

# Chapter 14

## Two-fold legislation: market regulation and workplace prevention

Laurent Vogel

The ESENER survey conducted by the Bilbao Agency emphasises the importance of precise and comprehensive legislation to organise prevention (Rial González *et al.* 2010). According to this survey, which was conducted on the basis of a sample of 36,000 companies, the main factor encouraging companies to develop a prevention policy is the existence of legislation. Ninety percent of companies state that fulfilment of legal obligations is what spurs them to act. In 22 of the 27 countries, this factor heads the responses. In the field of occupational cancer prevention, the importance of a precise and detailed legislative framework is heightened by the dearth of economic incentives within companies, especially as the cost of occupational cancers is almost totally externalised to social security and public health structures.

This contribution briefly analyses the following elements: the development of Community legislation on the marketing of carcinogens and the protection of workers' health. It also addresses the main obstacles encountered in the application of these rules in different Member States. It will be restricted to cancers caused by chemicals, disregarding other carcinogenic factors such as night working, exposure to solar radiation, ionising radiation or biological agents.

In this chapter, we will not be discussing the ongoing process of revising the directive for the protection of workers against carcinogens. Because of the importance of this question, the chapter 18 is devoted to it (page 185).

### 1. Development of market regulation

For a long time, the European Union ignored the importance of occupational cancers, failing to establish a coherent legislative framework to prevent them. In this field, Community developments were not very different from national developments in its Member States.

The question of harmonising legislation on the marketing of chemicals first arose at the time of creation of the European Economic Community, with the diversity of national legislation considered a potential obstacle to the establishment of the common market. Community rules were adopted with the priority objective of allowing the free circulation of goods. It was only quite slowly that other concerns were taken into account: public health, occupational health and environmental protection. It is therefore not surprising that, on the basis of the Treaty of Rome (1958), the first legislative developments concerned market rules.

## 2. The 1967 Directive: the illusion of self-regulation by industry

The first Directive adopted goes back to 27 June 1967 (Directive 67/548/EEC). It laid down rules relating to the classification, labelling and packaging of chemicals. It instituted the principle of producer self-regulation, originally without any checks and balances, leaving it up to the chemical industry to determine the intrinsic hazards associated with the substances they were producing. Classification therefore depended mainly on data gathered and selected by the industry, even though the Directive gradually opened up the way to harmonised classification for the most hazardous substances. Such an approach ignored the conflict of interests between a correct assessment of the hazards and the economic profit associated with marketing the substances. Moreover, it took no account of the concrete conditions of use and did not provide for any feedback on the health effects to exposed workers.

In view of the obvious inadequacy of this legislative framework, three strategies were possible with respect to the level of regulation: to strengthen national regulation (this is what France did via its law of 12 July 1977 on the control of chemical products), to count on reform of the Community legislation (the main option for Germany, being mindful of guaranteeing access to the European market for its chemicals) or to wait for hypothetical international agreements (there were lengthy negotiations under the auspices of the OECD, which resulted in 1982 in a purely optional text concerning the data which States *could* require from producers prior to marketing<sup>1</sup>).

Reform of Community law took place piecemeal. It multiplied the legislative instruments with respect both to the general market in chemicals and to specific uses (pesticides, cosmetics, etc) or the safety of hazardous installations (the first Seveso Directive 82/501/EEC adopted on 24 June 1982). REACH, the European legislation currently in force for the marketing and use of chemicals, only partially dealt with the drawbacks of a highly fragmented legislative framework, meaning that there are still specific legal systems in different fields.

The 1967 Directive had to be amended many times and has been since supplemented by other legislative instruments intended to mitigate the shortcomings of a self-regulation by the chemical industry limited to the classification and labelling of substances.

In 1976, Directive 76/769/EEC provided for the possibility of restricting the marketing of certain hazardous substances, with fifty-nine measures adopted in 33 years<sup>2</sup>. The asbestos ban, only decided in 1999, shows the slowness of this process.

In 1979, the sixth amendment of the 1967 Directive (Directive 79/831/EEC of 18 September 1979) imposed a distinction between existing substances (about 100,000 substances present on the European market as at 18 September 1981) and new

- 
1. Decision of 8 December 1982 of the Council of the OECD concerning the minimum pre-marketing set of data in the assessment of chemicals [C(82)196(Final)].
  2. Since the adoption of REACH, the pace of adopting restrictions has slowed down, from the previous average of two new measures a year dropping to just one (Musu 2013).

substances (marketed after 18 September 1981). As regards the latter, manufacturers were required to submit a pre-marketing notification to the competent authorities of one of the Member States. The procedure provided for four elements: a technical dossier supplying the (eco)toxicological data necessary for evaluating the risks which the substance might entail for humans and the environment; a statement concerning the unfavourable effects of the substance in terms of the various uses envisaged; the proposed classification and labelling if the product is hazardous according to the criteria in the Directive; proposals concerning the precautions to be taken for its safe use and disposal. The information required varied depending on the production volume calculated individually (per producer or importer and per year) and independently of an overall estimate of the production volumes for the European market. This shortcoming was mitigated by the fact that the production volume as of which notification was required was 10 kg per year per producer. On this point, the combined rules of REACH and the new CLP Regulation<sup>3</sup> represent a regression, illustrating their inability to provide an adequate framework for regulating nanomaterials<sup>4</sup>. Henceforth, the data on substances supplied through the registration dossiers in REACH is only required as of a production volume of 1 tonne per year. The notification of classification required by the CLP regulation can be made after the go-to-market date (within 30 days) and comprises a classification rather than a proposed classification.

