Chapter 15
Contributions of the REACH and CLP Regulations to preventing CMR risks

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The vast majority of chemical substances present on the European market have been marketed without sufficient knowledge of their effects on human health or the environment (European Commission 2001). Consumers and professional users are faced with labelling not adequately informing them of the hazards of the substances and mixtures to which they are exposed. Similarly, in the workplace, workers who handle hazardous substances and mixtures use safety data sheets ill-suited to risk prevention.

In order to overcome these problems, the European Union adopted the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) at the end of 2006 and the CLP Regulation (Classification, Labelling and Packaging) in 2008. One of the main aims of these regulations is to ensure a high level of health and environmental protection against risks linked to exposure to chemical substances, including carcinogenic, mutagenic or reprotoxic (CMR) substances.

1. More than 8,000 CMR substances in circulation in Europe …

Estimated at 323 million tonnes in 2015, the total volume of chemical substances produced each year in the EU28 is impressive. 10% of this (i.e. 32.3 million tonnes) involves CMR substances (Eurostat 2014). One of the benefits of the REACH and CLP Regulations managed by the Helsinki-based European Chemicals Agency (ECHA) is that they ensure more accurate information on the identity and number of these substances. According to data provided by suppliers, over 120,000 different hazardous substances are present on the European market, of which 8,268 are regarded as CMR (category 1A, 1B or 2). These figures are taken from the Classification & Labelling Inventory maintained by the ECHA as a result of the obligation under the CLP Regulation for suppliers to notify the Agency of the classification and labelling of all hazardous substances that they market in the EU, whatever the volume of production.

2. … but only 1,500 CMR substances with a harmonised classification

The CLP Regulation also stipulates that all category 1A, 1B or 2 CMR substances and category 1 respiratory sensitisers shall normally have a harmonised classification and labelling. The aim is to force the various companies marketing these substances to provide the same information on their intrinsic hazards to all participants in the supply chain.

When the list of around 8,000 CMR substances notified to the ECHA is compared with the list of chemical substances with a harmonised classification (Annex VI to the CLP Regulation), it is clear that only around 1,500 substances (~20%) have a harmonised classification and labelling as CMR substances (see Table 1). The rest are marketed with the classification and labelling determined by their suppliers based on the rules defined in the CLP Regulation. This self-classification system, which also applied under the previous legislation (Directive 67/548/EEC), is therefore used for ~80% of the CMR substances present on the European market. This has a major drawback: the classification and labelling of the same CMR substance may vary from one supplier to another depending on their interpretation of the classification rules. The raison d'être of the ECHA public inventory is therefore to highlight the different self-classifications of the same substance in order to encourage companies marketing those substances to agree on a single classification.

Table 1 **Number of CMR substances officially listed in the EU in July 2017**

Type of CMR substance (category 1A/1B/2)	ECHA Classification and Labelling Inventory	Annex VI to the CLP Regulation	Self-classifications proposed by manufacturers
Carcinogenic	4,427	1,224	3,203
Mutagenic	2,413	620	1,793
Reprotoxic	4,566	389	4,177
Total	**8,268**	**1,517**	**6,751**

Note: category 1A: known for humans; category 1B: presumed for humans; category 2: suspected for humans.

The harmonised classification of CMR substances is important, not only because it allows all European workers and consumers to be informed through the same labelling, but also because it automatically brings these substances within the scope of around 20 other pieces of European legislation controlling their use. These include regulations on pesticides, biocides and cosmetics, as well as various directives on worker protection. For instance, although formaldehyde was classified as carcinogenic for humans in 2004 by the International Agency for Research on Cancer (IARC), it has only been covered by the Carcinogens and Mutagens Directive since May 2015, when it was included in Annex VI to the CLP Regulation under the harmonised classification of a category 1B carcinogen. This now forces employers to eliminate or replace this industrial compound in the workplace with a less hazardous substance or process. This tightening of the regulations should result in reduced exposure for millions of workers in Europe due to changes to production facilities.

An ECHA report on CMR substances confirms that around 6,000 CMR substances are being marketed in Europe without a harmonised classification (ECHA 2015). Unfortunately it is clear that this harmonisation work, undertaken by an ECHA scientific committee following the adoption of the CLP Regulation, is quite slow. The harmonised classifications of almost all the 1,500 CMR substances in the current Annex VI were adopted under the previous European legislation (1967 Directive on the classification of dangerous substances). According to another report of the Agency, between 2009 and 2016 only 35 new CMR substances were added to Annex VI to the CLP Regulation, and

only 10 former CMR substances on this list saw their harmonised classification updated (ECHA 2017).

3. What about the missing data on CMRs in circulation in the EU?

Companies are also required, this time by the REACH Regulation, to provide the ECHA with a registration dossier for each chemical substance manufactured in or imported into the EU above 1 tonne per year. Around 22,000 substances are estimated to be registered out of the 120,000 substances currently listed. This system, based on the 'no data, no market' principle, was designed to force registrants to collect and supply ECHA with the missing data on the substances that they market. Throughout the supply chain, companies are also required to provide the information needed for safe use of their substances by means of safety data sheets.

