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Pillars of European chemicals legislation

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ABSTRACT: This article examines key European regulations concerning hazardous substances. To this end, the relevant provisions were analyzed and their requirements identified.
The REACH and CLP regulations form the basis for the registration, classification, labeling, and handling of chemicals and chemical products within European Union member states. They are supplemented by other EU regulations addressing particularly hazardous chemicals, covering areas such as import and export (PIC Regulation) as well as manufacture and storage (Seveso III Directive). Furthermore, regulations concerning specific product groups—such as biocides, pesticides, persistent organic pollutants, and detergents—are discussed. The regulations clearly indicate that both individual chemicals and mixtures may be subject to registration and/or notification obligations.

KEYWORDS: European laws, hazardous substances, REACH, CLP, PIC

INTRODUCTION

In 1957, six European nations (Belgium, France, Italy, Luxembourg, the Netherlands, and the Federal Republic of Germany) founded the European Economic Community (EEC) [1]. The states sought to establish a common market and foster greater economic growth. In 1967, this community was integrated into the European Communities (EC) [2]. The number of member states grew over the years, reaching 12 by 1986. Consequently, further action was required. The Treaty on European Union (EU), concluded in 1992/1993 redefined the Community's objectives, adding, among other things, the protection of people and the environment [3]. This laid the foundation for a common environmental and chemicals policy. Another 15 years later, Article 191 of the Treaty on the Functioning of the European Union [4] set out fundamental protective aspects of this policy: prevention, precaution, and addressing pollution at source. The package was rounded off by provisions holding polluters accountable - and sanctioning them where appropriate - if they violate the rules. This remains the status of the European Union's current preventive chemicals legislation to this day.
As early as the 1957 founding treaty of the European Economic Community, it was agreed that member states would adopt uniform legislation in certain areas. Under Article 189, there are several ways to enact such Community legislation [1]. If the Community wishes to address all member states collectively and implement its measures without alteration, it employs a so-called regulation. This applies immediately and directly to all members from a specified date, effectively overwriting the national law of the member state concerned. If, however, member states are to incorporate EU rules into their existing legal frameworks, the EU issues a directive. While the objective set out in a directive is binding, the measure allows for a degree of discretion when being transposed into national law. In contrast to these two options, a decision addresses only specific member states; it governs concrete situations and is binding on the nation to which it is addressed. Finally, there are recommendations and opinions. As the names imply, these are non-binding expressions of views, though they can certainly indicate future trends. The chemical regulations presented below take the form of either regulations or directives. They constitute a significant part of European chemicals legislation. There are also other relevant EU regulations that have not been included in this article, as doing so would extend the scope too far.

MATERIALS AND METHODS

To analyze European chemicals legislation, the fundamental legal frameworks were reviewed and evaluated in their original versions. The analysis began with the REACH and CLP Regulations, which establish requirements for individual chemicals and the mixtures produced from them. Additionally, legislation governing the import and export of particularly hazardous chemicals was selected for review. Finally, regulations concerning specific categories of use were examined.

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RESULTS

After the United Nations adopted a harmonized classification and labeling system in late 2002 [5], the EU decided to follow suit and revise its legislation accordingly. Until then, the European chemicals market had been regulated by the 1967 Substances Directive [6] and the 1999 Preparations Directive [7]. These directives were superseded by two new regulations.

1. Registration, Evaluation, Authorisation and Restriction of Chemicals

Since 2007, the new regulatory framework for chemical substances has been REACH [8]. The acronym stands for Registration, Evaluation, Authorisation and Restriction of Chemicals, succinctly abbreviating the regulation's unwieldy full title. In essence, it establishes a new regulation governing the registration, evaluation, authorization, and restriction of chemical substances. Additionally, a new body - the European Chemicals Agency (ECHA) - is created, and existing directives and regulations are amended or repealed.

