



**Report  
on penalties applicable for infringement  
of the provisions of the REACH Regulation  
in the Member States**

**FINAL REPORT**

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Directorate General Environment  
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ENVIRONMENTAL LAW & POLICY

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## **Executive summary**

This study gathers, compiles and analyses the national legislation setting penalties for infringements of the provisions of REACH adopted across all EU Member States and EEA countries. The report covers twenty-nine countries (all EU Member States and EEA countries, except Spain), and provides an overview of the sanctions set by these countries. The information gathered is based on the notifications the national authorities provided to the European Commission<sup>1</sup> as required under Article 126 of the Regulation. The study also provides a comparative analysis of the types of offences and levels of penalties between countries, and the levels of penalties compared to the costs of compliance and to comparable offences under other national legislation.

The analysis begins with an overview of the articles of REACH considered as enforceable on the basis of a close study of the Regulation and including the work carried out by the Forum for Exchange of Information on Enforcement on that topic. It shows that many articles of the Regulation may require enforcement. However, while such articles should all be equally enforced, the level of priority for enforcement can vary and some practical difficulties for implementation and enforcement may arise with respect to some articles. The overview indicates that most provisions of the Regulation considered as enforceable are subject to penalties in the national law, and therefore breaches of obligations under REACH are punishable under national legislation in most cases.

The analysis then considers whether the penalties provided in Member State legislation are be dissuasive, proportionate and effective. An effective penalty should provide adequate incentive for complying with regulatory obligations, so as to ensure that private and public actors do not compromise citizens' health and safety, pollute the environment, distort the market or violate consumers' rights. It is moreover important to make penalties proportionate to the offence committed in order not to discourage undertaking as a whole, and to include a proportionate array of penalties that correspond to the gravity of the offence and the intention of the offender, including economic, financial, administrative and criminal sanctions. Consistency across Member States concerning the enforcement mechanisms under REACH will help to ensure a level playing field for businesses across the EU. Finally, penalties are supposed to decrease the risk of recidivism by, for instance, creating increased penalties for repeat infringements.

The comparative analysis then studies in sequence different aspects of the Member States' systems for ensuring the enforcement of REACH. It concludes with some indications as to the level of dissuasiveness, proportionality and effectiveness of the measures adopted in the different countries.

### ***Types of offences***

In view of the many offences possible under REACH and the number of national systems surveyed, the information from the twenty-nine countries under study on the behaviours identified as offenses under REACH was entered into four tables corresponding to the main obligations under REACH. The four categories are the following:

- Registration and evaluation, which corresponds to Title II on registration,<sup>2</sup> Title III on data sharing and avoidance of unnecessary testing,<sup>3</sup> and Title VI on evaluation.<sup>4</sup>

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<sup>1</sup> and the EFTA Surveillance authority for the EEA countries.

<sup>2</sup> Articles 5 to 24 of REACH.

<sup>3</sup> Articles 25 to 30 of REACH.

<sup>4</sup> Articles 40 to 53 of REACH.

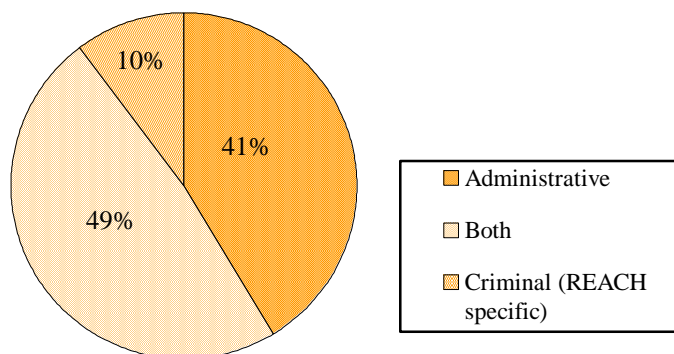
- Authorisation and restrictions, which corresponds to Title VII on authorisation<sup>5</sup> and Title VIII on restrictions on the manufacturing, placing on the market and use of certain dangerous substances.<sup>6</sup>
- Supply chain, corresponding to Title VI on information to the supply chain,<sup>7</sup> and
- Downstream users, corresponding to Title V of REACH.<sup>8</sup>

These tables compare the types of offences for the infringement of REACH provisions across Member States, *i.e.*, whether criminal or administrative.

The methods of enforcement vary from one country to another, and the choice of enforcement regime depends on the legal cultural background of each country. The common law countries have based enforcement mostly on criminal law, with an emphasis on the use of notices before applying criminal sanctions. The Nordic countries have based their enforcement policy on coercive measures and aim first at compelling the offender to comply with the legislation through the issuance of notices or coercive fines, rather than at punishing the breach of law. The remaining countries are divided between those enforcing REACH mostly at the administrative level (12 countries) and those combining administrative and criminal approaches (14 countries). Countries with a combined approach have usually inserted an element of intentional infringement or of endangerment to justify the use of criminal sanctions.

The pie chart below shows the types of enforcement regimes Member States have chosen to address infringements of REACH obligations:

**Chart 1 Regime of enforcement**



The study focuses on the provisions that specifically enforce the obligations set by the REACH Regulation. The tables on the types of offences therefore do not include provisions in the national legislation containing general obligations that could impact on the implementation of REACH.

In some countries, the list of situations that will be regarded as an offence is quite extensive, and aimed at providing an exhaustive overview of the cases constituting an infringement of the REACH Regulation. This is the case in Belgium, Bulgaria, Cyprus, Greece, Hungary, Italy, Lithuania, Portugal, Romania, Slovakia, Slovenia and the United Kingdom. Other countries (Austria, Finland, France, Germany, Luxembourg, the Netherlands, Poland and Sweden) have

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<sup>5</sup> Articles 55 to 66 of REACH.

<sup>6</sup> Article 67(1) of REACH.

<sup>7</sup> Articles 31 to 36 of REACH.

<sup>8</sup> Articles 37 to 39 of REACH.

made use of more general terms reflecting the main obligations under REACH. Still other countries have used so-called “catch-all” provisions (*i.e.*, Austria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Malta, Norway), meaning that the situations regarded as being in violation with REACH are not exhaustively defined in the text of the enforcement legislation, but rather included through a more general reference to violations of the Regulation.

Two of the three countries where enforcement is primarily done via criminal law have used a catch-all provision (Ireland and Malta). The use of a catch-all provision to cover breaches of the REACH obligations is less frequent among the countries where the legislation is mainly (or only) enforced through administrative law, *i.e.*, five out of twelve countries (Austria, Czech Republic, Estonia, Hungary, and Latvia).

The use of the catch-all provision has taken two different forms. In some cases (Czech Republic, Denmark, Estonia, Iceland, Ireland, Liechtenstein, Malta, Norway) the legislation provides only a catch-all provision, while other countries (Austria, Cyprus, France, Germany, Hungary and Latvia) provide a residual catch-all provision, to allow the sanctioning of any other breach of legislation not expressly mentioned.

Given the extensive numbers of REACH obligations considered as enforceable by Member States, many countries used a so-called “by-reference provision”. This is not to be confused with a catch-all provision, as it tends to list the provisions of REACH, infringements of which will be considered as an offence. Such provisions were used in Belgium, Bulgaria, Finland, Greece, Hungary, Italy, Latvia, Luxembourg, the Netherlands, Poland, Romania, Slovenia, Sweden and the United Kingdom.

### ***Type and level of penalties***

Article 126 of REACH refers to the obligation for Member States to impose “penalties”. In the context of this provision, this term is understood as equivalent to “sanctions”. The sanctions are characterised by their punitive or repressive character. However, this repressive character does not prevent a sanction from having also a preventive dimension.

The type of penalty varies among the countries under study. In general, the Member States under study have systematically included fines in their penalty systems, as a continuation of their existing systems. Other types of penalties include injunctions (including market withdrawal), prison sentences, and name-and-shame methods where non-compliance is made public.

With regards to administrative measures, the main type of sanction is economic. Fines are the only instrument foreseen at the administrative level in Bulgaria, Cyprus, Estonia, Hungary, Italy, Latvia, Liechtenstein and Romania. Some countries, although having the possibility to apply fines, rarely use them since their systems are mostly based on coercive measures, including initial warnings and formal notices, and fines are imposed only as an *ultima ratio*. On the other hand, the Nordic countries consider the fine as a coercive instrument, rather than as a punitive tool. The fine is then calculated on a case by case basis, depending on varying criteria, such as the size of the company, the importance of the interests affected by the offence or the severeness of the infringement.

