS takes place by the actors in the supply chain
- Different approach for inspections of SDSs under REACH as new approach should preferably be control of whole supply chains rather than inspections of SDSs in single companies
- Concern that controls in SDS will be less effective than those currently implemented under workplace provisions eg Chemical Agents Directive and Carcinogens and Mutagens Directive
- Compliance with existing SDS Directive is low, REACH is relying on a flawed system
- Special emphasis will be needed to enforce that SDS has to be written in the national language.

- Concern that there will be different quality of SDS dependent on the tonnage been registered by the supplier, as the requirement of information is dependent by the tonnage.

Recommendations:

4. Introduction of clear obligations about submission of SDS to be included into the regulation.
5. Guidance/Training for inspectors, including information about uses/exposure scenarios/intended uses, how to handle the supply chain.
6. Distribution of tasks concerning control of provisions related to the working place: MSs have to delegate the responsibility of the enforcement of REACH to the proper authorities.

Title V Downstream users

Problems:

- Many of DUs (Downstream users) are SMEs (Small & Medium Enterprises), so lack of legal knowledge is expected
- Parallel control of the CSR provisions concerning protection of workers/environment is expected: control of use under workplace legislation *vs.* chem. Legislation
- DUs get the same substance from different suppliers and not all of them have registered the specific use.

Recommendations:

7. Establish a sound system for workplace control in the different Member States.

Title VII: Authorisation

Problems:

- Wording of Art. 53, 1 (authorisation only with respect to substances, not preparations and articles, then substances of high concern can legally be imported if they are used in preparations or incorporated in an article even if the authorisation of the use within EU has been denied).
- Identification of CMR Cat 1,2 substances if they are not registered ie<1t/a will be difficult.
- Identification of authorised use/condition: authorisation number is given to a company for a particular use, not to a substance. Will there be a different number for each use for the same substance?
- Concern companies may use the authorisation number of another company. The problem is to identify such companies, so it will be possible for the enforcement authorities to visit them whit the purpose to control if the conditions sat in the authorisation is kept by the DU.

- Responsibility of DU for authorisation is needed as it is not allowed to buy substances which are not authorised (except they apply for authorisation themselves).
- There will in many MSs be more than one enforcement authorities, which will be responsible for the enforcement of REACH in order to control if an authorised substance is used in accordance with the authorisation and if the conditions, such as monitoring the emissions, is met.

Recommendations:

8. Clear scope of authorisation is needed in Article 53. Explicit reference should be made to preparations and substances in articles.
9. A mechanism is put in place to share information between enforcement authorities for (CMR Cat 1, 2, <1t/a) which are not subject to registration and therefore difficult to identify.
10. Training of enforcement authorities concerning the regulatory aspects of authorisation, i.e. How to identify if the authorised use/condition is met. Ensure lying down of enforceable descriptions concerning conditions for use of the substance.
11. It is a need for downstream users to make sure that the supplier has an authorisation for the specific use of a substance.

Title VIII: Restrictions

Problems:

- Difficulties are expected because of the difference between national and EU law concerning the transition period for maintaining national provisions (wording of Article 64, 5)
- Lack of information concerning enforcement methods, esp. analysis methods

Recommendations:

12. Clarification on maintenance of national restrictions in Article 64, 5 is needed.
13. Lay down testing/laboratory methods for compliance checks on restricted substances/preparations/articles.

Title IX: Agency

Problems:

- Concern that enforcement will be overlooked during preparation of the Agency. The Agency has many prescribed tasks as soon as REACH will enter into force and enforcement may not be a priority

Recommendations:

14. Preparation of the Agency performed in context especially with relevant provisions for enforcement, i.e. Members of the Forum should be familiar with

CLEEN in order to avoid parallel structures responsible for enforcement tasks. Also they should be well informed about the activities of other regulatory committees such as Chemex

15. The Agency should dedicate sufficient resources for enforcement tasks as demanded in Article 73, 2.
16. Ensure national coordination of enforcement activities.

Title X: Classification and labelling Inventory

Problems:

- Annex I, as useful tool for control activities will disappear in its present comprehensive form. The inventory will be voluntary compared to the mandatory characteristic of Annex 1. Problems expected in case of lacking of information sources if it is not a legally binding C&L (Classification & Labelling), e.g. C&L appointed by manufacturer
- Problems expected during transfer of data into GHS (Globally Harmonised System). Will Annex 1 and the C&L of new substances, which are regarded as already registered, be transferred into GHS?
- Unclear wording about the deadline of application the C&L in Article 113: the required deadline is referred to Art. 21 (1) including different deadlines for tonnage triggers, however, for C&L only the 3-years-deadline should apply.