Out of the roughly 8,000 CMR substances present on the European market, at least 1,169 (~15%) have been registered with the Helsinki Agency (ECHA 2015). This relatively modest proportion is explained by the registration rules laid down by the REACH Regulation. In essence, if less than one tonne of the substance is produced per year and per manufacturer, there is no registration obligation. The same applies to all substances falling within the scope of other specific European legislation (pesticides, biocides, cosmetics, medicinal products) or that are used for research and development purposes. This means that the number of CMR substances marketed in Europe for which REACH ensures that some of the missing data is collected (physical properties, (eco)toxicological information, uses, identity of manufacturers, volumes) is limited. However, this still covers a large part of the 32.3 million tonnes of CMR substances that circulate each year on the European market.

The data currently required for REACH registration does not always allow new CMRs to be identified. For example, serious doubts have been raised over the likelihood that potential effects on hormonally mediated carcinogenesis will be detected for registered substances on the basis of current requirements (Kortenkamp *et al.* 2011).

4. The REACH system of authorisation

In addition to the registration system provided for by REACH, companies must obtain authorisation for each of the uses made of CMR substances and other substances of very high concern[1] that are included in Annex XIV to REACH (authorisation list).

These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. This system was designed to encourage manufacturers to progressively replace

1. Substances of very high concern under the REACH Regulation are substances that are carcinogenic, mutagenic and reprotoxic (categories 1A and 1B), PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) as well as substances giving rise to an equivalent level of concern (endocrine disruptors or sensitisers).

substances of very high concern with safer alternatives. The authorisation procedures are in fact long and costly and companies have a vested interest in avoiding them if the use of these substances is not essential to their industrial activities.

To obtain authorisation, the applicant must demonstrate, through an application dossier, that the risk from the use of the substance is 'adequately controlled'. If not, authorisation may still be granted if it is proven that the socio-economic benefits of using the substance outweigh the risks and if there are no suitable alternative substances or technologies available. Authorisations are granted by the European Commission based on an opinion prepared by the ECHA. They are issued for a set period and on a case-by-case basis. The authorisation procedure could in theory be applied to all CMRs (1A and 1B) registered under REACH, whatever their volume of production. However, in practice, a system of selection is provided for by the Regulation because the Helsinki Agency can only deal with a limited number of applications for authorisation per year. Substances are initially included in a candidate list, before being transferred, where applicable, to the list of substances subject to authorisation (Annex XIV). Ten years after the REACH Regulation entered into force, the candidate list contains only 174 substances (including 151 CMRs) and Annex XIV itself contains only 43 substances (including 39 CMRs). The substances included in Annex XIV are selected from among those on the candidate list, in particular by prioritising those produced in large volumes. This means that numerous CMR substances produced in low or average volumes (< 1,000 t/year) will continue to be used pending their possible inclusion in the REACH authorisation system. At the rate that substances are being included in the candidate list and then transferred to the authorisation list, it will be a very long time before all CMR substances (1A or 1B) registered under REACH are assessed. Following criticism of the slowness of the system, in 2013 the European Commission, in collaboration with the Member States and the ECHA, adopted a Roadmap on Substances of Very High Concern (Council of the EU 2013), undertaking to ensure that all relevant and currently known substances of very high concern are included in the REACH candidate list by the end of 2020. Environmental NGOs and trade unions have drawn up their own lists of substances that they consider should be included in the REACH candidate list. In total, the SIN list of the NGOs (Chemsec 2014) and the list of the European Trade Union Confederation (ETUC 2011) identity nearly 900 substances of very high concern. With only 174 substances on the candidate list just three years before the deadline set by the Commission, it is highly likely that the civil society organisations will be sorely disappointed by the results of the roadmap.

5. Initial assessment of the authorisation system

From January 2013 until the end of December 2016, 111 applications for authorisation for a total of 22 substances of very high concern had been received by the ECHA from 195 applicants (see Table 2). The Helsinki Agency and its scientific committees must prepare an opinion on each application to help the Commission decide whether or not to grant the authorisation requested. Out of the 119 opinions already adopted, the ECHA has not yet given a negative opinion to the Commission. In all cases the Agency has recommended granting the authorisation for use requested by the applicants, and

the Commission has already formally granted 34 of these authorisations. It is likely that the Commission will systematically follow the ECHA's opinion.