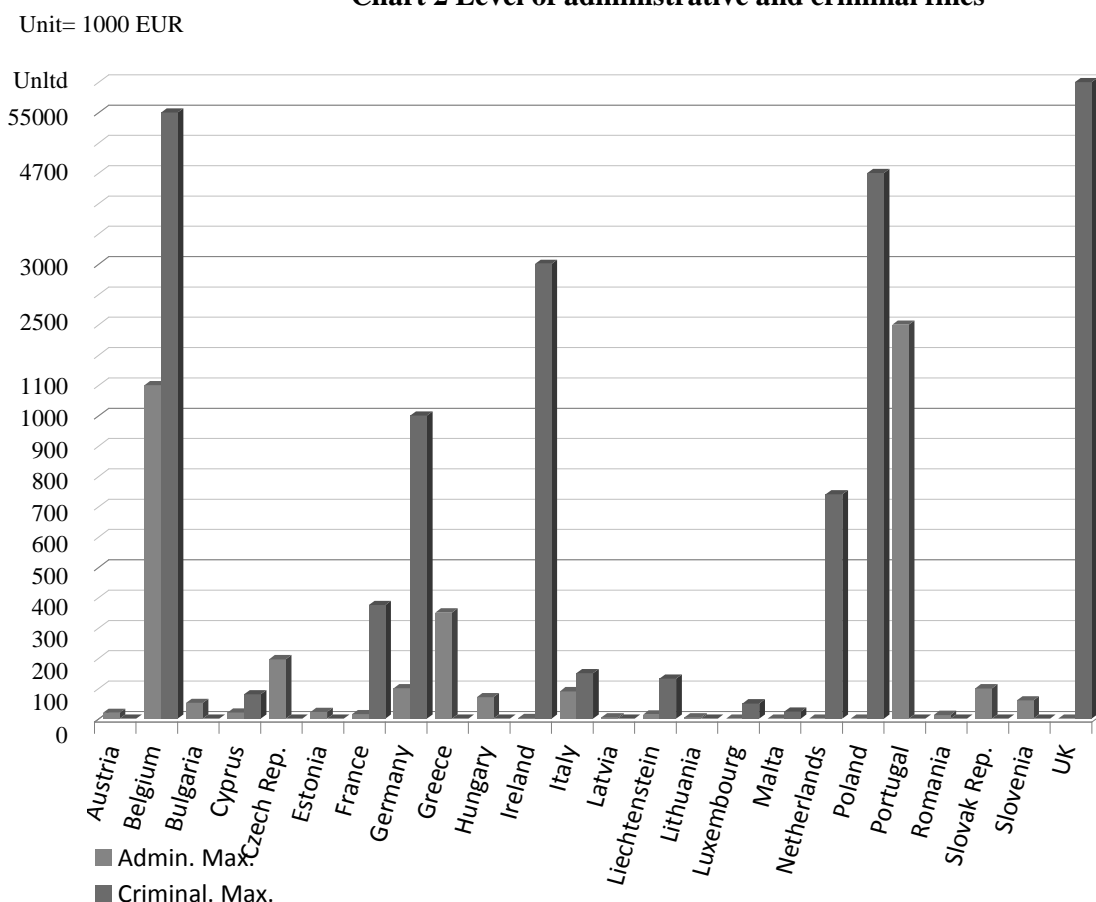
With regards to criminal sanctions, three main types of measures - pecuniary, deprivation of rights and prohibitions and orders - can be identified. Fines and prison sentences are the main criminal sanctions in all countries where criminal law is applied. The fine can be extremely high, and will usually be higher than the administrative fine, in the countries where fines can be imposed both under criminal and administrative law. In almost all countries with criminal sanctions, the most serious breaches of the REACH regulation are punished with imprisonment.

When a range of sanctions is foreseen in the legislation, the authorities and/or the courts have the possibility to adjust and to choose the most appropriate sanctions.

Overall, the fine is the most commonly used sanction. Most countries provide for fines between 50 000 and 1 000 000 Euros maximum for the first infringement. A few countries have adopted significantly lower or higher fines. In Latvia and Lithuania, on the one hand, the maximum fine is below 5 000 Euros. In Belgium, on the other hand, the fine can go up to 55 000 000 Euros and in the UK the fine is unlimited.

The bar chart below demonstrates the variation in the level of fines employed by the countries under study.

**Chart 2 Level of administrative and criminal fines**



The above graph takes into account only the fines imposed upon first infringement, on natural as well as on legal persons. It does not include all of the countries under study, since five (Denmark, Finland, Iceland, Norway and Sweden) do not fix the amounts of fines in their legislation. It also does not reflect the possibility to cumulate sanctions for multiple offences, since it only shows the maximum amount that can be imposed, at administrative and criminal levels, for one offence.

In addition to the fine, different types of measures have been adopted in a significant number of countries. In the countries based on criminal law, imprisonment is very often provided together with the fine, and can range from 1 month to 25 years. Other measures commonly used are the closure of the establishment, the suspension of activities, the deprivation or suspension of rights (e.g., incapacitation to carry out an activity), confiscation of any economic gain from the violation of REACH and the confiscation or even destruction of the substance, article or mixture

at the cost of the offender, as well as the withdrawal from the market. A few countries also use the publication of the judgment. All these tools can potentially also have a strong economic impact and can be as dissuasive as a fine.

### ***Penalties compared to costs of compliance***

To assess whether the proposed levels of penalties achieve the goal of effectiveness, proportionality and dissuasiveness, the study compared the sanctions imposed for non-compliance with the costs of complying with the relevant REACH provisions.

First, standard cost values for compliance with the relevant REACH provisions were prepared for specific provisions and in general. These values were then compared to the levels of fines imposed in the different national systems.

In countries where the fine is very high, the penalties are proportionally much higher than the costs of compliance, providing a strong incentive for the companies to comply with their obligations rather than to avoid the costs of registration and/or authorisation. However, countries that provided for a maximum fine below 200 000 Euros, even if in most cases the fines imposed were higher than the costs of compliance, were found not to have sufficiently high penalties to override the costs of compliance, if the infringement was for a chemical produced in the highest tonnage range (1000 tonnes per year and more). This was considered quite problematic since this level of fine would not provide sufficient incentive for compliance for a large producer and would lead to a discriminatory impact on producers of small quantities.

### ***Penalties compared to those for comparable offences under other legislation***

The penalties set forth in Member State legislation for REACH infringements was then compared to those imposed for comparable offences, in order to assess the proportionality of the REACH penalties. This review also provided an indication of the values placed on the specific aspects that the Regulation is aimed at protecting, namely human health and the environment, while enhancing innovation and competitiveness.

For this comparison, EU legislation having obligations considered comparable to those foreseen under REACH (authorisation to place on the market, respect of conditions linked to an authorisation, supply of false information, supply of updated information) were selected, as follows:

- Directive 98/8 Biocides<sup>9</sup>
- Directive 2001/83 Medicinal products<sup>10</sup>
- Directive 91/414 Plant protection products<sup>11</sup>
- Directive 96/61 and 2008/1 IPPC<sup>12</sup>

Information on the types and levels of penalties imposed for the comparable offences in the above legislation was then gathered for each Member State. This information is presented in the tables in Annex V.

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<sup>9</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

<sup>10</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

<sup>11</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

<sup>12</sup> Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, repealed by Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control.



The analysis of the approaches taken to enforce REACH obligations and comparable obligations under other pieces of EC legislation shows that the measures for non compliance imposed for breach of REACH obligations and those imposed under other legislation are quite comparable (fine, similar complementary sanctions). There is however no harmonisation of the level of sanctions, except when obligations are very similar (supply of false information for instance), and when REACH and other acts are enforced in the national law at the same time. This is the case in a few countries with regards to the Biocides legislation, where enforcement is very consistent with that of REACH, if not identical.

### ***Conclusions***

The comparative analysis indicates that the penalties set forth in national legislation for breaches of REACH obligations vary significantly from one country to another. The penalties in place are based on the different national cultures of enforcement and the corresponding array of compliance instruments already in place in the countries. The overall level of harmonisation of the sanctions for infringement of REACH across the EU Member States and the EEA countries is quite low.

The discrepancies observed in the level of penalties could lead to a risk of some companies avoiding countries with a more stringent compliance system. This could eventually impair the functioning of the internal market, as well as reduce the level of protection of human health and the environment in those countries with less severe systems of penalties. Moreover, in most countries the levels of penalties do not reflect the specificities of the REACH regime in that when the tonnage of a production or import is more than 1000 tonnes, the level of fine is not high enough to meet the cost of compliance. Such lacunas carry the risk of providing insufficient incentive for companies to comply with their obligations under REACH, particularly for those which produce or import chemicals in large quantities.

## **Abbreviations**

BIA	Business Impact Assessment
CLEEN	Chemical Legislation European Enforcement Network
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CWG	Commission Working Group on Practical Preparations of REACH
DU	Downstream user
EC	European Community
ECHA	European Chemicals Agency
MS	Member States
MSCA	Member States Competent Authorities
JRC	Joint Research Centre
KEURO	Kilo euro
OR	Only representative
PPORD	Product and Process Orientated Research and Development
QSAR	Quantitative Structure Activity Relationships
REACH	Registration, Evaluation and Authorisation and Restriction of Chemicals
R&D	Research and development
RIPE	REACH Information Portal for Enforcement
SC	Supply chain
SDS	Safety Datasheet
SEA	Socio-economic analysis
SIEF	Substance Information Exchange Forum
SME	Small and medium enterprise
SVHC	Substances of very high concern
UK	United Kingdom

## 1. Introduction

### 1.1. Background and methodology

#### *Background to the study*

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) sets the framework for the control of chemicals in the EU for the foreseeable future. It entered into force on 1 June 2007. However, most of its provisions only came into force on 1 June 2008.

Recital 120 of REACH calls for enhanced cooperation, coordination and exchange of information between the Member States (MS), the European Chemicals Agency and the Commission regarding enforcement in order for the system established by REACH to operate effectively. Article 126 of REACH on «Penalties for non-compliance» imposes on the EU MS the obligation of enforcement of REACH. This Article states that “*Member States shall lay down the provisions on penalties applicable for infringement of the provisions of REACH and shall take all measures necessary to ensure that they are implemented*”. Under Article 126, Member States are obliged to establish a system to enforce the relevant provisions of REACH that includes effective, proportionate, and dissuasive penalties for non-compliance with those provisions. The Member States were required to notify the Commission of their enforcement legislation by 1 December 2008.