The notification obligation introduced for new substances from 1981 onwards was formulated in a particular context. In 1976, the United States had adopted the federal Toxic Substances Control Act (TSCA) after five years of intensive debate in many respects reminiscent of the polemic surrounding the REACH negotiations. At the time, the United States were tending towards a more ambitious policy than the European Union with regard to chemical risks. The reform taking place in Europe in 1979 appeared to be a reaction to this regulatory activity in the United States, provoking the hostility of the European chemical industry (Brickman *et al.* 1985). The debate at that time gave a kind of inverse image of what had occurred at the time of development of REACH, at least with respect to the positions of the state players.

The 7<sup>th</sup> amendment of the Directive adopted on 30 April 1992 (Directive 92/32/EEC) introduced the obligation for the manufacturer, importer or distributor to provide professional users with a safety data sheet containing the information needed for protecting human health and the environment.

Rules concerning hazardous preparations were instituted with the 1988 adoption of Directive 88/379/EEC<sup>5</sup>. Amended several times, it was completely revised with the adoption of Directive 1999/45/EC.

3. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.
4. For numerous nanomaterials, the production volumes are less than one tonne per year per producer. In this case, no registration is obligatory under the terms of REACH. Also, producers tend to under-estimate the fact that the physico-chemical properties of nanomaterials differ appreciably from those of larger particles with the same chemical composition.
5. In this text, a preparation is defined as a mixture or solution comprising two substances or more. In the current terminology, reference is made to mixtures.

In 1993, Regulation (EEC) No 793/93 provided for public authorities to conduct risk assessments of existing substances, but results were disappointing. The inadequate resources allocated to the public toxicological expert bodies combined with the reluctance of the chemical industry to communicate all relevant data made it impossible to overcome the enormous dearth of knowledge on the effects of substances already on the market. Just 141 substances were included in the list of priority substances to be assessed. Thirty-nine assessments were performed before the Regulation was repealed following the entry into force of the REACH reform in 2007.

As time went by, various European regulations were adopted for more specific categories such as medicines, food additives, biocides, waste, cosmetic products, pesticides, detergents, etc. These regulations will not be examined in this article.

The interplay between the provisions of REACH and those of the specific regulations sometimes gives rise to problems. As regards the European regulations on biocides and pesticides, their application has been severely hampered by the European Commission, which has not met its obligations to define criteria concerning endocrine disruptors. These substances play an important role in the increase in hormone-dependent cancers such as breast cancer in women and prostate cancers in men. The Commission's inertia resulted in open conflict with the Member States. In May 2014, Sweden decided to bring a legal action against the European Commission for its failure to meet the obligation to define such criteria by December 2013. The Swedish complaint received the support of several Member States and of the Council of Ministers and the European Parliament. On 16 December 2015, in an unprecedented decision, the General Court of the European Union ruled that the Commission was in breach of EU law by failing to publish the criteria for defining endocrine disruptors.

### **3. The need for a deep-going reform**

By 1995, with the accession of Sweden, Finland and Austria to the EU<sup>6</sup>, the need for radical reform had been acknowledged. The candidates for accession (mainly Sweden) had far more advanced regulation than the Community. Their public opinion would not have allowed just simple alignment with Community rules. During the negotiations over this enlargement of the European Union, the need for a general overhaul of the legislation in force was acknowledged. The act of accession included provisions allowing Austria and Sweden to maintain, for a transitional period of four years, stricter conditions with regard to certain aspects of regulating the chemicals market. Highly symbolically, the first Swedish Commissioner in the European Commission, Ms M. Wallström, was given the environment portfolio between 1999 and 2004. She was to play a very important role in giving impetus to REACH.

Preparations for the reform were undertaken gradually during 1998. The Environment Ministers of the Member States held an informal Council in April 1998 in Chester,

---

6. The negotiations for enlargement also involved Norway. Norway's accession was rejected by referendum in autumn 1994.

acknowledging the need for reform. On 18 November 1998, the Commission adopted a report on the application of the existing rules<sup>7</sup>, showing that regulation was incoherent, incomplete and poorly applied. It should however be noted that the European Commission was far from adopting a unanimous point of view on this matter. The careful wording of the 1998 report performed the diplomatic function of concealing a certain number of fundamental differences of opinion. Meeting on 20 and 21 December 1998, the Council of Ministers approved the Commission's report, backing a thorough reform.

The differences within the Community institutions came to the fore during 1999. The Commission decided to support a Swedish businessman who was challenging his national legislation. The case involved the general prohibition of the use of trichloroethylene for industrial purposes. The Swedish enterprise Toolex Alpha AB manufactured compact discs and used trichloroethylene to remove grease from production residues. The Swedish chemical product inspectorate refused it authorisation to continue using this substance since the enterprise had not submitted a plan for its substitution.

In July 2000, the European Court of Justice rejected the Commission's point of view and justified its support for the Swedish legislation by means of a general principle of substitution established in Community law (Toolex Alpha AB judgment, 11 July 2000, Case C-473/98). Despite the legal arguments, this trial showed that the Commission remained divided on the imperative need for reform of the Regulation on chemical products and on its content. The support given by the Commission to the Swedish businessman was all the more surprising in that, on 10 May 1999, Parliament and the Council had adopted Directive 1999/33/EC, which extended for a period of two years the derogation allowing Sweden and Austria to apply stricter national rules with regard to certain aspects of the marketing of chemicals. This Directive restated in its recitals the need to undertake a revision of all of the Community rules. Recital 6 stated in particular: 'whereas, during that period [the two years granted for extension of the derogation], coherence of the marketing conditions of hazardous substances and preparations should be sought'. According to the evidence we have gathered from former officials of the European Commission, the Commission's intervention had given rise to deep misgivings in different Directorates-General, which considered that DG Enterprise was aligning itself with the positions of the chemical industry.