The REACH Regulation comprises 141 articles and 17 annexes. It places obligations on manufacturers, importers, and downstream users regarding the registration, submission of data, and self-classification of chemicals intended for the EU market. The guiding principle is "No data, no market." Whereas under previous directives the authority acted as a party subject to reporting requirements, under REACH it serves as a supervisory and support body for the registering parties. This shift in roles results from the sluggish cooperation between the authority and the industry regarding the provision of additional substance data. Under REACH, manufacturers and importers are responsible for basic chemical data; they must obtain this information and submit it during registration. When marketing products, they are required to provide essential substance information to their customers - known as downstream users - typically via a document called a Safety Data Sheet.

A similar set of information was already addressed in 1988 in Directive 88/379/EEC [9]. In 1991, Directive 91/155/EEC [10] established a template for a safety data sheet, mandating a structure of 16 sections with prescribed headings. Article 1(2) of this Directive stipulates that the information must be provided to the recipient free of charge - no later than the first delivery of the chemical substance or preparation, and subsequently following any revision made due to significant new information regarding safety, health protection, and the environment. The REACH Regulation draws upon this framework. Communication within the supply chain regarding hazardous substances continues to rely on mandatory safety data sheets, although additional options for conveying information remain possible.

A review of Article 1 of the REACH Regulation clarifies that the objectives originally set out in the treaties of the European Community and the European Union are here specifically applied to chemicals policy. In addition to the protection of human health and the environment, animal welfare is also addressed; Paragraph 1 calls for the pursuit of alternative methods for assessing hazards posed by substances. Furthermore, it is emphasized that the obligations placed on all parties contribute to fostering competitiveness. Paragraph 3 explicitly reiterates the responsibilities of manufacturers, importers, and downstream users, as well as the importance of the precautionary principle.

Under Article 2, exemptions from the Regulation's registration requirements apply to substances governed by other legislation, such as radioactive substances, chemicals in transit, medicinal products, and so forth. Additional exemptions are listed in Annexes IV and V to the REACH Regulation. Article 15 of the REACH Regulation defines substances that are deemed to be already registered. These include substances manufactured or imported exclusively for use in plant protection products or biocidal products that are covered by the relevant directives.

In accordance with Articles 6 and 7, the registration obligation for manufacturers or importers applies once an annual volume of one tonne is reached - whether for the substance itself, its presence in preparations, or its inclusion in articles. Following the submission of the substance dossier, the European Chemicals Agency (ECHA) has a three-week period to raise objections; this ensures prompt processing by ECHA. If no objection is raised, the manufacturer or importer may proceed.

Article 10 governs the information to be submitted. This includes a technical dossier containing predefined information and, where necessary, a chemical safety report. The predefined information in the dossier also includes the identification of the expert who assessed specific substance properties. Information requirements are tiered according to tonnage in Article 24. The greater the intended market volume, the stricter the requirements become. The increments follow powers of ten. Basic information must be submitted for quantities of 1 tonne or more. The first increase in the scope of information occurs at 10 tonnes or more, followed by thresholds of 100 tonnes or more and 1,000 tonnes or more.

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The communication of substance-related information within the supply chain is specifically regulated in Articles 31 to 33. Information is frequently passed on via the aforementioned safety data sheet. If a safety data sheet is not required - because the substance exhibits no hazardous properties and there are no threshold values to be monitored - relevant information must still be passed on to downstream users. This applies to both substances and mixtures.

Safety data sheets do not need to be prepared for articles containing hazardous components. However, for articles containing specific hazardous constituents at a concentration exceeding 0.1%, the substance in question must at least be identified in accordance with Article 33.

The substances referred to here are carcinogenic, germ cell mutagenic, toxic to reproduction, (very) persistent, (very) bioaccumulative, or toxic in nature. Alternatively, they may be endocrine disruptors.

REACH is subject to continuous further development. The European Commission is currently focusing on the group of highly persistent per- and polyfluoroalkyl substances [11]. These substances accumulate permanently in the environment and have various adverse effects; consequently, plans are in place to restrict their manufacture and use.