Enforcement of EC law by the national authorities is essential for the effective application of the rules developed at Community level. Over the years, the European Court of Justice (ECJ) developed effectiveness of EC law as a guiding legal principle, on the basis of Article 10 of the EC Treaty. The principle includes the obligation for national authorities to develop effective sanctions for breaches of Community law and for national courts to give adequate effect to EC law in cases arising before them.

In accordance with the EC Treaty and the principle of procedural autonomy, it is up to the Member States to determine the actual nature and severity of a penalty. Nevertheless, it is important to ensure a minimum of consistency between the various sanction regimes in the Member States through cooperation and consultation mechanisms, in order to avoid considerable distortions between Member States and relocation to the Member State with the lowest penalties.

The community legislator has the possibility to indicate in a specific piece of legislation which implementing measures should be adopted by the national legislators, and whether penalties should be adopted to ensure enforcement of specific obligations. In all Member States, the infringement of a particular provision of a Directive or Regulation will then be subject to penalties. To achieve full and effective application of EC law, the ECJ has indicated that Member States should ensure that violation of the Community obligations is penalised in a way that is similar to comparable obligations in national law. These penalties have to be dissuasive, effective and proportionate.<sup>13</sup>

This study is based on the notifications received by the Commission. It aims to provide an overview of the penalties applicable for infringement of the REACH obligations in the 27 Member States. It also aspires to be useful in the effort to achieve a consistent approach towards the enforcement of REACH across the EU Member-States.

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<sup>13</sup> *Commission v. Greece*, Case 68/88, 21 September 1989, ECR [1989] 2965.

### ***Methodology used***

This Final Report, submitted twelve months into the project, presents the results of the analysis conducted with respect to the penalties set by twenty six Member States<sup>14</sup>, and the three EEA countries.

It is based on the methodology used in the Interim Report<sup>15</sup>, which was tested on three countries: France, Hungary and the United Kingdom<sup>16</sup>.

The report was developed in different steps. As a first task, prior to the analysis of the national legislations as such, a review was carried out of work already undertaken by the Forum for Exchange of Information on Enforcement (Forum)<sup>17</sup> that specifically related to penalties for enforcement. The results of this research can be found in the next sub-section as part of the introduction to our analysis.

The second task was the comparative analysis as such. It involved a comprehensive review of the notifications submitted by Member States to the Commission concerning the provisions on penalties applicable for the infringement of REACH.

The notifications and other relevant information were analysed by experienced national legal experts, with a good knowledge of the national environmental legislation, and in particular of the chemicals legislation. They were asked to provide information with respect to the national legislation on: types of offences, level of penalties, sanctions compared to costs of compliance and comparable offences under other legislation. They were also encouraged to contact competent authorities at the national level to obtain clarification and additional information, both on general matters regarding the sanctions system chosen by the country, and on more specific questions on certain legal aspects (use of a catch-all provision, enforcement of ambiguous provisions of REACH, implementation measures, etc.).

Following this, Milieu compiled the information provided by the national experts into short reports gathering the most important elements on which the analysis is based (articles of REACH considered as enforceable, types of offences, level of penalties, and description of the system). These were then sent to the national competent authorities to be checked for inaccuracies and inconsistencies. This investigation received twenty replies<sup>18</sup>, and the country fiches, including the modifications suggested by the MSCAs if any, can be found in Annex VI to this report.

The comparative analysis was then carried out mainly through the use of comparative tables providing an overview of the information available, as follows:

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<sup>14</sup> At the date of submission of this Final Report, only Spain had not submitted its notification to the European Commission. Austria and Portugal adopted the legislation providing sanctions for the breach of REACH during the summer, and the analysis was based on that legislation. To Milieu's knowledge, the legislation is still in the process of being adopted in Spain. Therefore, this country could not be covered in this study.

<sup>15</sup> Submitted to the European Commission in May 2009.

<sup>16</sup> These countries were selected for their different legal cultures (common law and continental law) and their varying approaches towards enforcement. Moreover, the consultant was able to combine in-house languages, expertise and knowledge of the chemicals legislation for these specific countries. The analysis was based on the notifications provided by these countries, as well as complementary research done by Milieu's experts, mainly obtained through the consultation of legal databases and websites of national authorities and agencies.

<sup>17</sup> See on this point Section 1.2, p.3.

<sup>18</sup> Belgium, Portugal and Germany replied that they could not provide an answer within the given deadline, and any relevant changes will be included in the Final Report.

- Comparison of the types of offences. Four tables (one for each main type of obligation under REACH) compare the types of offences for the infringement of REACH provisions across Member States, be they criminal or administrative.
- Comparison of the penalties: Four tables serve to compare the level of penalties foreseen in the national legislation for each main type of obligation under REACH across Member States.
- Quantitative assessment of penalties against compliance costs: for each Member State, the financial penalties and other measures are set in a table and compared to the quantitative results in both the Commission's Extended Impact Assessment<sup>19</sup> and the JRC study 'Assessment of additional testing needs under REACH'<sup>20</sup>. The latter results were used to prepare standard cost values for compliance. Relevant conclusions concerning significant differences between the penalty and the cost of compliance for specific types of obligations and in general for each Member State are presented by Member State in tabular format and discussed in an accompanying text. In addition, the study has also assessed the UK impact assessment.
- Comparison with comparable offences: for this step in the analysis, comparable offences were identified in other legislation, and the types and levels of penalties imposed for their violations in each Member State were gathered in comparative tables.

On the basis of the tables developed under the steps above, a review was carried out of the major discrepancies between Member States and the different types of legal systems in both the level and type of penalties imposed for the infringement of REACH provisions. The study concludes with an overview analysis that describes the main characteristics of the penalties in place in each Member States and the context in which such sanctions are imposed (competent authorities, implementation).

## **1.2. Review of the work on enforcement to date**

This section review the work on enforcement performed to date by the Forum for Exchange of Information on Enforcement (Forum) on the question of penalties applicable for infringement of the REACH Regulation.

The Forum, introduced by Article 86 of REACH is a network of Member States authorities responsible for enforcement. It facilitates the exchange of information on, and coordination of the activities related to the enforcement of chemicals legislation. Among its main tasks are the spreading of good practices and the highlighting of problems at Community level. It aims to propose, coordinate and evaluate harmonised enforcement projects and joint inspections, as well as coordinate the exchange of inspectors. It also aims to identify enforcement strategies, develop working methods for local inspectors and liaise with industry, especially with producers of small quantities..

The Forum has already met five times<sup>21</sup>, first in December 2007, and second in May 2008. On the latter occasion, a working group on enforcement strategies was established, and the

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<sup>19</sup> Commission Staff Working Paper, Extended Impact Assessment, SEC (2003) 1171/3

<sup>20</sup> Pedersen, F., de Bruijn, J., Munn, S. and van Leeuwen, Kees., Assessment of additional testing needs under REACH: Effects of (Q)SARS, risk based testing and voluntary industry initiatives, September 2003.

<sup>21</sup> [http://echa.europa.eu/about/organisation/forum/forum\\_meetings\\_en.asp](http://echa.europa.eu/about/organisation/forum/forum_meetings_en.asp)

importance of harmonised enforcement of the “no data – no market” rule was advocated in order to ensure the equal treatment of companies across the EU<sup>22</sup>.

Prior to this second meeting, the Secretariat of the Forum submitted to the 27 Member States a template with several questions on the status of their preparations for REACH enforcement, including the status of their penalty legislation, which, according to Article 126 of the Regulation, had to be notified to the Commission before 1<sup>st</sup> December 2008. Twenty-five questionnaires came back on July 2008 and were compiled by the Secretariat in order to identify the most urgent field for harmonization, especially regarding penalty provisions. At the third meeting of the Forum, on 2<sup>nd</sup> December 2008, the results of the analysis of the questionnaires were made available to the Forum members. The results were so diverse that it was very difficult for the Forum Secretariat to set up a comparative analysis. Penalties ranged from administrative to penal instruments, including suspension or cancellation of licences, fines, banning of production, importation or use of chemicals. Administrative fines could range from 100 to 120 000 Euros. Criminal charges could amount up to 3 000 000 Euros and imprisonment penalties from only a couple of days up to 6 years. The Forum noticed that although the type of penalties was similar (fine and imprisonment), the levels varied considerably. The Chair of the Forum concluded that Forum members could play a role in the revision of penalties in order to harmonize them<sup>23</sup>.

Following the third meeting of December 2008, the Forum presented in March 2009 its “Strategies for enforcement of REACH”<sup>24</sup>. This report concluded that MS strategies should be based on five key elements:

- Policy objectives,
- Necessary organization
- Enforcement measures
- Progress monitoring and measurement
- Review, evaluation and update of the enforcement strategy.

All these elements are more or less linked to the importance of the legal requirements regarding penalties. When setting their policy objectives, the national authorities shall ensure that the main goals of the Regulation, i.e. a high level of protection of human health, the environment and the precautionary principle as well as the free movement of substances while enhancing competitiveness and innovation, are taken into account. A well structured organisation of enforcement authorities is crucial to achieve effective, efficient, transparent and systematic enforcement of the Regulation and is fundamental to an appropriate enforcement regime. Enforcement measures are of course one of the key elements of enforcement. The strategy stated that such measures should include compliance promotion, compliance enforcement and, if needed, administrative or criminal proceedings. As to progress monitoring, it should also cover the enforceability of REACH articles, and allow the national authorities to adjust their notions of offences and the level and type of penalties. The review of the strategy follows the same logic.