For 15 years, we have consistently noted a far more determined political will on the part of DG Environment in favour of policies favourable to human health and the environment<sup>8</sup>. DG Enterprise (renamed DG Growth in 2015) tends to see its own role as a kind of spokesperson for the interests of private companies, wishing to be considered the central decision-making body for chemical products<sup>9</sup>. DG Social Affairs remains

7. Document SEC(1998) 1986 final.

8. With the formation of the new Commission chaired by J.-Cl. Juncker in 2014, the role of DG Environment in European policies concerning chemical risks was greatly reduced. The biocides dossier has been removed from it. This reversal was criticised by environmental protection associations, which detected a sign of strengthening the role of industry lobbies.

9. Mr Geert Dancet, the first director of the European Chemicals Agency (ECHA) based in Helsinki came from the ranks of DG Enterprise and Industry. After the end of a first term of five years, he was reappointed in 2012.

passive. The resources available to it are derisory in comparison with the challenge of chemical risks for workers in Europe. It has fewer than five people working on these matters. The internal tensions came to the surface many times during both the negotiations for REACH and its implementation. Over the two terms of the Barroso Commission, DG Enterprise was able to consolidate its positions thanks to alliances between two successive Commissioners (the German socialist G. Verheugen between 2004 and 2009 and the Italian conservative A. Tajani between 2009 and 2014) and the President of the European Commission. These alliances sometimes damaged the principle of collective responsibility on the basis of which the Commission should adopt positions.

The Commission's White Paper of 27 February 2001 – Strategy for a future chemicals policy (COM(2001) 88 final) – constituted a critical assessment of existing arrangements and proposed significant changes. The different stages of the negotiations were marked by bitter conflicts. Lively debate also took place within the European trade union movement. The European Trade Union Confederation emphasised the need for fundamental reform while the European Mine, Chemical and Energy Workers' Federation (EMCEF) adopted positions close to those of the chemical industry.

Eventually, the most innovative aspects of the White Paper were watered down. It was not just in Europe that REACH came under attack. The Bush administration in the United States racked up the pressure on the European Union not to adopt a regulation increasing the safety obligations of producers of chemical products. In October 2003, the Commission presented its proposal for a regulation. Known by the acronym REACH (Registration, Evaluation, Authorisation of CHemicals), this text was less ambitious than the initial proposals in the White Paper and the draft submitted for public consultation in May 2003. The final compromise, covered by an agreement between Parliament and the Council in December 2006, is a second-rate version in comparison with the initial drafts. It allows industry only to supply highly fragmentary data for two-thirds of the 30 000 substances covered by REACH (for production volumes below 10 t per year per producer). It sets over-lax conditions for the authorisation of substances of very high concern and excludes polymers from the scope of application of the main provisions concerning the registration and evaluation of substances.

REACH was supplemented by Regulation (EC) No 1272/2008 on the classification, labelling and packaging [abbreviated to CLP] of substances and mixtures. Superseding Directives 67/548/EEC and 1999/45/EC, it established a new system based on the globally harmonised system negotiated at international level and is supposed to provide, at worldwide level, for equivalent rules for chemical substances and mixtures with regard to their classification, labelling and packaging. The globally harmonised system does not require the states implementing it to create public control mechanisms which would make notification by producers, examination of the content of the notification and the creation of a stringent harmonised classification determined by the public authorities mandatory. The principles of notification and harmonised classification have clearly been upheld within Europe.

## 4. A brief initial assessment of REACH

REACH entered into force on 1 June 2007. All CMR substances produced in Europe in quantities exceeding one tonne per year had to be registered before the deadline of 1 December 2010. Furthermore, whatever their production volumes, all substances marketed in Europe and classified as hazardous by their manufacturers had to be notified to ECHA (European Chemicals Agency) before 3 June 2011. Of the 1 300 CMR substances with a harmonised classification in Annex VI to the CLP Regulation, only 67% of them have been registered or notified to the ECHA (ECHA 2015)<sup>10</sup>.

According to 2015 ECHA data, 5 675 substances have been notified as CMR (categories 1A, 1B or 2) under the terms of the CLP Regulation, although they are not deemed to be CMR in the harmonised classification (ECHA 2015). Of these substances, 1 169 have been registered under the terms of REACH (which means that they are manufactured or imported at a volume exceeding one tonne per year per manufacturer or importer). These data lead to three conclusions. First, the harmonised classification probably includes significant gaps with respect to the reality of the substances marketed. Second, the fact of limiting the registration of CMRs to substances for which the annual production volume per producer is one tonne constitutes an obstacle to prevention since, according to producers' notifications, there are more than 4 000 different CMRs with production volumes of less than one tonne. Finally, the mechanisms put in place by REACH are too slow and inadequate to rid the market of CMRs.

An additional problem concerns the relative multiplicity of manufacturers (or importers) registering CMRs. The ratio between the number of substances registered and the total number of registration dossiers is of the order of 1 to 10: 419 substances registered as carcinogenic for 3 964 registrations, 223 mutagens registered for 1 642 registrations and 121 reprotoxic substances for 1 451 registrations. The same CMR substance is therefore produced by numerous different manufacturers in the EU and is covered by dossiers that may include significant differences as regards the preventative measures to be adopted<sup>11</sup>.