2. Classification, Labelling and Packaging

The second EU regulation that applies to all chemicals is the CLP Regulation [12]. It entered into force in 2009. CLP stands for Classification, Labelling and Packaging and is synonymous with Regulation No. 1272/2008. It governs the classification, labelling, and packaging of substances and mixtures, definitively repeals the 1967 Substances Directive and the 1999 Preparations Directive, and introduces amendments to the REACH Regulation. The CLP Regulation contains over 60 articles and 8 annexes. It aligns the European classification and labelling system for substances and mixtures with the United Nations' Globally Harmonised System (GHS) [13]. Based on this, there are now two types of classification in the EU: harmonised classification for well-known chemicals, also called legal classification, and self-classification. Legal classifications are binding within the EU and are listed in Annex VI, Part 3 of the CLP Regulation. This list includes substances such as hydrogen, sodium hydroxide, and sulfuric acid, whose chemical properties are well-established. New substances are subject to self-classification by manufacturers or importers. The classifications of all registered substances can be found online in a freely accessible database maintained by the ECHA, the so-called Classification and Labelling Inventory. Following alignment with the GHS system, 17 classes for physical and chemical hazards, 11 classes for health hazards, 4 classes for environmental hazards, and 1 class for ozone depletion are now available for classification.

The CLP Regulation governs the classification, labelling, and packaging of chemical products. It also obliges member states to establish or designate competent authorities and information centers. Details can be found in its eight annexes. Annex I provides the regulations for the classification and labelling of hazardous substances and mixtures. Annex II supplements these rules for the labelling and packaging of certain substances and mixtures, such as lead or cyanoacrylate, and defines child-resistant closures and tactile hazard warnings. Annexes III and IV contain hazard statements, supplemental hazard information, supplemental labelling elements, and precautionary statements. All of this is translated into the relevant national languages of the Member States. Annex V contains the hazard pictograms, and Annex VI lists substances that are harmonized. Annex VII provides a table for converting an old classification to one according to the CLP Regulation. Finally, Annex VIII contains harmonized information for emergency medical care and preventive measures. Specifically, it concerns the notifications for poison control centers, which must now include a unique formula identifier (UFI). This is an alphanumeric code that can be generated online using a UFI generator [14].

The CLP Regulation was revised again in the fourth quarter of 2024 [15]. New in the Classification section are the definitions for classifying complex substances. There is a five-year exemption for plant extracts, including essential oils. Another new feature in this section is that, in addition to Member States and industry, the European Commission can now also submit harmonized classification proposals. This could lead to a significant change in the regulatory approach. In the labeling section, online retailers are now required to display all labeling elements in their online offers. Often, little to no information is found on the internet in this regard. This is set to change. For labels, there are now requirements for minimum font size, font and background color, as well as line and letter spacing. Folded labels are an explicitly permitted labeling method. Specific requirements have been established for the use of digital labeling. These labels are QR or barcodes that direct the user to a website containing the relevant information. Finally, this section addresses the sale of chemicals via refill stations. In the future, certain requirements regarding packaging, labeling, and the type of product offered will have to be met. In the section on classification and labeling, applicants will be required to update their data records as needed. Furthermore, they will no longer be able to remain anonymous; their identity will be made

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public. New additions to the section on notifications to poison control centers include the option to designate the European Chemicals Agency as the body for receiving relevant information and a clarification regarding the obligations of distributors.

3. Import and Export

Since the general aim at the European level is to regulate the handling of hazardous substances and ensure they are as safe as possible, it is not surprising that there is a separate set of rules for the export and import of particularly hazardous chemicals in the form of the PIC Regulation [16]. It is intended to ensure that hazardous substances can be moved without delay when crossing the customs border of the zone.