While MS are required to set up an appropriate framework for penalties and even though a fully harmonised penalty system is not possible, some common elements should be integrated in the national provisions. As a first step towards this objective, the Forum identified in Annex I to the Strategy the articles they determined to be the most important to be enforced under REACH. This annex mentions that “Member States are strongly encouraged to have regard to these

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<sup>22</sup> Second Meeting of Forum Stressed Harmonised Enforcement of REACH, Helsinki, 16 May 2008, ECHA/PR/08/09.

<sup>23</sup> [http://echa.europa.eu/doc/about/organisation/forum/meeting\\_minutes\\_20080514.pdf](http://echa.europa.eu/doc/about/organisation/forum/meeting_minutes_20080514.pdf), Item 6.

<sup>24</sup> « Strategies for enforcement of Regulation (EC) no 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) », Forum for Exchange of Information on Enforcement, March 2009.

requirements when devising and implementing their own REACH enforcement strategies, and when setting priorities for REACH enforcement”.

In addition to this document, it shall also be mentioned that Annex I of the first Forum report “Access of inspectors to data from on REACH-IT” finalised in July 2008 provides an inventory of articles of REACH relevant for enforcement and the information needed by REACH enforcers to enforce them. This document was prepared in the context of gathering requirements for RIPE (REACH Information Portal for Enforcement). As the title indicates, this document identifies the articles to be enforced, the data required and the date of entry into force of the articles. It also provides some indications as to articles that may be difficult to enforce.

Another important aspect of enforcement that shall be mentioned here is the development of IT tools to enhance the effectiveness of inspections and to facilitate the exchange of information between inspectors.

The ECHA is currently developing RIPE, an application that will allow inspectors to directly access selected data held by ECHA. Inspectors currently have to liaise with the MSCAs to obtain data about submissions to ECHA. This situation prejudices the effectiveness of the REACH enforcement system at national level. The application is envisaged to be functional on 31 December 2010.

The Forum is also investigating the possibility to use one of the existing alert systems to exchange information between REACH inspectors or whether a new system would need to be built.

It shall also be mentioned that during the Forum meeting of April 2009, the first coordinated REACH enforcement project has been launched. REACH-EN-FORCE-1 focuses on checking pre-registrations, registrations and SDS where applicable. This project aims at giving a first impression on the level of compliance and may hence trigger the application of the penalties set for REACH in the Member States.





## **2. The REACH Regulation and provisions subject to penalties**

The establishment of comparable penalty regimes across the EU Member States requires a common understanding of those provisions that are enforceable under REACH. The identification of these requirements is crucial for an overview of the scope of intervention of the national enforcement authorities, and for identification of the types of offences to be covered by penalties. The classification of the enforceable articles is also important to identify the areas where enforcement shall be made a priority, and where penalties should be imposed in a more systematic way.

This section identifies the enforceable articles under REACH in the form of tables clustering the articles following the structure of the Regulation. Four main topics for enforcement have been identified:

- Registration and evaluation
- Authorisation and restrictions
- Supply chain
- Downstream user.

As many articles of the Regulation may require enforcement, it is important to consider the degree of enforcement that these articles would require in order to identify priorities. For each of these topics, a short analysis provides information as to the level of priority for enforcement, as well as some practical difficulties that may arise for implementation and enforcement of some articles.

The identification of enforceable articles is based on a close analysis of the Regulation, as well as on the documents issued by the Forum concerning enforceable articles<sup>25</sup>. The articles identified in Annex I to the Forum's "Strategies for enforcement"<sup>26</sup> as essential requirements are highlighted in blue. It should however be emphasised that all articles mentioned below, even if not identified as a priority, need to be enforced.

### **2.1. Registration and evaluation**

Registration is one of the pillars of REACH. The whole mechanism of REACH is based on the "no data, no market" rule. It requires an active involvement of companies, which are to provide basic information on the substances they produce or import. If not correctly enforced, there would be no guarantee that health and safety information for the substances put on the market is sufficient to ensure a safe use of the substance.

Data sharing and evaluation are also inserted under this heading, as they are part of the same procedural scheme. Direct data sharing concerns registration, while evaluation results from the registered information.

#### ***Title II***

Title II presents the requirements regarding registration of substances. Table 2.1 includes the enforceable articles identified under this Title. Requirements on fees are not included as they

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<sup>25</sup> A few articles, although considered as enforceable under other reports or by the legislation in some countries, have not been taken into account based on the analysis carried out in this section. This is the case for Article 113 on classification and labelling, as Title XI of REACH was repealed at the entry into force of the CLP Regulation No 1272/2008.

<sup>26</sup> Enforcement of REACH, Final report from the EU REACH enforcement project, February 2008.

may be difficult to enforce in practice, and are, as a matter of fact, self-enforcing. So is Article 20.2 (procedure in case of incomplete dossier for registration) and Article 9.2 (submission of relevant information when seeking to rely on exemption for PPORD).

The main obligation here is provided by Article 5, which sets the “no data, no market” rule. Articles 6 and 7 requiring registration are directly related to this article. Articles 17 and 18 on the other hand provide for the obligation to register for isolated intermediates. It may be argued that since those articles are the direct consequence of Article 5, they do not have to be enforced on their own. At the same time, one may consider that Article 5 and the other articles may be enforced separately, as the breach of these obligations would result in two slightly different offences, one being the placing on the market without registration, the other being the absence of registration as such. Even though Member States may have different approaches towards the enforcement of these articles, both views can be accepted, as they eventually result in the same obligation.

Articles 10 to 12, 14, 19, 22 and 24 indicate the information to be provided for registration. Their enforcement ensures that the data produced are complete, accurate and up to date. Although they ensure that the articles on registration are correctly fulfilled, they provide detailed information, and therefore should be enforced separately.

For a few articles, enforcement implies an exchange of information between ECHA and the MS competent authorities, and consequently between MSCAs and the competent enforcement authorities, as only the Agency will be able to inform the authorities and hence the enforcers as to the data provided to them by the companies, and whether there is a problem with them (e.g. conditions imposed by ECHA, as in Article 9.4, joint submission, as in Article 11 or 19, limitation of testing as in Article 13). As the ECHA will receive this information directly, it may be difficult to define the role of the national authorities regarding enforcement.

National authorities questioned on this matter have adopted varying approaches. Some consider that these articles are self-enforceable and do not need to be enforced at the national level (e.g., Czech Republic). Along the same line, Ireland mentioned that as ECHA is responsible for the evaluation of dossiers, it may, if further information is required, prepare a draft decision which may be ratified by the Member State Committee as provided for under Title VI of REACH (Article 41.3). Some others plan to enforce these articles, and have emphasised the importance of a good communication between ECHA and the MSCA to succeed in the enforcement of such articles. The IT tools currently developed by the Forum can provide an answer<sup>27</sup>.

**Table 2.1 Title II Registration of substances**

Article	Key Provisions
5	Prohibition on manufacture or placing on the market of substances on their own, in mixtures or in articles unless they have been registered
6(1)	Requirement on a manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year to submit a registration to the Agency.
6(2)	Obligation to register for monomers that are used as on-site intermediates or transported isolated intermediates
6(3)	Requirement on a manufacturer or importer of a polymer to submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain (under conditions).
7(1)	Requirement on a producer or importer of articles to submit a registration to the Agency for any substance contained in those articles (under conditions).
7(2) and (4)	Requirement on a producer or importer of an article to notify the Agency of information provided in Article 7(4).
7(3)	Requirement on a producer or importer to supply appropriate instructions to the recipient of the article.
7(5)	A registration shall be submitted if the Agency takes this decision based on the criteria set in Article 7(5).

<sup>27</sup> See p.5 of the report.