The current period corresponds to the gradual implementation of REACH, which is to continue until 2018. This is a decisive stage, during which vital future trends will be decided. The quality of registration dossiers needs in particular to be evaluated. An initial check is undertaken electronically by ECHA, restricted to verifying that all the relevant headings contain information, regardless of their content. The quality of the content of numerous dossiers seems highly problematical. According to ClientEarth, which has reviewed the dossiers for different substances whose effects as endocrine disruptors are known, much of the available and relevant scientific information is not mentioned in the dossiers. The list of candidate substances likely to be subjected to authorisation procedures remains very limited in comparison with all the substances

10. [https://echa.europa.eu/documents/10162/13562/cmr\\_report\\_2014\\_en.pdf](https://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf)

11. REACH provided for different methods for exchanging data. As part of a forum for the exchange of information on a single substance, several producers (and/or importers) may decide to establish a consortium to submit a single registration dossier. The formation of a consortium resulting in the submission of a single registration dossier is just an option and not an obligation.

defined as being of great concern under the REACH criteria: 191 substances or groups of substances as of July 2018.

This figure is still far from the 334 substances or groups of substances which are particularly hazardous for workers and which are included in the list of priority substances drawn up by the European Trade Union Confederation (Musu 2011).

The central role played by ECHA also gives rise to legitimate concerns (Schaible and Buonsante 2012). To what extent will it be able to operate without succumbing to the pressure exerted by industry? Does the interpretation it adopts with regard to the content of REACH meet the objectives of the whole REACH text? Two examples illustrate the urgency of these questions.

1. There have already been great controversies with regard to the very restrictive definition which ECHA proposes for the concept what an 'Article' is<sup>12</sup>. The number of articles notified due to the presence of a particularly hazardous substance included in the list of candidate substances is very small. Less than 40 substances of extremely great concern had been notified in November 2014. In the great majority of cases, the number of notifications for each substance is limited to less than five different articles. A whole section of the system envisaged by REACH is just not working. To a certain extent, the criteria defined by the Agency have contributed to this paralysis. On 10 September 2015, the European Court of Justice ruled that the ECHA interpretation of 'Article' was too restrictive. For the Court, each of the articles incorporated as a component of a complex product is covered by the duties to notify and to provide information when they contain a substance of very high concern in a concentration above 0.1% of their mass.
2. The introduction of a concept of derived minimal effect level (DMEL) is in no way justified in the text of REACH. The Agency has developed this concept in 'guidance documents'. An examination of DMELs determined by producers with regard to CMRs shows that the levels of health protection they provide are very variable and that the concept of 'tolerable risk' they reflect is clearly less favourable than the OELs [Occupational Exposure Limit Values] defined in Germany for the same substances (Püringer 2011).

The proper functioning of REACH also depends on the active involvement of the public authorities in the different Member States. This involves both the political will and the resources needed to enable public toxicological expertise to be developed. Otherwise, the information available under the terms of REACH depends excessively and dangerously on the data supplied by industry. At present, only a limited number of states are actually cooperating in the proper functioning of REACH. This can be measured quantitatively: of 173 substances proposed for possible inclusion in the list of candidate substances for authorisation, a little fewer than 100 have been proposed by states<sup>13</sup>. The vast majority

---

12. This conflict pits ECHA, supported by the European Commission, against six states that interpret the concept of Article more in conformity with the aims of REACH: Belgium, Denmark, France, Germany, Norway and Sweden.

13. Data available in December 2014.

of proposals originate from just 7 states: Germany (40 substances), France (17), Sweden (13), the Netherlands (12), Austria (11), Denmark (9) and Norway<sup>14</sup> (7). Other states with a large chemical industry only collaborate marginally: the United Kingdom (2 substances proposed), Belgium (3), Poland (1) and Italy (0).

## 5. The evolution of European rules for the protection of workers

The European legislation on the protection of workers was introduced later than the market rules. Paradoxically, the question arose over a highly specific situation. In the late 70s, a scandal arose over vinyl chloride monomer (Soffritti *et al.* 2013; Markowitz and Rosner 2013), where it was established that the chemical industry had intentionally concealed vital information concerning the risks of cancer among exposed workers. This explains why, as of 1976, the first Directive adopting measures to limit marketing included vinyl chloride. In 1978, Directive 78/610/EEC was adopted for the protection of workers. Since the legal basis for such a Directive remained uncertain under the terms of the Community Treaty in force at that time, justification for the Directive rested on the assertion that unequal levels of protection for workers had a direct impact on the functioning of the common market.

Framework Directive 80/1107/EEC of 27 November 1980 defined a new approach to health and the safety at work. Centred on industrial hygiene, it provided for the adoption of a set of occupational exposure limit values (OELs) which would be binding in nature for Member States, while allowing them to adopt rules ensuring better protection for workers. These OELs were to be regularly updated to take account of the experience acquired and technical and scientific progress. The Directive provided for the short-term adoption of OELs for nine chemical agents or families of agents: acrylonitrile, asbestos, arsenic and its compounds, benzene, cadmium and its compounds, mercury and its compounds, nickel and its compounds, lead and its compounds, chlorinated hydrocarbons (chloroform, paradichlorobenzene and carbon tetrachloride). Between 1980 and 1988, only two OELs were defined for chemical agents: lead (1982) and asbestos (1983). The inability to reach agreement on a proposed directive concerning benzene brought the whole process to a halt. In 1988, the Framework Directive of 1980 was revised by Directive 88/642/EEC. Henceforth, indicative limit values were adopted, without any binding effect for Member States. The development of indicative OELs has been laborious. On the basis of the 1980 Directive, two lists have been produced (Directives 91/322/EEC and 96/94/EC). Following the adoption of the Directive on chemical risks (Directive 98/24/EC), four lists were adopted on this new legal basis: the first in 2000, the second in 2006, the third in 2009, the fourth in 2017. In all, there are around 120 substances for which an indicative Community OEL has been defined.

