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OVERLAP BETWEEN REACH AND WORKER PROTECTION DIRECTIVES

UNICE VIEW

1. Introduction

REACH COM 2003 0644(03) - the REACH proposal - was introduced after a review of the working of four major directives dealing with the supply and use of chemical substances.

- Directive 67/548 on classification, packaging and labelling of dangerous substances;
- Directive 1999/45/EC on classification, packaging and labelling of dangerous preparations[1];
- Directive 76/769 on restricting marketing and use (M&U);
- Existing Substances Regulation (ESR) 793/93.

The REACH proposal is driven by environmental and public health concerns and proposes an ambitious scheme that will bring major change to the existing laws that manage the supply and use of substances. Since production and use is within the scope of the REACH proposal, it clearly overlaps with worker protection provisions that deal with the use of chemicals in workplaces. By seeking to make the scope of REACH all-embracing to cover all manufacture, importation, placing on the market and downstream use of substances over one tonne per year (for registration purposes) and substances in preparations and in articles, there are unnecessary duplications and conflicts between REACH and worker protection legislation, in particular, the Chemicals Agents Directive 98/24/EC (CAD) and the Carcinogens Directive 2004/47/EC (CD) and its associated legislation.

2. General concerns

The costs of REACH were initially justified on the basis of a report produced for the EC estimating occupational health benefits of € 18-54 billion over 30 years. After the calculations in this report had been proven to be ill-founded (Zober and Nasterlack 2003), the EU Commission in its Extended Impact Assessment did a re-calculation of the expected health benefit of REACH, which again yielded alleged savings of € 50 billion over the next 30 years. Although also this calculation was demonstrably unfounded and arbitrary (Krämer et al., 2004), this figure has since been used by the EU for quantification of the benefits. UNICE believes that the figures are implausible for several more reasons. One in particular is that occupational benefits should, in principle, have been achieved by application of the Chemical Agents Directive, the Carcinogens Directive, and other supporting tools. Therefore it is more than questionable whether REACH can lead to any additional health benefits, let alone benefits of the suggested order of magnitude.

[1] The above two measures set out the EC scheme for classification and labelling (C&L), Directive 67/548 also includes an EC new substance notification system.

REACH may provide occupational safety and health (OSH) benefits, if more reliable data for hazard and risk assessment can be established in practice and intensified communication in the supply chain occurs. However, UNICE is concerned that the demand on resources may challenge, marginalise and conflict with existing OSH arrangements. Both REACH and CAD are challenging regimes in their own right. Each on its own requires considerable resources that, unless aligned with the grain of the market, could undermine the competitiveness and innovation of the EU chemicals-based industry. Their combined effect needs to be carefully considered and managed. The risk of confusion, particularly for downstream users, could undermine benefits. Without an integrated and straightforward approach, REACH may impose an extra layer of requirements that would present difficulties for prioritisation between OSH and REACH for employers and users, tie up resources in administration and paperwork rather than favour the improvement of technical solutions on the ground, and result in loss of credibility in the overall frameworks for both OSH and REACH.

CAD provides for minimum requirements, with Member States free to introduce higher standards if deemed appropriate, whereas REACH provides for a harmonised approach under article 95 in the EU Treaty. There is, in reality, a shared liability between the Commission, registrant and user or employer in the whole REACH/CAD interface that will be shifted when authorisation under REACH becomes a reality

In most Member States, a very comprehensive, effective and well developed system for controlling chemicals at the workplace has been put in place, e.g. involving the use of limit values or prohibition of the use of substances as the most extreme risk management measure. However, there is considerable diversity in Member States' practice, which will become an issue. Some Member States may have bans or restrictions on workplace use of substances of high concern. It is unclear how these onerous provisions will interact with the conditions of an authorisation that may come from the REACH process, which will have to optimise decisions on substitution in relation to comparative environment, health and safety impacts of substances and preparations.

3. Specific concerns with overlaps

Duplication of the risk assessment process for workers

On one hand, it is the responsibility of employers to perform risk assessments for the use of chemical agents in all workplaces under the requirements of CAD. On the other hand, REACH integrates a wide chemical safety assessment covering the effects of substances on men and the environment. REACH is likely to bring additional information on intrinsic properties (hazard) and on exposure and risk management, which can contribute to improving the availability of data and thus the quality of the risk assessment performed under CAD. However, it cannot be overlooked that the coexistence of OSH legislation and REACH will lead to a number of overlaps and duplications in this area, which will be unnecessary, burdensome and challenging for companies. This is in contradiction with the EU's commitment to better law-making, simplification of legislation and a stronger focus on administrative burdens and competitiveness issues within the framework of impact assessments.

Risk assessment by manufacturers

REACH requires that a manufacturer/importer assesses and implements health, safety and environmental risk management measures at his own sites. The occupational safety and health dimension has already had to be addressed by CAD and CD (if relevant) and many environmental controls are also dealt with by specific rules, of which some are generic and some recognise site-specific conditions. This situation can be expected to create overlaps and confusion.

Risk assessment for and by downstream users

REACH requires that a manufacturer or importer of a substance, or a substance in particular preparations or articles, assesses the health, safety and environmental risks for identified uses for his product. The results of this assessment should be made in the form of the Chemical Safety Report (CSR), sufficient to enable the product to be used safely and not undermine sustainable development. Whilst recognising that this is optimistic, REACH then requires downstream users outside of the scope of the (identified) use which is described in the exposure scenarios, to fill the knowledge gap, assessing the risk, drafting a relevant CSR and informing the Agency. At the same time, every downstream user will already have had to assess the occupational safety and health risks of chemical agents to fulfil requirements from CAD. There are, of course, a whole chain of downstream users between the manufacturers/importers of substances and the end user.