Table 2 **Overview of applications for authorisation received and processed by the ECHA (Jan 2013 - Dec 2016)**

Substance	Intrinsic properties	Received applications	Number of applicants	Number of uses	ECHA opinions per use	Commission decisions per use
DEHP and BP	CMR	8	10	17	17	10
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	12
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	13	15	19	19	5
Lead chromate	CMR	1	1	1	1	-
Chromium trioxide	CMR	25	61	41	21	-
Sodium dichromate	CMR	17	23	23	15	-
Sodium chromate	CMR	2	4	3	1	-
1,2-Dichloroethane (EDC)	CMR	15	17	19	5	-
Chromium trioxide, Sodium dichromate and Potassium dichromate	CMR	1	6	3	3	-
Potassium dichromate	CMR	4	4	7	4	-
Ammonium dichromate	CMR	3	5	4	2	-
Dichromium tris(chromate)	CMR	1	2	2	2	-
Chromium trioxide ; Dichromium tris(chromate)	CMR	1	2	4	4	-
Strontium chromate	CMR	1	10	2	2	-
Potassium hydroxy octaoxodi zincate dichromate	CMR	1	5	2	2	-
bis (2-methoxyethyl) ether Diglyme	CMR	8	8	9	1	-
Arsenic acid	CMR	1	1	1	-	-
Chromic acid	CMR	1	1	1	1	-
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	CMR	1	1	2	-	-
2,2-dichloro-4,4'-methylenedianiline (MOCA)	CMR	1	1	1	-	-
Total		**111**	**195**	**180**	**119**	**34**

Note: an application for authorisation may be submitted by one or more companies. The application may cover one or more uses. Authorisations are granted (or refused) for a specific use and to each applicant.

Source: https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2017_en.pdf

However, in the view of certain observers, several dossiers do not meet the conditions for authorisation to be granted. This is the case, for example, with the application for authorisation of DEHP, a substance in the phthalate family used as a plasticiser in recycled PVC articles. According to the environmental NGOs, safer alternatives are available on the market and the ECHA should logically have given a negative opinion. The ECHA recognises in its opinions that certain alternatives exist, but as these are more expensive to use than DEHP, the Agency regards them as economically unfeasible for applicants. This practice of the ECHA is debatable because the REACH legislation does not define what constitutes an economically feasible alternative.

6. The ECHA's pro-industrial attitude

It would appear that the ECHA's strategy is to systematically give a favourable opinion to show that the system works and so that future applicants are not deterred from applying for authorisation. The Helsinki Agency also, on its own initiative, organises information sessions prior to the submission of dossiers in order to better prepare those companies using Annex XIV substances. When poor-quality dossiers are submitted, an analysis of the opinions adopted to date shows that the ECHA prefers to grant the authorisation for a short period rather than give a negative opinion. This pro-industrial attitude of the ECHA is not new. The aims of REACH also include the efficient functioning of the internal market and enhanced European competitiveness. The Helsinki Agency has already shown that it is ready to protect the interests of companies, such as, for example, when it had to decide on the balance between protecting commercial data in its possession and transparency vis-à-vis the public (EEB and ClientEarth 2012). In assessing applications for authorisation, two factors have certainly influenced its policy. First, the economic crisis. The ECHA takes the view that, if companies apply for an authorisation that can cost them over EUR 200,000, this is because they really need this authorisation and they should not be penalised by a refusal, particularly against the background of an economic slump. Secondly, there is the Commission's REFIT deregulation programme. All European legislation is being screened to check whether it is truly fit for purpose. As far as the Agency is concerned, it is therefore essential to show that the REACH authorisation system works and is not an obstacle to the efficient functioning of the internal market.

Although we may wonder whether an authorisation system under which no application is ever refused is efficiently functioning, it is worth noting that the aim of encouraging substitution seems to be bearing fruit. For example, no application for authorisation was received by the ECHA before the cut-off date for certain substances of very high concern included in Annex XIV (this was the case, for example, with the fragrance Musk Xylene and the processing agent 4,4'-methylenedianiline). All uses of these substances are therefore automatically prohibited in Europe and only their replacements may be used. Small and medium-sized enterprises in the craft glass production sector have also chosen to find alternatives to the use of arsenic trioxide, rather than trying to obtain authorisation to continue using this carcinogenic substance (Alhaique 2013). It is also generally noted that, when substances are included in the candidate list, many companies stop using them in anticipation of their potential transfer to Annex XIV and the possible break in supply if authorisations were to be refused.

7. Conclusions

The REACH and CLP Regulations have undoubtedly improved European legislation on the use and marketing of chemical substances, including CMR substances. The obligation to register all CMR substances (category 1A and 1B) produced above 1 tonne per year has led to new knowledge being acquired and the quality of labelling and of many safety data sheets being improved for professional users. The obligation to notify classifications and labelling has enabled an inventory to be made of all CMR substances present on the European market (whatever their volume of production). As this inventory is public, it ultimately ensures greater transparency with regard to the CMR substances around us. It is also useful to the authorities in selecting priority CMR substances for harmonised classification.

Although these two regulations now ensure a better understanding of the hazards and risks of numerous CMR substances synthesised by humans, it should be noted that very many European workers are exposed to carcinogens not covered by these regulations. These are CMR substances that result from industrial processes and that are not intended to be marketed, such as diesel emissions, crystalline silica, wood dust, etc. The reduction of occupational cancers, which we should remember are the primary cause of occupational mortality, cannot therefore rest entirely on these two pieces of legislation and their correct application.

However, the fact remains that the authorisation system provided for under REACH genuinely encourages the replacement of carcinogens and therefore prevents occupational cancers. It is regrettable that it is not being fully used by the ECHA, the Commission and the Member States, not only to reduce the huge direct and indirect costs of using substances of very high concern, but also to encourage innovation and the green economy.

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