On the basis of Directive 80/1107/EEC, Directive 88/364/EEC was adopted, banning four aromatic amines. More general in scope, this Directive banned certain agents or certain activities. The four prohibited carcinogenic substances were included in a list

14. REACH is also applied in the countries of the European Free Trade Association, which includes Norway, Iceland and Liechtenstein.

designed to be supplemented gradually. In reality, this turned out to be the swansong of this period of legislative development.

Fortunately, the political will to improve working conditions was reflected in the adoption of Article 118a of the Treaty under the terms of the provisions of the Single European Act. This made it possible to move on without excessive delay to a new stage in the production of Community legislation. This involved defining, first of all, the essential aspects of prevention in companies, whatever the risk in question and, next, legislating on the different risks by developing more specific texts. This concept formed the basis for Framework Directive 89/391/EEC of June 1989, which extensively updated occupational health law in most Member States.

## **6. The impetus provided by the Framework Directive of 1989**

Since the adoption of Framework Directive 89/391/EEC of 1989, the matter of prevention of cancers has been addressed more systematically. In 1990, a specific Directive was adopted: Council Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work. This text remains the basis for the legislation currently in force. Partially amended in 1997 and 1999<sup>15</sup>, an ambitious revision was launched in 2016 (see page 185).

At the time of its adoption, this Directive constituted a positive contribution for the great majority of Member States, which had only highly fragmented and ineffective regulations in the field of protecting workers against carcinogenic chemicals. The Directive went beyond the basic requirements of Framework Directive 89/391 by formulating a general obligation to substitute any carcinogenic agent insofar as technically possible. If this was not possible, the production and use of a carcinogenic agent had to take place in a closed system insofar as technically possible. Otherwise, exposure had to be reduced to the lowest technically possible level. Other preventive measures were envisaged, dependent not on a risk assessment but on the intrinsic hazard characteristics presented by any carcinogenic agent. The Directive clearly sets out the role played by OELs, with its recitals specifying that, even if current scientific knowledge does not make it possible to set a level below which the health risks cease to exist, a reduction in exposure to carcinogenic agents will nonetheless reduce the risks. They emphasise the need to define OELs for all carcinogenic agents: 'limit values and other directly related provisions should be established for all those carcinogens for which the available information, including scientific and technical data, make this possible'.

This important Directive, however, included problematic elements. The experience acquired over more than 25 years shows that these weaknesses have significantly reduced the efficacy of prevention.

---

15. The version currently in force is Directive 2004/37 of 29 April 2004, which represents a consolidation of the original Directive with the amendments adopted in 1997 and 1999.

The current scope of application of the Directive concerns workers exposed to carcinogenic and mutagenic substances or preparations<sup>16</sup>. When substances have been subject to harmonised classification in categories 1 or 2 (since 2008, the new terminology is 1A and 1B, with the Directive amended correspondingly by Directive 2014/27/EU of 26 February 2014), the scope of application of the Directive is clearly determined. When they meet the criteria for possible classification, the legal uncertainty is major. This is reflected in considerable differences in preventive practices between countries and, in each country, between companies. The Directive does not address the question of substances which have been classified or meet the criteria for classification as suspected carcinogens (former category 3, now category 2). In practice, there is sometimes a difference between the assessments made by the International Agency for Research on Cancer and those used for Community classification. This is the case in particular for formaldehyde, which the IARC considers to be a confirmed carcinogen for humans (group 1), but which was only considered as a suspected carcinogen in the Community classification until 2014 (current class 2) and therefore did not fall within the scope of application of the Directive for the protection of workers<sup>17</sup>. But the major difference is to be found elsewhere: the purpose of the Community classification is to facilitate the market while the IARC classification has public health objectives in mind when identifying carcinogenic agents. This means that exposure to carcinogens resulting from the degradation of a substance or, generally, produced by an industrial process are not likely to be incorporated into the Community classification.

The Directive also applies to a list of specific substances, preparations or processes (Annex I to the Directive). This list has just five entries. The discrepancy in scientific knowledge is far more considerable here. As an example, the list mentions hardwood dust, while data exists on the carcinogenic nature of all wood dust. It mentions neither crystalline silica<sup>18</sup> nor diesel particulate emissions, never mind leather dust or rubber dust and fumes, etc. The inadequacies of Annex I also give rise to huge inequalities with regard to prevention. The terminology used is more restrictive than for substances and preparations. Unlike what happens for substances for which a Community classification would be possible, there is no provision for the inclusion of processes meeting the criteria identifying an occupational risk of cancer. Since this is a directive that formulates minimum requirements, the inclusion of other processes depends on national legislation.

The binding OELs (BOELs) determined by the Directive only concerned three substances until 2017: vinyl chloride monomer, benzene and hardwood dust (to which asbestos and lead should be added, for which binding limit values are defined in other directives). This caused two problems. First, these BOELs did not reflect technical progress and need to be revised. Second, the catalogue of binding Community BOELs only covered a very small proportion of workers exposed to carcinogenic or mutagenic

---

**16.** Mutagenic substances were added to the scope of application by Directive 1999/38/EC.

**17.** A harmonised classification of formaldehyde as carcinogen 1B came into force in the EU in April 2015.

**18.** Crystalline silica was introduced in 2017 when batch 1 of the revised directive was adopted.

substances. Referring to the data from the SUMER 2010 survey<sup>19</sup>, it can be seen that, of the 10 carcinogenic chemicals constituting the greatest exposures in France, only two were subject to a binding Community OEL before 2017. These were wood dust (the Community BOEL only concerns hardwoods) and lead (which is not considered carcinogenic in the Community classification and is subject to far too high a limit value from the point of view of health protection). Extending the sample to the 20 agents constituting the most frequent exposures, we see that the contribution of the list of Community OELs to prevention was minimal. A calculation performed on the basis of the SUMER data indicates that the binding Community OELs covered less than 20% of the exposure situations registered for carcinogenic agents<sup>20</sup>. At national level, there are very great disparities between the number of carcinogenic substances subject to a national OEL and the levels of health protection taken into account. A comparative study by the European Agency for Safety and Health at Work in Bilbao on OELs concerning CMRs shows that the accumulated logjams at Community level have resulted in highly divergent occupational cancer prevention policies in the Member States (Schneider and Kosk-Bienko 2009).