Complexity of exposures and scenarios

Experience with the implementation of CAD has proved challenging, particularly to SMEs as it requires considerable occupational safety and health expertise to make robust judgements about risk assessment and risk management measures to control the occupational dimensions of chemicals in use. CAD applies not just to single substances but to the wide range of chemical agents regardless of the quantity used at work and without any exemption. The provision of Safety Data Sheets (SDS) to the professional user has been of assistance as a starting point but does not provide the breadth of circumstances likely to be encountered in every workplace, thereby representing a challenge, particularly to SMEs. REACH will add other onerous requirements and challenges in terms of coming to grips with the complexity of very different use situations and require consideration of the further environmental dimensions of the use of substances.

Administrative arrangements of REACH marginalising occupational health

The timetabling for registration, which is currently largely based on tonnages, distorts the ability to take a holistic approach to evaluating comparative risks of substances and their alternatives in all dimensions – for worker health and safety and environmental protection. The decision-making is complex and there are inevitable trade-offs to be considered. Without a full evaluation of all risks and hazards, the decisions from the REACH process, which is more volume-based rather than risk-based, may not be the optimum for those who have to handle substances and preparations in the occupational context.

Market decisions

Manufacturers and importers may be driven to remove low-volume, but less hazardous substances or those with a lower worker protection risk profile, from the market because the costs associated with the registration system cannot be justified by the sales likely to be generated. There may be circumstances when an ‘orphan substance’ approach, similar to that for low-profitability therapeutic products may appear necessary for producers. This points to some potential risk of REACH giving wrong incentives for the OSH area.

4. Options

In order to eliminate some of the overlaps between REACH and OSH two main scenarios can be foreseen – a radical approach or an adaptation approach.

A radical approach

Theoretically if a holistic approach to environmental, health and safety (EHS) risk management of substances was taken

- Either manufacturers'/importers' workplace OSH conditions and the OSH aspects of downstream use could be removed from REACH and all EHS matters could be assessed holistically as workplace risk assessments and REACH should then just address the EHS issues associated with placing a chemical or preparation on the market, or
- REACH should address all EHS downstream uses, and the relevant elements of CAD and CD should be repealed.

If this approach is not adopted then the interfaces and lack of coherence must be identified, addressed and better managed. In this context, the adaptation approach provides some recommendations that should be explored.

An adaptation approach to both to complement each other

- CSR under REACH is a substance-specific Risk Assessment concerning health and environmental considerations whereas the employers' assessment under CAD is a work-activity-based risk assessment dealing only with OSH. They could be complementary (one informs the other) though the different scopes will always be an issue. Risk assessments under REACH could be generic for the part of the process already covered by CAD. Duplication of work or conflicts must be avoided to prevent an already confusing bureaucratic burden on business turning into an unworkable situation. To avoid ambiguity, good communication and guidance for industry is needed.

- CAD risk assessment results for workers should be used within REACH to reinforce a risk-based approach. Testing requirements or proposals should take into account the result of these risk assessments and the need to consider additional information to improve the quality of the conclusions.

- If the exposure scenario drawn up under REACH is totally valid for the downstream use situation, then it should be accepted that no further work is required to comply with CAD.

- The scientific, technical and socio-economic basis for any occupational limit values, indicative or binding, will have to be reconsidered within the context of REACH, in the light of the environmental dimension and in particular the authorisation procedure. The carcinogens directive has a different scope of substances (e.g. by-products/processes) from the proposed REACH authorisation, which will consider not only carcinogenic, mutagenic and repro-toxic properties but also persistent environmental properties.

- There is no relationship between occupational exposure limits in workplace air (OELs) in CAD and derived no-effect limits (DNELs) in the REACH proposal. When official OELs are available, these should be taken into account in consideration of whether further work is required to establish a DNEL. In any case, the links between

DNELs and OELs and the process of establishing DNELs should be clarified, to ensure that the effort being placed in developing OELs is still valid for the future.

- There may be a continuing need for an EU process on the setting of occupational exposure limits (OELs), but the current system will have to be improved, to be faster and more transparent for it to make any contribution within a REACH framework. The role and impact of OELs in the risk management process needs to be considered further.

- There is much information on risks and risk-reduction measures already in use in practice but this is not adequately shared amongst workplaces, let alone along the supply chain. A variety of mechanisms for collecting this information are being developed within industry and national governments. This should be collated at EU level and reviewed in terms of quality and relevance. If both the REACH and worker protection systems remain in place, this information must be integrated, with both systems using the same language and understanding for it to be of any use to manufacturers, importers, users and workers.

- The employer (downstream user) will still be responsible for workplace safety, but may be assisted in this by information especially on hazard and risk management measures provided under REACH by the SDS. However the optimum benefit will only be gained if there is an efficient two-way communication process in the supply chain between suppliers and users about risk management measures. The rules for this have to recognise the realities of the supplier/customer relationship and the competitive advantage of innovative uses for substances, in terms of confidentiality issues and the complexity of supply chains.

- EU developments must be considered in relation to global developments such as the Global Harmonised System so that information, language and understanding are shared. Substances, preparations and mixtures are a sophisticated global market.

5. Conclusion

UNICE believes that the Commission needs to give serious consideration to the issue of overlaps between REACH and occupational safety and health legislation. UNICE is willing to participate with the Commission in a process to identify areas of overlaps and define and assess different options to address, overcome or minimise them.

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