1
Introduction

REACH or **REACh** is the widespread and well-known abbreviation for a European regulation that is entitled "Regulation (EC) No 1907/2006 of the European Parliament and of the Council" [1]. This regulation entered into force on 18 December 2006.

The single letters of the word REACH go back on the subtitle of this regulation [1] that tells us something about the content of this piece of legislation – **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals (REACH) [1].

1.1
History

The concept to notify substances is not completely new. Before REACH entered into force European manufacturers or importers of new substances were obliged to notify these substances with the national authorities when they intended to produce or import a new substance in amounts of 10 kg/year or more. This was demanded by the predecessor(s) of REACH [1], whereas in Directive 67/548/EEC [2] also classification, packaging and labeling of dangerous substances was regulated. Directive 67/548/EEC [2] was repealed by the Regulation (EC) No 1272/2008. The former notified new substances are called NONS (notified new substances).

Already well-known substances that had been marketed before 1981 and therefore were listed in the EINECS [3] were not considered at all.

In the past there had been national laws and rules concerning the handling of chemical compounds. EU enterprises doing business with other companies in different countries had to struggle with a jungle of not clearly arranged rules in their daily business. It was hardly possible to follow up all amendments of the different laws being in force in different countries.

Therefore, it was an aim to harmonize the laws in the member states of the European Union. As a starting point the European Commission in Brussels made directives. Every directive had to be converted into national law(s) by all member states.

Very often this resulted in smaller or greater discrepancies between certain member states, because the directive was transformed in a slightly different way

REACH Compliance – The Great Challenge for Globally Acting Enterprises, First Edition.
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European Economic Area (EEA)	
28 EU Member States	**plus 3 further states**
Austria	Norway
Belgium	Iceland
Bulgaria	Liechtenstein
Croatia*	
Cyprus	
Czech Republic	
Denmark	
Estonia	
Finland	
France	
Germany	
Greece	
Hungary	
Ireland	
Italy	
Latvia	
Lithuania	
Luxembourg	
Malta	
Netherlands	
Poland	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
United Kingdom	

* Access of Croatia in July 2013.

Figure 1.1 European Economic Area (EEA) consisted of 30 states (June 2012).

into national laws. In some cases it was necessary to amend existing national laws, because European right has a higher priority than already existing laws in a member state.

The situation is completely different with REACH as it is a European regulation. Therefore, REACH is directly valid in the whole European Economic Area (EEA), consisting of the member states of the European Union plus Norway, Iceland and Liechtenstein (see Figure 1.1) without any necessity to transform it into national law.

As a direct consequence there had to be established a new European Authority the so-called **E**uropean **Ch**emicals **A**gency (ECHA) that is located in Helsinki (Finland) [4].

ECHA is in charge of all European manufacturers, importers and Only Representatives (ORs) that registered already or intend to register chemical substances under REACH as a prerequisite to manufacturing and selling chemical compounds within the European Union/EEA.

Completely new and maybe the most important amendment to former laws is that now industry is responsible for the protection of humans and the environment. "No data, no market" [5] is the burden industry has to bear in mind.

The fact that REACH applies not only to new chemical compounds but also to all the substances listed in EINECS is also new [3].

As mentioned before, at present REACH is applied in the European Economic Area (28 EU member states plus Norway, Iceland and Liechtenstein). Although REACH does not apply in Non-EU countries, REACH also has a great influence on globally acting enterprises outside of the EEA.

In particular, it is a great challenge for companies located in states on the European continent, but who are not a member of the European Union itself, for example, Swiss companies. However, in having a certain knowledge of REACH matters, these internationally acting enterprises sometimes can even benefit from REACH. We will see that in detail at a later stage.

1.2 The REACH Regulation – A Short Overview on the Table of Contents

The REACH regulation is a bulky document but as it is subdivided into several parts that are themselves divided up into single articles you will be in the position to have an overview of this complex topic within a short time.

After having understood the general principles you can study the relevant parts of this piece of legislation in depth whenever it should become necessary.