## **7. Elements for an overall assessment: obstacles in the way of preventing occupational cancers in Member States**

The prevention of occupational cancers implies a set of conditions influencing the effectiveness of any prevention policy. These play an enhanced role with respect to risks which are both extremely diffuse and not very socially visible. The experience acquired in the field of prevention makes it possible to identify two core elements in an overall assessment, going beyond the extreme variety of national practices. They relate to the need for collectivisation procedures and to better understanding the great diversity of work involving hazardous exposure.

A coherent legislative framework is a *sine qua non*. Research conducted by the European Agency for Safety and Health at Work shows that, as a driving force for prevention, the existence of legislation is the factor most often cited by employers to explain the implementation of prevention measures (Rial González *et al.* 2010). As a general rule, both at Community level and in the different countries, the legislation enacted essentially concerns the first circle of prevention, putting obligations on employers and providing a framework for prevention activities in companies. Beyond this key dimension, questions should be asked about the weakness of public structures, mainly with respect to collectivisation and control.

- 
19. There is no European data comparable with SUMER. The CAREX programme intended to evaluate the number of workers exposed to carcinogenic substances in Europe supplied data for the '90s (Kauppinen 2000). It was then interrupted. Since 2000, the European Commission has no longer supplied any statistical data on this matter. The European survey on working conditions does not draw any distinction between exposure to carcinogenic agents and exposure to other chemical risks.
  20. Of 3,316,000 exposure situations recorded by SUMER 2010, about 600,000 are covered by a binding Community OEL. The actual percentage is lower if it is considered that the Community OEL only concerned hardwood dust, while SUMER lists all of the situations of exposure to wood dust.

The dearth of data originating from different Member States suggests that substitution is only being implemented by a small number of companies and with respect to a limited number of substances. It is more frequent for CMRs used as inputs to the production cycle than for CMRs generated during the production cycle. One of the obstacles to substitution is the weakness of public structures providing access to precise data on alternatives. At Community level, the legislation has never been supplemented by such collectivisation structures. In the Member States, experiences are varied but remain globally inadequate. Public collectivisation bodies are called upon to play a role not just in the field of substitution but in all prevention measures: better knowledge of the risks associated with processes, OEL usefulness and limits, *de facto* performance of personal protection equipment, methods for integrating the prevention of cancers into risk assessments, the role of prevention services and the contribution of a multidisciplinary approach, in particular through ergotoxicology.

The status of prevention services in almost all Community countries also gives rise to problems. Only a few very large companies have in-house prevention specialists with all the skills needed to fight occupational cancers. The majority of services are inter-enterprise services working in a competitive market. They generally design their interventions in a contractual framework with companies which are seen as 'clients'. The control exerted over their independence with respect to employers and over the quality of their work both by workers' organisations and by the labour inspectorate is weak. The services tend to neglect their role in public health (or, worse, they confuse this role with a vague promotion of individual health in a context totally foreign to their mission to transform working conditions). They contribute little to the implementation of collective monitoring systems, whether involving toxicovigilance or mapping actual exposures in relation to work activities. Also, in numerous European countries, there has been a significant weakening of occupational medicine within the prevention services.

The public authorities also have a responsibility in these shortcomings. Though they have access to a set of information defined by the Community Directive, they take few initiatives for information to be effectively gathered, analysed and used to improve prevention. There is no real interaction between workplace prevention services and the public health structures involved in the fight against cancer. Apart from the Nordic countries (Pukkala *et al.* 2009), the national cancer registers are not used systematically to establish links between the work done by patients throughout their working lives and cancer locations. There is generally no monitoring of post-employment health.

The implementation of public information systems is an important issue. Practice shows that numerous companies using chemical products often only have fragmented, and sometimes contradictory information. The data they obtain from suppliers only partially meets their prevention needs. Some data is inaccurate or is formulated in too unspecific terms. An improvement in the information supplied is one of the anticipated consequences of the implementation of REACH but this is not enough. A more effective fight against occupational cancers therefore also involves prevention strategies able to overcome the shortcomings of a fragmented approach, company by company. Though a European strategy in this field would make it possible to achieve greater effectiveness, in the current political context this is considered unlikely. National strategies,

accompanied by cooperation between the public prevention institutions in different countries, are more likely to be put in place.

The development of research is also an important element. The prevention of occupational cancers is still largely guided by knowledge and depictions essentially going back to the '70s and '80s, without consistently incorporating new scientific data on carcinogenesis (Clapp *et al.* 2007). Similarly, findings from epigenetic research and the study of the role played by endocrine disruptors along with the transgenerational effects of certain occupational exposures are ignored. Beyond the incorporation of new scientific data, questions should also be asked about the social construction of prevention practices and their underlying depictions. In particular, the depiction whereby working conditions only play a marginal role in cancers in women merits critical analysis. Although it is true that the share of work where exposure is very high (in particular in construction) is male-dominated, this does not mean that women are sheltered from other types of carcinogenic exposure at work. It is likely that there is a vicious circle between the priority given to male groups in the epidemiology of occupational risks of cancer, the weakness of prevention systems in highly feminised activities and the particularly dramatic levels of under-recognition of occupational cancers in women. Recent studies have highlighted high risks of breast cancer among women in various occupational groups (Engel and Rasanayagam 2015). For some occupations, exposures to chemical substances are the main explanatory factor. For instance, the risk of breast cancer is 5 times higher in the hairdressing and cosmetics sectors, as also among food and beverage production workers. It is 4.5 times higher among dry cleaning and laundry workers, and 4 times higher among workers in the paper and printing industry and among those making rubber and plastic products.