<b>Article</b>	<b>Key Provisions</b>
8(1) and (2)	A person established outside the Community may designate a person inside the Community as its OR, which will be done through a letter of appointment. The OR will then have to fulfil the obligations for registration imposed on importers. Requirement on a representative to keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the SDS.
9(4) and (6)	Requirement on manufacturers, importers and producers of articles to comply with conditions imposed by ECHA regarding the PPORD process.
10	The information to be submitted for registration shall contain the technical dossier and the CSR.
11(1) and (3)	When a substance is intended to be manufactured by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under article 7, some information shall be submitted only by the registrant acting with the agreement of the other assenting registrant(s), while other information shall be submitted by each registrant separately. If he submits the information separately, the registrant shall submit, along with the dossier, an explanation to justify this decision.
12(1)	Requirement to include in the technical dossier all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant.
12(2)	Requirement on a manufacturer and importer to notify ECHA with additional information where it reaches the next tonnage threshold
13(1)	In particular for human toxicity, requirement to generate information whenever possible by means other than vertebrate animal tests, through the use of alternative methods, in vitro methods or QSAR models or from information from structurally related substances.
13(3)	Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other internationally recognised test methods.
13(4)	Requirement to carry out ecotoxicological and toxicological tests and analyses in compliance with the principles of good laboratory practice.
13(5)	A new registrant shall be entitled to refer to a study summaries for the same substance submitted previously, except when it is to provide information on the identification of the substance.
14(1), (3) and (4)	A CSA shall be performed and a CSR completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant. The CSA shall follow the steps described in Article 14(3) and the additional steps of Article 14(4) if the substance is classified as dangerous according to D.67/54/EEC or is a PBT or vPvB
14(6)	Requirement on a registrant to identify and apply the appropriate measures to adequately control the risks identified in the CSA and where suitable recommend them in SDS.
14(7)	The CSR shall be kept available and up to date.
17(1) and (2)	Requirement on a manufacturer to register on-site isolated intermediate manufactured in quantities of one tonne or more per year. Registration shall include information as listed in Article 17(2).
18(1), (2) and (3)	Requirement on a manufacturer to register transported isolated intermediate manufactured or imported in quantities of one tonne or more per year. Registration shall include information as listed in Article 18(2). Requirements on manufacturers registering transported isolated intermediate manufactured or imported in quantities of more than 1000 tonnes per year to include information specified in Annex VII.
19(1) and (2)	When an isolated intermediate is intended to be manufactured by one or more manufacturers and/or imported by one or more importers, some information shall be submitted only by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s), while other information shall be submitted by each registrant separately. If information is submitted separately, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.
Article 20(2)	Requirement to complete the registration and to submit it to the Agency within the deadline set in case of incomplete registration.
21(1)	Prohibition to start or continue the manufacture or import of a substance or production or import of an article, if there is an indication to the contrary from the Agency within the three weeks after the submission date.
21(2)	Prohibition for the registrant to start the manufacture or import of a substance or production or import of an article if there is an indication to the contrary from the Agency if the Agency has informed the registrant that he is to submit further information and the registrant has submitted further information,
21(3)	Prohibition, if a lead registrant submits parts of the registration on behalf of one or more other registrants, for any of the other registrants to manufacture or import the substance or produce or import the articles before the expiry of the time-limit if there is an indication to the contrary from the Agency in respect of the registration of the lead registrant.
22(1)	Requirement on a registrant to update its registration whenever needed.
22(2)	Requirement on a registrant to submit ECHA an updated registration providing information as required by a decision.
24(2)	Requirement on a registrant to notify, in accordance with articles 10 and 12, where the quantity of a notified substance reaches the next tonnage threshold.

### Title III

Title III presents the requirements regarding data sharing and avoidance of unnecessary testing. Table 2.2 below includes all enforceable articles under this Title. None of the requirements under Title III have been classified by the Forum as priority for enforcement. It shall be noted that, as for some articles under Title II, for all enforceable articles under Title III, enforcement requires an exchange of information between ECHA and the MS enforcement authorities.

**Table 2.2. Title III Data sharing and avoidance of unnecessary testing**

Article	Key Provisions
25(1)	Requirement to resort to testing on vertebrate animals only as a last resort, and requirement to avoid duplication.
26(1)	Requirement on a potential registrant of non-phase in substance or phase in substance who has not pre-registered to inquire if the same substance has been registered.
27(1) to (3)	Requirement on a potential registrant to request information on vertebrate animals tests from the previous registrant(s). Requirement on potential and previous registrants to make every effort to reach an agreement on the sharing of information (Article 27(2)) and on the costs of sharing (Article 27(3)).
27(4)	On agreement on the sharing of the information, requirement on a previous registrant to make available to the new registrant the agreed information and to give the new registrant the permission to refer to the previous registrant's full study report.
27(6)	Provided he makes the full study report available to the potential registrant, requirement on a previous registrant(s) to have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts
28(1)	Requirement on registrants to submit a pre-registration for phase-in substances in quantities of one tonne or more per year until December 2008.
28(6)	Requirement on registrants who manufacture or import for the first time phase-in substances in quantities of one tonne or more per year after December 2008 to submit the information as per Article 28(1).
29(3)	Requirement on SIEF participants to provide other participants with existing studies, to react to requests.
30(1) in conjunction with 30(6).	Requirement on a registrant to enquire with members of the SIEF if relevant studies are available, in which case it shall request them. Requirement on an owner of the study to prove its costs to the participant requesting it. Requirement on participant(s) and the owner to make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way.
30(2)	Only one study shall be conducted per information requirement within each SIEF by one of its participants. Requirement on participants to take all reasonable steps to reach an agreement within a deadline set by ECHA as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to ECHA.

### Title VI

Title VI covers the requirements on evaluation. Table 2.3 below includes enforceable articles under this Title. Articles 40(4), 41(4) and 46(2) have been identified as a priority for enforcement. These articles require the submission of information for ECHA.

Here again, for those, as well as for most enforceable articles under this title, enforcement requires an exchange of information between ECHA and the MS enforcement authorities, and may be enforced only if ECHA asks for it.

**Table 2.3 Title VI Evaluation**

Article	Key Provisions
40(4)	Requirement on a downstream user and the registrant to submit information required regarding testing proposals to ECHA.
41(4)	Requirement on a registrant to submit information required after compliance check of registrations by ECHA to the Agency.
46(2)	Requirement on a registrant to submit further information in accordance with the decision prepared by the competent authority during a substance evaluation.

<b>Article</b>	<b>Key Provisions</b>
49(a)	Requirement on a registrant to submit further information on request of the competent authority in relation to the risk identified for on-site isolated intermediates.
50 (2-3)	Requirement on registrants to inform the Agency if manufacture or import or use has ceased.
50(4)	Requirement on a registrant to provide, in accordance with Article 46, further information even though the activity has ceased.
53(1) to (3)	Requirement on a registrant or downstream user required to perform a test upon decision of the Agency to make every effort to reach an agreement as to who shall carry out the test. Requirement on registrants or downstream users to share the costs and requirement on the person performing the test to provide the others with the results of the test.
53(4)	A person concerned may claim for prohibition for another person to manufacture, import, or place on the market if that other person has failed to pay his share of the costs or fails to hand over a copy of the study report.

## **2.2. Authorisation and restrictions**

As with registration, authorisation is a procedure that reflects the will to make REACH a unique instrument of protection of health and the environment while also enabling the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation.

Indeed, special authorisations are issued by the Commission for substances of very high concern (SVHC). The enforcement of the provisions on authorisation need to be correctly enforced to ensure that the placing of the market of the most dangerous substances will be strictly regulated, and that those potentially exposed to the substances will be particularly protected.

Restrictions are also inserted under this section, as they are also related to particularly dangerous substances.

### ***Title VII***

Title VII presents the requirements regarding authorisation. Table 2.4 below includes all enforceable articles under this Title. As for the previous titles, requirements on fees are not included as they may be difficult to enforce in practice, and are self-enforcing.

More than half of the enforceable articles of Title VII have been identified by the Forum as a priority. Article 55, while describing the aim of authorisation as the effective functioning of the internal market together with the control of SVHC, requires a consideration of substitution for these substances. This control over the use of the most dangerous substances is crucial, and in that respect should be enforced by the national authorities. Article 56 provides for the obligation of authorisation as such for substances of very high concern. Article 60(10) aims at limiting exposure to SVHC. Articles 61 to 65 require the submission of information. Article 65 is particularly important for enforcement as it ensures a direct protection of the user of the substance.

Article 66(1) imposes on the downstream user an obligation of notification. This will allow the national enforcement authorities to check whether the conditions of authorisation are respected at the end of the chain.

It should be noted that Article 62(4) specifies the information that shall be submitted when applying for an authorisation. As the information will be submitted to the Agency, the enforcement of this article suggests an exchange of information between ECHA and the Member States' authorities.

**Table 2.4 Title VII Authorisation**

Article	Key Provisions
55	Requirement on all manufacturers, importers and downstream users applying for authorisations to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.
56(1)	Requirements on manufacturers, importers or downstream users not to place a substance on the market for a use or use it itself if that substance is included in Annex XIV unless sub-paragraph (a), (b), (c), (d) or (e) are satisfied.
56(2)	Requirements on downstream users not to use a substance otherwise than in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
60(8)	Requirement to ensure the respect of the conditions linked to the authorisation.
60(10)	Requirement on a holder of an authorisation to ensure that the exposure is reduced to as low a level as is technically and practically possible.
61(1)	Requirement on a holder of an authorisation to submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant R&D activities by the applicant, and any substitution plan submitted under Article 62(4)(f). If the update shows that there is a suitable alternative, requirement to submit a substitution plan. If the holder cannot demonstrate that the risk is adequately controlled: submission of an update of the socio-economic analysis. If he can demonstrate that the risk is adequately controlled: submission of an update of the CSR. If any other elements of the original application have changed, also submission of updates of these element(s).
61(3)	In case of amendment or withdrawal of the authorisation, if suitable alternatives become available, requirement on a holder of the authorisation to present a substitution plan to the Commission if he has not already done so as part of his application or update.
62 (4) and (5)	Requirements on the manufacturer(s), importer(s) and/or downstream user(s) of the substance to make an application for authorisation to ECHA. Applications may be made by one or several persons, for one or several substances, and for one or several uses. Requirement for the application to include the information of Article 62(4) (a) to (f).
63(3)	Before referring to any previous application, requirement on a subsequent applicant to update the information of the original application as necessary.
65	Requirement on a holder of an authorisation and downstream users to include the authorisation number on the label before they place the substance or mixture on the market for an authorised use.
66(1)	Requirement on a downstream user using a substance in accordance with article 56(2) to notify ECHA within three months of the first supply.

### **Title VII**

Title VIII indicates the requirements regarding restrictions. The table below shows the only enforceable article under this title (see Table 2.5). This article has been identified as a priority for enforcement, as it ensures that the restrictions on use, placing on the market and use of dangerous substances are respected as per Annex XVII to the Regulation.