Within this chapter I will give only a short overview on the content of the REACH regulation as the aim of this book is to concentrate on the most important aspects.

The title of the "Regulation (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006" [1] gives in the first part the number of the regulation (No 1907) and the year when it entered into force (No 1907/2006) and it is also stated who passed the law (OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL), and finally, followed by the exact date (18 December 2006) when it entered into force.

The subtitle describes the subject of the regulation, in this case "concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC" [1].

In the beginning of the regulation there is a rationale as to why it has been taken into consideration to work out this piece of legislation. There are also references to already existing directives and regulations and the kind of influence they will have on REACH or how REACH will have an influence on the already existing laws. It is a sort of evaluation of which regulation or directive will have an effect on other pieces of legislation and of which one will have a higher priority. As in

Section (15) of this statement in the beginning of the regulation the conclusion is made that it is necessary to establish a European Chemicals Agency "to ensure effective management of the technical, scientific and administrative aspects of this Regulation at Community level" [4], all registrants to cooperate with the same European Authority. This "independent central entity" is the well-known ECHA in Helsinki.

After 131 short sections of such statements as mentioned above, finally the table of contents can be found within the REACH regulation [1].

The REACH regulation consists of fifteen Titles and so far seventeen Annexes. Each title is subdivided into several chapters. Each chapter contains several articles. However, the articles of the REACH regulation are numbered consecutively and independently of the chapters (see Figure 1.2).

The most import titles are the following:

Title I deals with general issues. First, we find a chapter about "Aim, scope and application" [6], followed by "Definitions and general provision" [7].

Title II devotes to "Registration of substances" [8], whereas **Title III** deals with "Data Sharing and Avoidance of unnecessary testing" [9].

Passing on information within the Supply Chain and obligations of Downstream Users are administered in **Titles IV and V** [10, 11].

Title VI [12] is engaged in Evaluation of dossiers.

Authorizations are the subject of **Title VII** [13] and Restrictions are the topic for **Title VIII** [14].

Concerning the annexes it is important to know that **Annex IV and V** contain "Exemptions from the obligation to register" [15, 16].

Annex VI [17] lists information requirements referred to in Article 10. Article 10 is entitled "Information to be submitted for general registration purposes".

In Section 2 of **Annex VI** can be found the requirements concerning analytical information and analytical methods that have to be submitted to ECHA with Inquiry dossiers and also with dossiers for a full registration.

In **Annexes VII to X** [18a,b,c,d] there are lists with standard information requirements depending on the tonnage band that is relevant for the registration of a certain substance.

Annex XI [19] is important in cases where the standard testing regime described in **Annexes VII to X** [18a,b,c,d] seems not to be appropriate and therefore a registrant intends to deviate from the standard testing regime.

Annex XIV [20] contains a list of substances subject to authorization. This section was an empty one at the time REACH entered into force, but in the ongoing process when substances are identified for becoming subject to authorization this section will be amended regularly. This annex is a sort of living document.

1.3 Purpose and Scope of REACH

As usual in regulations in the first chapter of the REACH regulation [1] we find a statement concerning aim and scope.