Recommendations:

17. The C&L inventory should be transparent about the source.
18. Transfer of C&L data of new substances into GHS via registration data.
19. Preference to maintain Annex I of directive 67/548/EEC (Dangerous Substances Directive) and transfer it into GHS.
20. Clear statement in Article 113 that 3 years are meant here.

Title XI: Information

Problems:

- Problems for inspectors during their control work particularly where there is generic information, e.g. non precise use, function or application of a substance/preparation
- No indication about language of database given in the legislation

Recommendations:

21. Access to the Agency database including confidential data should be provided for all authorities including local inspectors.
22. To make database useful data should be available at least in English language.

Title XII: Competent Authorities

Problems:

- Different provisions for CAs (Competent Authorities) in MSs under REACH
- New requirement for MSs CAs in terms of its cooperation with the Agency

Recommendations:

23. MS CAs should be established in advance of entry into force of REACH to ensure coordination with the Agency.
24. Clarification is needed about a possible duty of CAs/inspectorates to evaluate registration dossiers.

Title XIII: Enforcement

Problems:

- Article 122 ("other activities" by MSs) is ambiguous
- Inconsistency expected concerning identification (typification) of violations and sanctions in the different MSs

Recommendations:

25. Ensure better comparability concerning identification of violations and sanctions (Article 123). A solution could be, that the Commission publishes a guidance where possible violations may be graduated into few categories depending of severity of the violation.*

* This recommendation will be problematic as it would strongly influence the national policy of the MS; this has also been the opinion of the participants of the 7th CLEEN Conference. The issue of elaborating such guidance would be more an issue for the Agency rather than for the European Commission.

Annex:

Recommendations:

Legal recommendations to European Council and European Parliament:

2. Clear definition and descriptions of articles is needed for a proper enforcement of the legal provisions. Descriptions should cover an intended/unintended release and when an article contains substances that are subject to registration/notification
4. Introduction of clear obligations about submission of SDS to be included into the regulation.
8. Clear scope of authorisation is needed in Article 53. Explicit reference should be made to preparations and substances in articles.
19. Preference to maintain Annex I of directive 67/548/EEC (Dangerous Substances Directive) and transfer it into GHS.
20. Clear statement in Article 113 that 3 years are meant here.

Recommendations to European Commission:

1. Develop guidance (probably introduction into RIP, REACH Implementation Project) that covers the regulatory steps of registration; consortia formation (identifying a company, what happens with responsibility of registration dossiers and authorisation); aggregation of tonnages where companies have subsidiaries in other MSs and identifying violations.
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11. It is a need for downstream users to make sure that the supplier has an authorisation for the specific use of a substance.
12. Clarification on maintenance of national restrictions in Article 64, 5 is needed.
13. Lay down testing/laboratory methods for compliance checks on restricted substances/preparations/articles.
15. The Agency should dedicate sufficient resources for enforcement tasks as demanded in Article 73, 2.
17. The C&L inventory should be transparent about the source.
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Recommendations to Member States:

5. Guidance/Training for inspectors, including information about uses/exposure scenarios/intended uses, how to handle the supply chain.
6. Distribution of tasks concerning control of provisions related to the working place: MSs have to delegate the responsibility of the enforcement of REACH to the proper authorities.
7. Establish a sound system for workplace control in the different Member States.
10. Training of enforcement authorities concerning the regulatory aspects of authorisation, i.e. How to identify if the authorised use/condition is met. Ensure lying down of enforceable descriptions concerning conditions for use of the substance.
14. Preparation of the Agency performed in context especially with relevant provisions for enforcement, i.e. Members of the Forum should be familiar with CLEEN in order to avoid parallel structures responsible for enforcement tasks. Also they should be well informed about the activities of other regulatory committees such as Chemex.
16. Ensure national coordination of enforcement activities.
22. To make database useful data should be available at least in English language.
23. MS CAs should be established in advance of entry into force of REACH to ensure coordination with the Agency.

Recommendation to the CLEEN Network:

3. Launch CLEEN campaign (until FORUM is established) to raise awareness in MSs inspectorates concerning the responsibility of industry about content of the imported articles.

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