Another important obstacle in the way of improving prevention strategies is the fact that legislation, both at European level and in the different countries, solely imposes minimum obligations on employers. In numerous cases, the reality of risks is more complex. They tend to be concentrated in subcontracting chains and, in any case, to be subject to less systematic prevention throughout such chains. A broadened approach not limited to the employer, but instead assigning prevention obligations to the overall contractor could considerably improve prevention effectiveness. Among the significant data in the results of the SUMER 2010 survey, the two areas of occupational activity where employees are most exposed to carcinogenic agents are maintenance (43%) and building and public works (32%), both of which are greatly associated with subcontracting. Moreover, a sector approach could also make a useful contribution, in particular by developing prevention measures which take account of the frequency of multiple exposures and by identifying 'cocktails' relatively typical for certain activities.

## **8. Conclusions**

In such a complex field, market rules are in constant interaction with occupational health rules. Regulation must be based on public research in numerous different fields and collectivisation tools are essential in order to improve prevention practices. The added value of a Community policy seems obvious. Suffice to note that, before the adoption of

the 1990 Directive on occupational exposure to carcinogenic agents, national legislation was piecemeal and purely reactive, addressing – without any overall coherence – just a few specific risks (asbestos, vinyl chloride, benzene, etc.). In 1990, the majority of Member States of the European Union had not yet ratified ILO Convention 139 (the Occupational Cancer Convention) of 1974, even though its provisions are minimalist<sup>21</sup>.

As shown by more than 40 years' experience, the obstacles in the way of a Community policy are considerable. The challenge is far more antagonistic than for work-related accidents. Effective prevention of occupational cancers would bring to the fore an important factor in social inequalities in health, running contrary to the dominant trend towards an increase in inequalities in most fields. Beyond this challenge for society, it may also be stated that there are few financial incentives pushing employers to upgrade prevention. The morbidity and mortality caused by occupational cancers only involve marginal costs for companies, in particular owing to the often very long latency periods between exposure and the appearance of pathologies. In the great majority of cases, exposure to carcinogens is not associated with a dysfunction in the production process and does not disrupt it. The pressure exerted by the trade union movement is also less strong than in other prevention fields. Different factors contribute to this situation: lower social visibility, great differentiations in the levels of risk depending on the sectors, difficulties in supporting collective intervention at an appropriate level of expertise, the tendency to delegate the most complex questions of prevention to specialists.

Although in some countries, including France, the question of asbestos triggered an acute awareness of the importance of preventing occupational cancers (Henry 2007), the European Union has an institutional culture distancing it from societal expectations. Though the health catastrophe was no less severe in the other countries of Europe, the asbestos scandal did not really leave its mark on the European political scene. Suffice it to note the relative indifference to the European Commission's decision to allow Germany to import several tens of tonnes of asbestos each year until 2017. Discrete lobbying by the companies involved (mainly Dow Chemical) was enough for the European Commission to postpone until 2025 the date of the total ban on asbestos initially planned for 2005<sup>22</sup> and to turn a blind eye to the clear illegality of the exemption granted by the German authorities to Dow Chemical<sup>23</sup>. The possible health impact of this measure is no doubt minor (except, of course, for asbestos mine workers located in Brazil and in transport activities from the mine to the ports) but its symbolic impact is considerable: it is hampering efforts to ban asbestos worldwide.

Apart from questions of health at work, another factor is increasingly involved. The Community institutions share, to varying degrees, the ideology whereby the ultimate legitimacy of any legislation lies in its economic efficacy. This is a common base for the beliefs of different institutions from the Commission to the European Court of Justice.

**21.** As of January 2015, 13 EU Member States had not yet ratified this convention: Austria, Bulgaria, Cyprus, Spain, Estonia, Greece, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania and the United Kingdom.

**22.** ECHA supports the maintenance of this derogation until 31 December 2025. This position reflects the intense lobbying conducted by the multinational Dow Chemical.

**23.** On the basis of Community law, Germany was able to grant an exemption concerning the import of membranes containing asbestos fibres. The exemption has been extended to the import of fibres.

This instrumental vision of legislation expresses a convergence between the apologists for market laws in the liberal tradition and the political and economic elites of Central and Eastern Europe trained in the Stalinist tradition. While not ruling out debate between different political options, this view considerably impoverishes it and above all shuts the door on social mobilisations and debates on social projects. This tendency can be seen, often like a caricature, in the implementation of a regulatory strategy whose watchwords are impact assessments, the reduction of ‘administrative burdens’ and the simplification of companies’ obligations (Vogel and Van den Abeele 2010). The legitimacy of legislation on occupational cancers lies in the reduction of social inequalities in health and in the coherence of rules intended to reduce an employee’s life, body and health to the status of goods (‘human *resources*’) to be exchanged for a salary. Such legitimacy justifies a significant limitation of the freedom to engage in enterprise and of employers’ prerogatives in technological choices and the organisation of work. This is one of those fields where it seems obvious that the sum of individual egos never results in collective happiness, whatever trust is put in the invisible hand of the market.