Table of contents

TITLE 1	**General issues**	*Articles 1 to 4*
	Chapter 1	Aim, scope and application
	Chapter 2	Definitions and general provision
TITLE 2	**Registration of substances**	*Articles 5 to 24*
	Chapter 1	General obligation to register and information requirements
	Chapter 2	Substances regarded as being registered
	Chapter 3	Obligation to register and information requirements for certain types of isolated intermediates
	Chapter 4	Common provisions for all registrations
	Chapter 5	Transitional provisions applicable to phase-in substances and notified substances
TITLE III	**Data Sharing and Avoidance of unnecessary testing**	*Articles 25 to 30*
	Chapter 1	Objectives and general rules
	Chapter 2	Rules for non-phase-in substances and registrants of phase-in substances who have not preregistered
	Chapter 3	Rules for phase-in-substances
TITLE IV	**Information in the Supply Chain**	*Articles 31 to 36*
TITLE V	**Downstream Users**	*Articles 37 to 39*
TITLE VI	**Evaluation**	*Articles 40 to 54*
	Chapter 1	Dossier evaluation
	Chapter 2	Substance evaluation
	Chapter 3	Evaluation of intermediates
	Chapter 4	Common provisions
TITLE VII	**Authorization**	*Articles 55 to 66*
	Chapter 1	Authorization requirement
	Chapter 2	Granting of authorizations
	Chapter 3	Authorization in the supply chain
TITLE VIII	**Restrictions on the manufacturing, placing on the market and use of certain dangerous substances and preparations**	*Articles 67 to 73*
	Chapter 1	General issues
	Chapter 2	Restriction process
TITLE IX	**Fees and charges**	*Article 74*
TITLE X	**Agency**	*Articles 75 to 111*
TITLE XI	**Classification and Labeling Inventory**	*Articles 112 to 116*
TITLE XII	**Information**	*Articles 117 to 120*
TITLE XIII	**Competent authorities**	*Articles 121 to 124*
TITLE XIV	**Enforcement**	*Articles 125 to 127*
TITLE XV	**Transitional and final provisions**	*Articles 128 to 141*

Figure 1.2 Short overview on the table of contents of the REACH regulation including the list of Annexes.

List of Annexes

ANNEX I	General provisions for assessing substances and preparing Chemical Safety Reports
ANNEX II	Guide to the compilation of Safety Data Sheets
ANNEX III	Criteria for substances registered in quantities between 1 and 10 tonnes
ANNEX VI	Exemption from the obligation to register in accordance with Article 2 (7) (a)
ANNEX V	Exemption from the obligation to register in accordance with Article 2 (7) (b)
ANNEX VI	Information requirements referred to in Article 10
ANNEX VII	Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more
ANNEX VIII	Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
ANNEX IX	Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
ANNEX X	Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more
ANNEX XI	General rules for adaptation of the standard testing regime set out in ANNEXES VII to X
ANNEX XII	General provisions for Downstream users to assess substances and prepare Chemical Safety Reports
ANNEX XIII	Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances
ANNEX XIV	List of substances subject to Authorization
ANNEX XV	Dossiers
ANNEX XVI	Socioeconomic analysis
ANNEX XVII	Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

Figure 1.2 (*Continued*)

In Article 1 (1) [21] is stated "The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."

This statement sounds pretty good, but it is difficult to judge whether it is possible to increase the level of protection of human health and the environment while also competitiveness and innovation shall be influenced in a positive way.

Representatives of the chemical industry normally have the perception that REACH is a great burden starting with purchasing of raw materials but not ending in selling a product to the customers.

In REACH Article 1 (2) [21] it is mentioned that the REACH regulation lays down provisions that shall apply to the whole lifecycle of a substance from manufacture, placing on the market until the use of the substance [21].

It is very important that "this Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary

principle" [21]. That means that the responsibility for ensuring a high level of protection of human health and environment lies within the chemical industry. A company in this sense is not only responsible to take care of the workers within the company but also responsible to take care of the protection of consumers and the environment. However, obligations and responsibility do not end at the moment a substance is sold to customers, because a registrant under REACH has in the registration dossier also to take care to cover all identified uses and corresponding exposure scenarios of his customers and the whole supply chain until the end of the lifecycle of the substance to be registered.

European Authorities, namely ECHA, carry over the responsibility concerning all risks that result for human beings and the environment from manufacturing and use of a certain substance to the registrant.

In practical terms this means every company has to ensure a manufacturing process by using state-of-the-art technologies to reduce risks for human and environment to a minimum. Furthermore, passing on information concerning safe handling to all customers and all members of the supply chain in an appropriate way is required.

1.4 Other Regulations and Directives that are Important in the Context of REACH

Already in the subtitle of REACH [1] there are cited some Directives and Regulations that were influenced by REACH [1].