The abbreviation PIC stands for Prior Informed Consent Regulation. This regulation stipulates that basic information about the chemicals in question must be exchanged before their transport can take place. The product in question only leaves or enters the territory of the European Customs Union once the express consent of the destination country has been obtained. The particularly hazardous products addressed are chemicals and pesticides that are banned or subject to strict restrictions in the Community. They are listed by name in Annex I of the PIC Regulation. Well-known examples include the solvents benzene and chloroform, and the herbicide atrazine. There are also exceptions to this regulation. For example, it does not apply to narcotics, radioactive materials or waste.

4. Production facilities and storage areas

There are also special requirements for establishments that manufacture or process particularly hazardous chemicals. The so-called Seveso III Directive applies to production and storage facilities where toxic, explosive, flammable, oxidizing, or other particularly hazardous substances are present [17]. This directive dates from 2012 and replaced the Seveso I Directive of 1982 [18] and the Seveso II Directive of 1997 [19]. Its aim is to prevent serious industrial accidents by increasing plant safety. With its catalog of measures, it places obligations on operators, the regulatory authorities, and the respective Member State by requiring safety reports outlining the safety management system, as well as emergency plans and response plans. It also mandates the provision of information to the public, an inspection system, and an information system. Annex I of this directive lists the hazard categories addressed (Part 1) and names the particularly hazardous substances (Part 2). The categories and substances are assigned quantity thresholds with tonnage specifications. These quantities determine the required actions and implementation within the company. Depending on the chemical, just a few hundred kilograms are enough to trigger compliance with the requirements of this directive.

5. Biocidal products

Furthermore, the EU has established regulations for certain product groups. These include, for example, biocides, which are generally subject to authorization. The relevant regulation is the Biocidal Products Regulation of 2012 [20]. Article 3 defines biocidal products as substances or mixtures used to control harmful organisms. Annex V of this regulation specifies which products are included. It lists biocides in four main groups with a total of 22 product types.

The first main group includes disinfectants. The second main group comprises preservatives. The third group of biocides comprises agents for controlling pests of various sizes, such as mice, rats, birds, mites, etc. The fourth main group is a collective group. It includes other biocidal products such as antifouling agents or fluids for embalming and taxidermy.

The Biocidal Products Regulation governs the making available on the market and the use of biocidal products. ECHA reviews the authorization dossiers and makes decisions on the respective applications. It has established a register for biocidal products and provides important information there. Anyone looking for an overview of the active substances that may be used in biocidal products will find it in the REACH-CLP-Biocidal Products Helpdesk [21]. There, the active substances are listed according to the individual product types.

6. Pesticides

Another important product group that is frequently the subject of controversial media discussions is pesticides. According to the now-obsolete 1991 directive on the placing on the market of plant protection products [22], these are active substances and preparations intended to “protect plants and plant products from harmful organisms, to influence the life processes of plants in a manner other than a nutrient (e.g., growth regulators), to preserve plant products, to destroy unwanted plants or plant parts, or to inhibit or prevent unwanted plant growth." Pesticides are also subject to authorization. After all, these are products that are specifically used in agriculture, and their residues can have direct effects on the food chain. However, it is primarily the users who

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are affected by health risks. A look at the 2022 Pesticide Atlas [23] shows the quantities involved and the associated health risks. According to this source, approximately 478,000 tonnes of pesticides were applied in Europe alone in 2019, and this figure is rising. Worldwide, this source also states that approximately 385 million people suffer from pesticide poisoning each year.

The 2009 Plant Protection Products Regulation [24] defines the requirements and conditions for the authorization of pesticide active substances and their ready-to-sell formulations. The authorizations specify, among other things, which product may be used for which purpose, in what quantity, and how often per year. Unlike the biocidal products procedure, applications are not submitted to the ECHA, but to the competent authority of a Member State. This regulation also contains annexes with important information. Annex I defines the geographical zones for the authorization of plant protection products. Annex II contains procedures and criteria for the authorization of active substances, safeners, and synergists. Annex III lists substances whose use in plant protection products is prohibited. Annex IV describes the comparative evaluation of plant protection products containing candidate substitutions, and Annex V provides an overview of the repealed directives.