**Table 2.5 Title VIII Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles**

Article	Key Provisions
67(1)	Prohibition on the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article for which Annex XVII contains a restriction unless the manufacture, placing on the market or use of a substance on its own complies with the conditions of that restriction.

### **2.3. Supply chain**

Communication between the actors of the supply chain is crucial to ensure that all information regarding the substance is known by any person who will at one point use the substance or mixture. The main instrument of communication in the supply chain is the safety data sheet (SDS) presented in Article 31 of the Regulation.



As mentioned in the Strategies for enforcement carried out by the Forum<sup>28</sup>, the SDS is a well-known document for enforcement authorities, and they are well-experienced at controlling it. However, new elements that will have to be taken into account by inspectors include exposure scenarios annexed to safety data sheets, information requirements when a safety data sheet is not needed, information about SVHC in articles, and requirements to pass information back up the supply chain in certain circumstances.

Besides Article 31 on the requirements for SDS, all articles ensuring that the relevant actors will be provided with the relevant information on substance or mixtures are considered as priorities for enforcement, be it between actors of the supply chain (Article 32(1), 33, 34) or for workers (Article 35).

**Table 2.6 Title IV Information on the supply chain**

Article	Key Provisions
31(1)	Requirement on a supplier of a substance or a mixture to provide recipient with a SDS compiled in accordance with Annex II.
31(2)	Requirement on any actor in the supply chain who has been requested to perform a CSA to ensure that information in the SDS is consistent with the information in the assessment.
31(3)	Requirement on a supplier to provide a SDS when requested for a mixture which falls within paragraph 3.
31(4)	Requirement on a supplier to provide downstream user or distributor with a SDS when requested for a mixture or dangerous substance which is offered or sold to the general public.
31(5)	The SDS shall be provided in the language of the Member State concerned.
31(6)	The SDS shall contain the information listed in article 31(6).
31(7)	Requirement on actors in the supply chain to place the relevant exposure scenarios in an annex to the SDS. Requirement on a downstream user to include the exposure scenarios in their own SDS for identified uses. Requirement on a distributor to pass on relevant exposure scenarios and use other relevant information from the SDS when compiling his own data sheet.
31(8-9)	The SDS shall be provided free of charge either electronically or on paper. Requirement on a supplier to update the SDS and provide it free of charge to all former recipients.
32 (1)	Requirement on a supplier of a substance who does not have to supply a SDS to provide the recipient with the information in paragraph (1).
32(2-3)	Requirement on a supplier to provide information free of charge no later than the time of first delivery of a substance on its own or in a mixture after 1 <sup>st</sup> June 2007. Requirement on a supplier to update the information when required by paragraph (3). Requirement on a supplier to provide to all recipients to whom they have supplied within preceding twelve months updated information.
33(1 and 2)	Requirement on a supplier of an article to provide the recipient with sufficient information to allow safe use, including as a minimum the name of that substance. Requirement on a supplier of an article to provide a consumer on request with sufficient information to allow safe use, including as a minimum the name of that substance, free of charge and within 45 days of the request
34	Requirement on every actor (including distributor) in the supply chain to communicate the information on new information or any other information that might call into question the appropriateness of the risk management measures to the next actor or distributor up the supply chain.
35	Requirement on an employer to provide workers and their representatives with access to information received in accordance with articles 31 and 32 in relation to substances or mixtures which they may use or be exposed to in the course of their work.
36(1)	Requirement on each manufacturer, importer, downstream user and distributor to assemble and keep available for at least ten years after it last manufactured, imported, supplied or used the substance or mixture, all the information it requires to carry out its duties under the Regulation. Requirement on each manufacturer, importer, downstream user and distributor to submit or make available the information to a CA or ECHA when requested to do so.
36(2)	Requirement on a party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned to comply with Article 36(1).

<sup>28</sup> “Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)”, March 2009, p.19.

## 2.4. Downstream users

To ensure an efficient protection of health and the environment while enabling the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation, at all stages of use of the substance, REACH implies an involvement not only of manufacturers and importers, but also downstream users. Article 37, together with Article 38(1) and 39, requires downstream users to identify, apply and recommend risk reduction measures and to report information within a certain period of time. These obligations have been designated as “the most important of all articles for enforcing authorities” by the Forum<sup>29</sup>, and the incorrect use of a substance should systematically result in the authorities taking measures to remedy the situation.

**Table 2.7 Title V Downstream users**

Article	Key Provisions
37 and 39	<i>All obligations under article 37 shall be read in conjunction with article 39, which states that downstream users shall comply with these obligations at the latest 12 months after receiving a registration number.</i>
37(2)	Requirement on a downstream user to have the right to make a use known in writing. Requirements on distributors to pass on such information to the next actor up the supply chain.
37(3)	Requirement on a manufacturer, importer or downstream user to comply with Article 14 for registered substances. Requirement on a manufacturer, importer or downstream user to comply with Article 14 for a phase-in substance. Requirement on a manufacturer, importer or downstream user to provide the Agency and downstream users with reasons why a use identified by a downstream user cannot be included in the CSR. Requirement on a manufacturer, importer or downstream user not to supply a downstream user with a substance without including these reasons in the information referred to in Articles 31 or 32. A manufacturer or importer shall include the use notified under Article 37(2) in the update of the registration under Article 22(1)(d).
37(4)	Requirement on a downstream user to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against.
37(5)	Requirement on a downstream user to identify and apply appropriate measures to adequately control risks identified in (a) a safety data sheet supplied to it; (b) its own chemical safety assessment or (c) any information received in accordance with article 32. Requirement on a downstream user to recommend, where suitable, measures to adequately control the risks identified in (a) a safety data sheet supplied to it; (b) its own chemical safety assessment or (c) any information received in accordance with article 32.
37(6)	Requirement on a downstream user to identify and apply appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled.
37(7)	Requirement on downstream users to keep their chemical safety report up to date and available.
38 and 39	<i>All obligations under article 38 shall be read in conjunction with article 39, which states that downstream users shall comply with these obligations at the latest 6 months after receiving a registration number.</i>
38(1)	Requirement on a downstream user to report information in article 38(2) to ECHA before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain.
38(2)	Requirement on a downstream user to include the information listed in Article 38(2).
38(3)	Requirement on a downstream user to update the information provided in article 38(2) without delay in the event of a change in information.
38(4)	Requirement on a downstream user to report to ECHA if its classification of a substance is different to that of its supplier.

<sup>29</sup> Ibid., p.21



### 3. Summary and Analysis of Member State Provisions on Penalties

This section summarises information provided by the Member States under study as to the legislation in place regarding penalties applicable for the infringement of REACH. It aims at providing an overview of the enforceable articles of REACH for which the Member States have adopted legal provisions for enforcement.

#### 3.1. Overview of the provisions in place in the Member States on REACH penalties

The table on the next page has been compiled on the basis of the information provided in the notified legislation. The table indicates very briefly if provisions are in place, and where there are gaps. It arranges information on penalties by Member State and by enforceable provisions. As in the previous section, the articles identified in the document on “Strategies for enforcement” as essential requirements are highlighted in blue.

#### 3.2. Analysis of the Member State provisions on REACH penalties

The table on the next page provides an overview of the provisions in place in the Member States and EEA countries for enforcing the obligations of REACH. First, it shows that different approaches have been adopted to select the REACH obligations subject to sanctions, and second, the articles covered by sanctions in the national legislation and the gaps give good indications of the level of priority for enforcement given to each article in the different countries.

##### 3.2.1. The different approaches applied for the identification of the enforceable articles

While some countries have systematically covered all articles that Milieu identified as enforceable, in others, REACH provisions considered as subject to penalties are far less numerous. The differences lie in the identification for each country of what requirements of REACH are to be subject to enforcement. To address this issue, the countries have opted for various strategies.

Three different approaches can be distinguished. While half of the countries (15) have provided sanctions for specific offences corresponding to REACH provisions, others have adopted a “catch-all” provision, which provides for enforcement for the violation of REACH obligations in general<sup>30</sup>. Others have combined the two approaches.

##### **Different approaches towards enforcement**

- Provisions in place for each specific REACH related offence: Belgium, Bulgaria, Finland, Greece, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden and UK
- Catch-all provision only: Czech Republic, Denmark, Estonia, Iceland, Ireland, Liechtenstein, Malta and Norway
- Combination of catch-all provision and specific provisions: Austria, Cyprus, France, Germany, Hungary and Latvia

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<sup>30</sup> For more explanation on the catch-all provision, see p.23 of this Report.