Whereas Directive 1999/45/EC [22] is only amended by REACH [1], there are other directives and regulations that were repealed at the time REACH [1] entered into force. Repealed were Council Regulation (EEC) No 793/93 [23], Commission Regulation (EC) No 1488/94 [24], Council Directive 76/769/EEC [25], Commission Directive 91/155/EEC [26], Commission Directive 93/67/EEC [27], Commission Directive 93/105/EC [28] and as well Commission Directive 2000/21/EC [29].

Within the 131 short sections in the beginning of REACH [1] are further remarks concerning the influence of REACH on other regulations and directives and *vice versa*. In Section 9 [30] there is given the statement that by assessment of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC [2], Council Directive 76/769/EEC [25], Directive 1999/45/EC [22], Council Regulation (EEC) No 793/93 [23]) were identified a number of problems, resulting in disparities between the laws, regulations and administrative provisions in Member States. As the mentioned problems are history in so far that REACH applies in all Member States and existing national laws are ancillary to EU Law we will not go into details within this book. However, it may be that there are still some disparities in case of on-site inspections in chemical companies as the inspections are still accomplished by Member State competent authorities and not by ECHA.

There are other laws that remain unaffected by REACH [1] for example, the application of Directives on worker protection and the environment, especially

Directive 2004/37/EC [31] and there are also laws that do not affect REACH, for example, Council Directive 76/768/EEC [32]. The phase-out of testing on vertebrate animals for the purpose of protecting human health is restricted to the use of a substance in cosmetics [33]. When a substance is also used for other purposes than the use in cosmetics and these uses fall under the scope of REACH there will be no chance to outflank testing requirements demanded by REACH.

Within the 131 short sections in the beginning of REACH [1] we also find hints on substances that are excluded from the scope of REACH. We will focus on the exemptions from REACH in Section 3.9 of this book, therefore these cases are not discussed in this chapter.

Because of practical reasons it seems useful to mention some further legal documents that are of importance in the context of REACH in separate sections even when they are not mentioned in REACH [1] itself.

The selection cannot be complete, but the chosen ones have great influence in daily business. It is highly recommended that you are aware of the fact that these regulations exist and in case it should be necessary you will be in a position to consult the legal text concerning the details.

1.4.1 Fees and Charges Payable to the European Chemicals Agency

Article 74 (1) of REACH [1] states that fees that are required according to several Articles within this piece of legislation shall be specified in a Commission Regulation. In REACH [1] itself there are no concrete prices defined, but Article 74 (3) gives criteria to be considered in fixing prices for diverse types of services that ECHA provides: "The structure and amount of the fees . . . shall take account of the work required by this Regulation to be carried out by the Agency and the competent authority and shall be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of the Agency's revenue pursuant to Article 96(1) is sufficient to cover the cost of the services delivered." It is also laid down that there should be reduced fees for SMEs. The structure and amount of fees, furthermore, shall take into account whether the registration is done jointly or as a single submission.

Circumstances under which a proportion of the fees will be transferred to the relevant Member State competent authority should be based on REACH Article 74 (4) and also be considered in the piece of legislation dealing with the fees order.

On 16 April 2008 Commission Regulation (EC) No 340/2008 dealing with fees and charges payable to the European Chemicals Agency entered into force. As we will see some details concerning fees payable for diverse types of registrations and some further services as for example, PPORD and Authorization in other chapters of this book whenever suitable, here no details shall be provided. However, this section can be closed with the remark that figures that were given within the fee order from 2008 were already amended for the first time in March 2013. The amendment was done in accordance with the statement of the former valid regulation in Section (17): "Fees and charges provided for under this Regulation should

be adapted to take account of inflation and for that purpose the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonized indices of consumer prices should be used."

Dated 20 March 2013 the former valid Regulation (EC) No 340/2008 was amended. Now the COMMISSION IMPLEMENTING REGULATION (EU) No 254/2013 [34] is valid.

1.4.2 Competition Law

REACH demands that companies that pre-registered the same substance and intend to register this substance should cooperate aiming to prepare a Joint submission. Information on the intrinsic properties of a substance to be registered jointly has to be shared. Data sharing is demanded especially in the case of studies that have been done by using vertebrate animals. It is clear that financial compensation within a consortium should take place – it shall be determined in a fair, transparent and non discriminatory way [35].