Another set of rules for plant protection products is the 2009 Pesticide Statistics Regulation [25]. It aims to establish a framework for EU-wide Community statistics on the placing on the market and use of pesticides. The statistics include the annual quantities placed on the market and their agricultural use.

Even more relevant to consumers than a statistical overview is information on legally permitted pesticide residues. This is addressed by the 2005 Pesticide Residue Regulation on maximum residue levels in or on food and feed [26]. It describes a Community procedure for maximum residue level applications and establishes controls. Annexes II and III specify - sorted by food groups and examples of individual products to which the information applies - the permitted maximum residue levels of certain pesticides in mg/kg of food.

7. Persistent Organic Pollutants

Another group of chemicals receiving particular attention is persistent organic pollutants, abbreviated as POP. The 2019 POP Regulation [27] targets precisely this group of organic compounds, which degrade or transform very slowly in the environment. These include pesticides such as DDT, industrial chemicals such as polychlorinated biphenyls, and unintended by-products of industrial processes such as dioxins and furans. The regulation lays down detailed requirements regarding the manufacture, placing on the market, use, and release of these substances. Member States are required to draw up action plans to minimize these chemicals, with the ultimate goal of phasing out their production and use.

8. Detergents

Sixty to seventy years ago, several European nations faced a water-related problem. In addition to industrial wastewater, another culprit was easily identified by the mountains of foam on certain rivers: household detergents and cleaning agents. The phosphates they introduced into waterways acted as a potent fertilizer for algae, while their poorly biodegradable surface-active substances - the surfactants - created the aforementioned foam. Legislation was enacted at the European level to address both issues.

The Detergents Regulation of 2004 [28] governs the biodegradability of surfactants in detergents and restricts or prohibits their use based on biodegradability criteria. It mandates specific labeling requirements for detergent packaging and specifies the information manufacturers must make available to competent Member State authorities and medical personnel.

The Detergents Regulation underwent its first amendment in 2006 [29]. This amendment modified Annex III (methods for testing the ultimate biodegradability—mineralization—of surfactants in detergents) and Annex VII (labeling and ingredient data sheets). A second amendment in 2012 limited the content of phosphates and other phosphorus compounds in consumer products such as laundry detergents and machine dishwashing detergents [30].

A new Detergents and Surfactants Regulation was adopted in 2026 [31], set to replace the previous regulation from 2004 as of September 23, 2029. Key changes concern labeling, the introduction of a digital product passport for detergents and surfactants, biodegradability, and requirements for cleaning products containing microorganisms. In the future, market surveillance authorities

DISCUSSION

Formulating a comprehensive European chemicals policy took several decades. Throughout this process, all key stakeholders had a seat at the negotiating table and were able to voice their wishes and concerns. Today, a body of legal regulations exists that rests on the pillars of:

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- prevention,
- precaution,
- addressing issues at the source, and
- polluter liability.

A risk-based approach has thus prevailed within the European Union. With the establishment of the European Chemicals Agency (ECHA) in 2007, the EU also created an expert oversight body to effectively enforce the established rules against the interests of trade and industry [32]. ECHA plans to conduct Europe-wide inspections in the near future to monitor compliance with key regulations [33], while the legislator - represented by the European Commission - is working on issues such as the reduction of animal testing [34]. More far-reaching plans, such as the revision of REACH, have been put on hold for the time being.

CONCLUSION

This article provides an overview of current European chemicals legislation, which serves as a minimum standard for handling hazardous substances on the European market. Depending on the specific issue, national regulations may supplement these rules or impose stricter requirements than the European provisions. The guiding principle of European chemicals policy - “no data, no market” - means that chemicals and products are subject to registration or notification requirements.

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