Table 3.1 Overview of the provisions enforced in the Member States

Ctry Art	AT	BE	BG	CY	CZ	DK	EE	FI	FR	DE	GR	HU	ISL	IE	IT	LV	LI	LT	LU	MT	NL	NO	PL	PT	RO	SK	SI	SE	UK
Catch-all	*			*	*	*	*		*	*		*	*	*		*	*			*		*							
5	X	X	X	X	C	C	C	X	X	X	X	X	C	C		X	C	X	X	C	X	C	X	X		X	X	X	X
6(1)	X	X	X	X	C	C	C	X	C	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X
6(2)	X			X	C	C	C	X	C	C	X	X	C	C		C	C	X	X	C		C	X			X	X	X	
6(3)	X	X	X	X	C	C	C	X	C	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	
7(1)	X	X	X	X	C	C	C	X	C	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	
7(2)	X	X	X	X	C	C	C	X	X	C	X	X	C	C	X	X	C	X	X	C	X	C		X	X	X	X		X
7(3)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C					X	X	
7(5)	X	X	X	X	C	C	C	X	C	X	X	C	C	C		C	C	X	X	C	X	C	X				X	X	
8(1&2)	X	X(1)	X(2)	X	C	C	C	X	C	C	X	X	C	C	X(1)	C	C	X		C	X(2)	C		X			X		X
9(6)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X(&5)	C	C	X	X	C	X	C	X	X	X	X	X	X	X
10	X				C	C	C		X	C	X	X	C	C		C	C	X	X	C		C				X		X	
11(1&3)	X	X	X(1)	X	C	C	C	X	C	C	X	X	C	C		C	C	X	X	C	X(1)	C							
12(1)	X			X	C	C	C		X	C	X	X	C	C	X	C	C	X	X	C		C							
12(2)	X	X		X	C	C	C		C	C	X	X	C	C	X	C	C	X	X	C		C	X	X	X	X		X	X
13(1-5)	C	X (not 2&5)	X (not 4&5)	X	C	C	C		C	C	X	C	C	C		C	C	X		C	X (not 2&5)	C							
14(1)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C			X	X	X		
14(6)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C			X	X	X		X
14(7)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C		X	X	X	X		X
17(1&2)	X	X(1)	X(1)	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X(1)	C	X	X	X	X	X	X	
18(1to3)	X	X(1)	X(1)	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X(1)	C	X	X	X	X	X	X	
19(1&2)	X	X(1)	X(1)	X	C	C	C	X	C	C	X	X	C	C		C	C	X	X	C	X(1)	C					X		
21(1)	X			C	C	C	C		C	C	X	X	C	C	X	C	C	X	X	C		C	X	X		X			
21(2)	X			C	C	C	C		C	C	X	X	C	C	X	C	C	X	X	C		C	X	X					
21(3)	X			C	C	C	C		C	C	X	X	C	C	X	C	C	X	X	C		C	X	X					
22(1)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	
22(2)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	
24(2)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X		C	X	C		X			X		
25(1)	C	X	X	X	C	C	C		C	C		C	C	C	X	C	C	X	X	C	X	C	X						
26(1)	X	X	X	C	C	C	C		C	C		C	C	C	X	C	C	X		C	X	C				X	X		
27(1-3)	C			C	C	C	C		C	C		X	C	C		C	C	X	X	C		C					X	X	
27(4)	C			C	C	C	C		C	C		C	C	C		C	C	X	X	C		C							
27(6)	C			C	C	C	C		C	C		C	C	C		C	C	X	X	C		C							
28(1)	X			X	C	C	C		C	C		C	C	C		C	C	X	X	C		C							
28(6)	X			X	C	C	C		C	C		C	C	C		C	C	X	X	C		C							
29(3)	C				C	C	C		C	C		X	C	C		C	C	X	X	C		C	X			X			
30(2)	C	X	X	X	C	C	C		C	C		X	C	C	30(3-4)	C	C	X	X	C	X	C		X	X			30(1)(3-4)	
30(6)	C		X	X	C	C	C		C	C		C	C	C		C	C	X	X	C		C	X	X	X	X	30(1)(3-4)	X	
31(1)	X	X	X	X	C	C	C	X	X	X	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	X
31(2-9)	X	X- not 4,6	X- not 4,6	X	C	C	C	X	X	X	X	X	C	C	X	C	C	X	X	C	X- not 4,6	C	X- 3&9	X- not 4	X	X	X-3, 5&9	X	X

Report on the penalties applicable for infringement of the provisions of the REACH Regulation

	AT	BE	BG	CY	CZ	DK	EE	FI	FR	DE	GR	HU	ISL	IE	IT	LV	LI	LT	LU	MT	NL	NO	PL	PT	RO	SK	SI	SE	UK	
32(1)	X	X	X	X	C	C	C	X	C	X	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	X	
32(2-3)	X	X	X	X	C	C	C	X	C	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	
33(1&2)	X	X	X <sup>(n ot 2)</sup>	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	X	
34	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	X	
35	X		X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X		X	X	X		X	
36(1)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X	X	C	X	C	X	X	X	X	X	X	X	
36(2)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X		X	X		
37(2)	C	X	X	X	C	C	C	X	C	C	X	X	C	C		C	C	X	X	C	X	C	X		X		X			
37(3)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C		X	X	X	X		X	
37(4)	C	X	X	X	C	C	C	X	C	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	
37(5)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X		X	X	X	
37(6)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C		X	X		X	X	X	
37(7)	C	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X		X	X	X	
38(1)	X	X	X	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	
38(2)	X			X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C		C	X	X	X	X	X	X		
38(3)	X	X	X	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	
38(4)	X	X	X	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X		X	X	X	
40(4)	X	X	X	X	C	C	C	X	C	C	X	C	C		C	C	X	X	C	X	C	X			X	X	X			
41(4)	X	X	X	C	C	C	C	X	C	C	X	X	C	C		C	C	X	X	C	X	C	X			X	X	X	X	
46(2)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X			X		X	X	
49(a)	X	X	X	C	C	C	C	X	C	C	X	X	C	C	X	C	C	X		C	X	C							X	
50(2-3)	C	X	X		C	C	C		C	C	X	C	C	C	X	C	C	X		C	X	C				X	X			
50(4)	X	X	X		C	C	C		C	C	X	X	C	C	X	C	C	X		C	X	C					X		X	
53(1-3)	C	X <sup>-not 1</sup>			C	C	C		C	C		C	C	C		C	C	X		C		C								
53(4)	C				C	C	C		C	C		C	C	C		C	C	X		C		C								
55	C	X			C	C	C		X	C		C	C	C		C	C	X		C	X	C								
56(1)	X	X	X	X	C	C	C	X	X	X	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	X
56(2)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	X	C	X		C	X	C	X	X	X	X	X	X	X	
60(8)	X				C	C	C		C	C		C	C	C		C	C	X	X	C		C								
60(10)	X	X	X		C	C	C		C	C		X	C	C	X	C	C	X	X	C	X	C				X	X		X	
61(1)	X	X	X		C	C	C		C	C	X	C	C	C		C	C	X	X	C	X	C				X				
61(3)	X	X			C	C	C		C	C	X	C	C	C		C	C	X	X	C	X	C								
62(4&5)	X				C	C	C		C	X <sup>- 1&amp;4</sup>		C	C	C		C	C	X	X	C		C							X	
63(3)	X				C	C	C		C	C	X	C	C	C		C	C	X		C	X	C								
65	X		X	X	C	C	C		C	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X		X	
66(1)	X	X	X	X	C	C	C	X	C	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X		X		X	X	
67(1)	X	X	X	X	C	C	C	X	X	C	X	X	C	C	X	C	C	X	X	C	X	C	X	X	X	X	X	X	X	X

X: covered by a specific provision  
 C: covered by a catch-all provision

While the Benelux countries and the southern countries have more often adopted a “specific provisions” approach, the adoption of a sole catch-all provision seems to be a frequent choice in the Nordic Countries (Denmark, Iceland, and Norway). Other continental Member States, such as France, Austria and Germany have opted for a combined approach.

The countries having adopted only a catch-all provision justified this choice with two main reasons. For some countries, it is considered as clearer and simpler, as it avoids a misinterpretation of the REACH obligations. The Czech Republic considered this option as “preferable”, when drafting its legislation. For others, this is the approach usually used in the legislation with regard to sanctions. Estonia and Malta, for instance, indicated that the environmental legislation typically defines very broadly the scope of what is considered as offences.

As to the countries having chosen the combined approach, they mentioned inter alia the fact that the catch-all provision constitutes a “safety net” ensuring that the legislation will cover all potential breaches of the obligations of the Regulation, without any possible omissions. This is for instance the case in Hungary, where the catch-all provision is combined with a listing as extensive as possible of the potential enforceable provisions of REACH. The idea is to have all infringements covered and the most important obligations emphasised, as well as to facilitate for the enforcing authorities the identification of offences. For France, on the other hand, the REACH obligations expressly identified in the legislation are far less numerous and focus on the obligations that should be particularly closely monitored. In the case of Cyprus, the explanation of the choice of a combined approach is very different. There, criminal offences are covered by a catch-all provision, as this is the customary approach of sanctions in national law; and the administrative offences are expressly identified, because administrative sanctions are a new tool in the country, and, in that context, the enumeration of what is considered as sanctions has been the preferred approach of the authorities.

Lithuania provides what could be considered as another approach, with very general definitions of what can be considered as offences. This approach broadens the scope of what is defined as offences, and it was considered that all enforceable articles of REACH would be covered in the Lithuanian legislation, even though it does not contain a “catch-all” provision as such. It should also be mentioned that, in Lithuania, the Ministry of Environment drafted and presented to the Government a revised version of the sections on penalties introduced in the Code of Administrative Offences. The Draft is not available yet, but the authorities have indicated that Lithuania selected a so-called “catch-all provision” approach combined with a list of specific obligations with specific sanctions. This list aims at addressing what is considered as priority-obligations.

### 3.2.2. Analysis of main tendencies and gaps

A first glance at the table shows that provisions have been set for the enforcement of most obligations of REACH in the vast majority of the countries under study.

In some countries however, including Romania or Sweden, the sanctions in place cover substantially fewer provisions of REACH than in other countries (respectively 50% and 43.4% of the enforceable articles identified in the study).