REACH does not give details on how companies can fulfill the single tasks, but you have to be aware of the fact that REACH is not a Competition-law-free zone.

That means *inter alia* that you are not allowed to abuse meetings concerning REACH matters for illegal actions such as speaking about prices of your products or any other information that has to be handled as confidential business information in accordance with the competition law. The above-mentioned examples may be obvious to everybody, but there may occur other situations that are not so clear. In case costs within a consortium shall be divided among the members based on the individual tonnage of a substance produced by every member, it is necessary to have an independent trustee, for example, a consultant company acting on behalf of the consortium dealing with confidential information that is not given to other members of the consortium.

In some cases, providing a Substance Information Profile for doing the Sameness-Check within a consortium can cause difficulties for example, in the case that from identified by-products or impurities can be traced back to the manufacturing process. On the other hand, you are obliged to ensure that Sameness is given to prove that one can assume that studies/tests done with the substance from company A is as similar to the substance from Company B that Company B does not have to repeat the studies/tests with the substance as manufactured within company B. To avoid trouble with the competition law, it is recommended to provide less detailed Substance Identification profiles. Very often it will be justifiable to agree on the main constituent and no impurity present that would be relevant for classification of the substance.

It could even be critical to think about preparing eSDS to be shared within the consortium. In general, it seems useful to prepare an eSDS jointly within a consortium as it is less work for each member and there will be a chance to agree on a harmonized template. If several companies within a consortium are willing to

save money, because their customers are located only in a few EU countries and therefore the eSDS would be necessary only in a few languages, it will not be in accordance with the competition law to tell other members of the consortium in which countries your customers are located. It is highly recommended to provide either only an English version of the eSDS within a consortium to have a harmonized template and leave the necessary translations to each member or to provide the eSDS in all 23 EU languages.

As the Competition Law comprises several hundred pages and tasks under REACH are also very complex, it seems impossible to list all possible pitfalls within this chapter that may occur when you try to respect the Competition Law while fulfilling your obligations under REACH.

Whenever you are unsure whether there could arise any problem concerning competition law by doing your business for REACH, please check supporting Guidance documents [36], check the Competition Law in depth, ask a lawyer or employ a competent trustee.

1.4.3 GHS and CLP

The CLP regulation [37] incorporates the internationally agreed GHS criteria into Community Law. Within 79 short Sections in the beginning of this regulation one can find important remarks and references to other regulations that either have an influence on CLP or *vice versa*.

In Section 5 of the CLP regulation [38] we find a short note concerning the historical development of GHS: "With a view to facilitating worldwide trade while protecting human health and the environment, harmonized criteria for classification and labeling have been carefully developed over a period of 12 years within the United Nations (UN) structure, resulting in the Globally Harmonized System of Classification and Labeling of Chemicals (hereinafter referred to as 'the GHS')" [38]. In the next Section is mentioned: "This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonization of criteria for classification and labeling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law" [39].

The first crossreference to REACH is made in Section 12: "The terms and definitions used in this Regulation should be consistent with those set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), with those set out in the rules governing transport and with the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade. The hazard classes specified in the GHS should be set out in this Regulation for the same reason" [40].

In our daily business concerning REACH matters we have at least two situations where REACH is touched by GHS/CLP and *vice versa*.

First, we are obliged to fill in the Chapter 2 of a registration dossier information concerning classification and labeling in accordance with GHS and the obligation to submit a CLP notification can be fulfilled by submitting this information included in the registration dossier. For registrations done until 30 November 2010 by an Only Representative of a Non-EU manufacturer the inclusion of the classification and labeling in accordance with GHS meant that EU customers marketing the registered substance later did not have an obligation to do an CLP notification on their own. If an Only Representative will register at a later stage (registration deadline e.g., in 2013) EU customers purchasing from the corresponding Non-EU manufacturer and intending to market a certain substance had to do their own CLP notification until 3 January 2011.