The logjam in European policy concerning occupational cancers implies a clear risk of this core element of any prevention strategy being renationalised. This would have two major drawbacks: a loss of effectiveness through the dispersion of efforts among the 28 Member States (a trend already visible in the production of OELs and in the campaigns in favour of substitution) and a negative spiral of competition that would hamper the efforts made in those countries which have made most progress over the last 10 years. Eventually, the question is whether the European Union, which, in the ’90s, played a stimulating role in prevention policies in the field of occupational health, is at risk of becoming an obstacle to progress in this field.

## References

- Brickman R., Jasanoff S. and Ilgen T. (1985) *Controlling chemicals: the politics of regulation in Europe and the United States*, Ithaca, Cornell University Press.
- Clapp R., Jacobs M. and Loechler E. (2007) *Environmental and occupational causes of cancer: new evidence 2005–2007*, Lowell, University of Massachusetts.
- Cavet M. and Léonard M. (2013) *Les expositions aux produits chimiques cancérogènes en 2010*, Dares Analyses 54, Paris, Direction de l’animation de la recherche, des études et des statistiques. <http://travail-emploi.gouv.fr/IMG/pdf/2013-054-2.pdf>
- CEO (2015) *A toxic affair: how the chemical lobby blocked action on the hormone disrupting chemicals*, Brussels, Corporate European Observatory. <http://corporate.europe.org/food-and-agriculture/2015/05/toxic-affair-how-chemical-lobby-blocked-action-hormone-disrupting>
- Engel C. and Rasanayagam S. (2015) *Working women and breast cancer: the state of the evidence*, San Francisco, Breast Cancer Fund. <http://www.etui.org/content/download/21116/176339/file/working-womenand-breast-cancer-1.pdf>
- European Commission (2001) *White paper - Strategy for a future Chemicals Policy*, COM(2001) 88 final, 27 February 2001. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:en:PDF>

- ECHA (2015) 2014 CMR report, Helsinki, European Chemicals Agency.  
<http://dx.doi.org/10.2823/959490>
- Hansen J. and Lassen C.F. (2011) Occupation and cancer risk by use of Danish registers, *Scandinavian Journal of Public Health*, 39 (suppl. 7), 136-140.
- Henry E. (2007) *Amiante, un scandale improbable : sociologie d'un problème politique*, Rennes, Presses universitaires de Rennes.
- Heyvaert V. (2001) Balancing trade and environment in the European Union: proportionality substituted?, *Journal of Environmental Law*, 13 (3), 392- 407.
- Horel S. (2015) *Intoxication. Perturbateurs endocriniens, lobbyistes, eurocrates : une bataille d'influence contre la santé*, Paris, la Découverte.
- Kauppinen T. *et al.* (2000) Occupational exposure to carcinogens in the European Union, *Occupational Environmental Medicine*, 57 (1), 10-18.
- Legrand E. and Mias M. (2013) Zones d'ombre dans la prévention des risques cancérigènes, *Sociologies pratiques*, 2013/1 (26), 71-83.
- Markowitz G. and Rosner D. (2013) *Deceit and denial: the deadly politics of industrial pollution, with a new epilogue*, Berkeley, California University Press.
- Mengeot M.A. (2007) *Occupational cancer: the Cinderella disease*, Brussels, ETUI.
- Menvielle G. *et al.* (2008) Inégalités sociales de mortalité par cancer en France : état des lieux et évolution temporelle, *Bulletin épidémiologique hebdomadaire*, 33, 289-292.
- Michaels D. (2008) *Doubt is their product: how industry's assault on science threatens your health*, New York, Oxford University Press.
- Musu T. (2010) REACH: an opportunity for trade unions. Putting knowledge to work in the workplace, Brussels, ETUI.
- Musu T. (2011) Trade union priority list for REACH Authorisation, Brussels, ETUI.
- Musu T. (ed.) (2013) Special report - Chemical hazards: state of play 6 years into REACH, *HesaMag*, 08, 12-44.
- Pukkala E. *et al.* (2009) Occupation and cancer: follow-up of 15 million people in five Nordic countries, *Acta Oncologica*, 48 (5), 646-790.
- Püringer J. (2011) 'Derived Minimal Effect Levels' (DMELs): Defizite ein Jahre nach der REACH-Registrierungspflicht, *Gefahrstoffe-Reinhaltung der Luft*, 71 (11-12), 471-480.
- Puts C. and ter Burg W. (2015) *Identifying prevalent carcinogens at the workplace in Europe*, Bilthoven, National Institute for Public Health and the Environment.
- Rial González E., Cockburn W. and Irastorza X. (eds.) (2010) *European survey of companies on new and emerging risks: managing safety and health at work*, Bilbao, European Agency for Safety and Health at Work.
- Schaible C. and Buonsante V. (2012) Identifying the bottlenecks in REACH implementation: the role of ECHA in REACH's failing implementation, Brussels, European Environmental Bureau.
- Schmidt C.W. (2013) Uncertain inheritance: transgenerational effects of environmental exposures, *Environmental Health Perspectives*, 121 (10), A298-303.
- Schneider E. and Kosk-Bienko J. (eds.) (2009) *Exploratory Survey of OELs for CMR substances at EU Member States level*, Bilbao, European Agency for Safety and Health at Work.
- Soffritti M. *et al.* (2013) Vinyl chloride: a saga of secrecy, in EEA (ed.) *Late lessons from early warnings: science, precaution, innovation*, Copenhagen, European Environment Agency, 179-202.
- Thébaud-Mony A. (2006) Histoires professionnelles et cancer, *Actes de la recherche en sciences sociales*, 163, 18-31.

Vogel L. and Van den Abeele E. (2010) Better regulation: a critical assessment, Report 113, Brussels, ETUI.

Wriedt H. (2016) Carcinogens that should be subject to binding limits on workers' exposure, Report 136, Brussels, ETUI.

All links were checked on 24.07.2018.