The second situation were REACH meets CLP in the daily business of the chemical industry, is the preparation of Safety Data Sheets. There are several amendments in Safety Data Sheets compared to former days that have to be done to fulfill obligations concerning CLP. REACH [1] describes several demands concerning preparation and content of Safety Data Sheets in Article 31. Normally you can find the uses of a substance as registered in the Safety Data Sheet and in the case of standard registrations there will be also an Annex to the so-called "extended Safety Data Sheet" (eSDS) including Exposure scenarios.

1.4.4
Other Regulations Containing the Wording REACH

In almost every country of the world there are existing laws commanding conditions for manufacturing and use of chemicals. In many states manufacturer, of chemicals also have to inform national authorities concerning products that are manufactured or used at each site of a company. Data requirements may vary from country to country, but all these regulations have in common that protection of human health and the environment is important in the perception of the public. However, even when there is included the wording "REACH" in the name of such laws, as it is for example, in China REACH or Korea REACH, it has nothing to do with the European REACH regulation [1], although the EU REACH may have been a sort of benchmark example in the development of some national laws concerning chemicals.

So far, contrary to GHS, there have been no efforts made to implement a unique "REACH" legislation for the whole world.

References

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives

91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

2 Council Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC).

3 EINECS = European Inventory of Existing Commercial Chemical Substances, is available within the ESIS database under http://esis.jrc.ec.europa.eu/

4 See Title of [1] and within this regulation also Section 15 of the determinations made in the beginning of this regulation.

5 See Article 5 of the REACH regulation [1].

6 See Article 1 and Article 2 of the REACH regulation [1].

7 See Article 3 and Article 4 of the REACH regulation [1].

8 See Articles 5 to 24 of the REACH regulation [1].

9 See Articles 25 to 30 of the REACH regulation [1].

10 See Articles 31 to 36 of the REACH regulation [1].

11 See Articles 37 to 39 of the REACH regulation [1].

12 See Articles 40 to 54 of the REACH regulation [1].

13 See Articles 55 to 66 of the REACH regulation [1].

14 See Articles 67 to 73 of the REACH regulation [1].

15 See Annex IV "Exemptions from the obligation to register in accordance with Article 2 (7) (a)" of the REACH regulation [1].

16 See Annex V "Exemptions from the obligation to register in accordance with Article 2 (7) (b)" of the REACH regulation [1].

17 See Annex VI "Information requirements referred to in Article 10" of the REACH regulation [1].

18 (a) See Annex VII "Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more" of the REACH regulation [1]; (b) See Annex VIII "Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more" of the REACH regulation [1]; (c) See Annex IX "Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more" of the REACH regulation [1]; (d) See Annex X "Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes or more" of the REACH regulation [1].

19 See Annex XI "General rules for adaptation of the standard testing regime set out in Annexes VII to X" of the REACH regulation [1].

20 See Annex XIV "List of substances subject to authorisation" of the REACH regulation [1].

21 See Article 1 of the REACH regulation [1].

22 Directive 1999/45/of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. Directive as last amended by Commission Directive 2006/8/EC.

23 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.

24 Commission Regulation (EC) No 1488/94 – laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No793/93.

25 Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Directive as last amended by Directive 2005/90/EC of the European Parliament and of the Council.

26 Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article

10 of Directive 88/379/EEC – as amended by Commission Directive 93/112/EC of 10 December 1993.
27 Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC.
28 Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC.
29 Commission Directive 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC.
30 See Section 9 in the beginning of REACH [1].
31 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
32 Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Directive as last amended by Commission Directive 2005/80/EC.
33 See Section 13 in the beginning of REACH [1].
34 COMMISSION IMPLEMENTING REGULATION (EU) No 254/2013 of 20 March 2013 amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
35 See Article 27 (3) and Article 30 (1) of REACH [1].
36 ECHA, Guidance on data sharing, Version 2.0, dated April 2012.
37 Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
38 See Section 5 in the beginning of the CLP regulation [37].
39 See Section 6 in the beginning of the CLP regulation [37].
40 See Section 12 in the beginning of the CLP regulation [37].