In terms of articles, or groups of articles, most of the REACH enforceable provisions are subject to enforcement. However, some gaps can be identified. Two main reasons seem to explain this.

The first aspect is that some articles can be considered as self-enforcing. We have identified two articles as self-enforcing, (Article 9(1) and Article 20(2)), and therefore have not included them in the table. Other articles are considered as self-enforcing in certain countries. This is particularly the case for Articles 10 to 13.

Another aspect is that, in several cases, enforcement relies on information that ECHA should provide to the Member States’ enforcement authorities. REACH procedures imply that ECHA will require or

obtain information from companies (this may also require further action on the part of the companies). National enforcement authorities should intervene to ensure that the information is provided, that it is correct or that the necessary actions have been taken by the companies. REACH provisions that may necessitate such intervention (see for instance Articles 13, 19, 40(4)) have not necessarily been identified as enforceable by the Member States and EEA countries. When they have been taken into account in the national legislation, an effective exchange of information between ECHA and the enforcement authorities is crucial to ensure that the legislation is implemented<sup>31</sup>.

A closer look at the provisions within each of the main obligations under REACH shows where gaps can be found, and which obligations are intended by the countries to be particularly well enforced.

### ***Registration***

Regarding the main obligations related to registration of substances, the breach of the “no data, no market” rule of Article 5 is subject to sanctions in all countries except for Romania and Italy. Penalties have been well established for violation of Articles 6 and 7 in almost all countries. This is however not the case in the UK. Pursuant to the explanation provided in Section 2, the British authorities may have considered that the obligations under these articles resulted directly from Article 5, and that the enforcement of this article was sufficient in itself to ensure that all registration-related requirements would be well enforced. Conversely, Italy and Romania considered that sanctioning breaches of Articles 6 and 7 implied the enforcement of the obligation of Article 5.

The obligations of Articles 8 and 9, which are not considered as a priority for enforcement, have been well addressed with regard to sanctions. Only Luxembourg, Poland, Romania, Slovakia and Sweden have not set a penalty for the infringement of these provisions.

The essential obligations related to the information to be submitted for registration (Articles 10 to 12) have been more or less well covered. These obligations concern information to be provided to ECHA directly, which makes it difficult for the national enforcing authorities to know whether the information was indeed provided. Moreover, these provisions could be considered as self-enforcing, as an incomplete dossier will in any case be rejected by the Agency. And once again, if the substance is put on the market in that case, this would be in breach of Article 5 of REACH. However, the fact that these articles are not considered as enforceable in some countries is problematic, especially as they are particularly important to enforce. Only the non-respect of Article 12(2) regarding the obligation to notify ECHA with additional information if the tonnage reaches the next threshold has been almost uniformly subject to a sanction in all countries. The related Article 24(2) on the obligation to notify where the quantity reaches the next tonnage has also been made subject to sanctions in most countries.

The non-respect of Article 13(1-5), which is not identified as a priority article, is usually not subject to sanctions unless covered by catch-all provisions. The provisions on the avoidance of animal testing and good laboratory practice, as well as the provisions on animal testing in Article 25(1) and 27(1) have not been expressly taken into account by quite a few countries under study. However, for the United Kingdom, it can be argued that specific legislation on animal testing is already in place at the national level, based on national as well as EU policy. The provisions in the UK 1986 Animals Act are considered as sufficient to ensure the enforcement of the REACH obligations concerning the avoidance of animal testing.

Article 14 on the CSA and CSR is subject to enforcement in all countries except Poland, Sweden and partially Portugal. Articles 11, 19 and 21 are more or less well covered by sanctions. The breach of Article 11 and 19 on joint registration is not sanctioned in about 20% of the countries. This may lie in the fact that the possibility to enforce this article is conditioned by the provision of information on the breach by ECHA. Article 21 prohibits exercising an activity where ECHA has notified the registrant of a problem in the registration procedure. The infringement of this provision is sanctioned in Austria,

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<sup>31</sup> On this difficulty, see p.7 of the report.

Greece, Hungary, Italy, Lithuania, Luxembourg, Poland, Portugal and partially in Slovakia, in addition to the countries with a catch-all provision. This means that only 23 countries out of 29 have provided penalties for this provision. Article 22 concerning the obligation to update the registration is covered in all countries.

The adoption of provisions on enforcement of data sharing has been rather limited. Although not identified by the Forum as being priority articles, the articles of Title III of REACH should be enforced. As mentioned above, the provision on unnecessary testing seems to have been only very partially transposed due to the existence of specific legislation on animal testing. Concerning Article 27(4) and (6) on the sharing of existing data, a penalty was expressly adopted only by Lithuania and Luxembourg. However, it shall be noted that an entire procedure is provided for by REACH in case of problems regarding data sharing.

Another gap is in the enforcement of the pre-registration requirement (Article 28), which is only expressly foreseen in four countries (Austria, Bulgaria, Lithuania and Luxembourg). However, this provision can be considered as enforced under Article 5, since placing the substance on the market in such cases would be in breach of Article 5 (Portugal for instance). Article 29(3) on the sharing of information within a SIEF is also only partially penalised (expressly only in Hungary, Lithuania and Luxembourg). It is however a very abstract provision and therefore can be interpreted as a duty. Article 30, on the other hand, is more precise on the procedure to follow and the corresponding obligations regarding the exchange of data within a SIEF. This article has been subject to sanctions in most countries.

Articles 40(4), 41(4) and 46(2), which set out the most important requirements on evaluation have been made subject to sanctions in all countries, except Poland, Portugal and Romania, and only partially in Latvia, Slovenia and the UK. Other provisions on evaluation, considered as being less of a priority, have been more partially subject to sanctions. In particular, the obligations of Article 53(1-4) are enforced only, and partly, in Belgium. This article, which concerns sharing of costs and data for tests, can be considered as an abstract provision (“*make every effort to reach an agreement*”) and for this reason can be interpreted as a duty and difficult to enforce.

### ***Supply chain***

The main obligations concerning the supply chain have been overall very well covered. Articles 31 to 34 are subject to penalties in all countries under study. Only the breach of Article 35 is not sanctioned everywhere (four countries did not adopt a penalty for this provision).

Other less essential requirements regarding the supply chain (Article 32(2-3) and 36) have also been very well covered.

### ***Downstream users***

The essential requirements of REACH for downstream users are also covered in a very satisfactory way. Only the breach of Article 37(2) is not subject to penalties in all countries (25 out of 29).

The non respect of other requirements concerning the downstream users (Articles 37(6 and 7) and 38(2 to 4) has also been subject to penalties in most cases.

This study does not distinguish Article 39 as a separate enforceable article as it was considered that Article 37 and 38 shall be read in conjunction with that article, and hence the obligations of Article 39 would be covered. A few countries brought to the contractor’s attention the fact that Article 39 is covered separately in their legislation (Cyprus, Romania, Italy for instance).

### ***Authorisation and restrictions***

Penalties related to the obligations related to authorisation seem to be slightly more problematic.

The core requirements are usually covered: Article 56(1) and (2) of REACH on the respect of conditions of authorisation are enforced in almost all countries (but only partially in Luxembourg and the Netherlands), and the breach of Article 67(1) on restrictions is unanimously sanctioned. Moreover, the infringement of Articles 65 and 66(1), respectively on the obligation of labelling of the substance and on the obligation of notification of a use for the downstream user, is sanctioned in most countries (respectively by 90% and 93% of the countries). Nevertheless, the breach of Article 55 on the obligation to analyse alternatives has been subject to sanctions in half of the countries under study. Article 60(8) on the respect of the conditions linked to authorisation is enforced in 51% of the countries, and Article 60(10) on the reduction of the level of exposure is subject to a sanction in about 76% of the cases, which is, in comparison with other provisions, quite low. This last score can be explained by the fact that the obligation is relatively vague, and might be difficult to enforce.

For Articles 61 to 63, which contain obligations that are not considered as such a priority for enforcement, very few countries have adopted sanctions to ensure their respect. Articles 61(1) and (3) are expressly enforced in only seven countries (Austria, Belgium, Bulgaria, Greece, Lithuania, Luxembourg and the Netherlands). The possibility of enforcement is expressly provided even more rarely in the case of Article 62 (only enforced by five countries) and Article 63 (enforced expressly by 4 countries).





## **4. Comparative analysis of Member States Provisions on penalties**

The comparative analysis below is carried out in several stages. It studies sequentially different aspects of the information provided by the Member States on their systems to ensure the enforcement of REACH.

As already mentioned, penalties are to be dissuasive, proportionate and effective. An effective penalty should make sure that regulatory obligations are complied with and that private and public actors do not compromise citizens' health and safety, pollute the environment, distort the market or violate consumers' rights. It is moreover important to make penalties proportionate to the offence committed in order not to discourage undertaking as a whole. Finally, penalties are supposed to decrease the risk of re-offending by, for instance, creating increasing penalties for repeat infringements.

In order to create a sanction regime under REACH that integrates these principles, it is important to include a proportionate array of penalties that correspond to the gravity of the offence and the intention of the offender, including economic, financial, administrative and criminal sanctions. A minimum of consistency across Member States between the enforcement mechanisms under REACH will be important to ensure a level playing field for businesses across the EU.

### **4.1. Comparative analysis of the types of offences**

Given the extensive information and the many offences possible under REACH, **several tables corresponding to the main obligations** under REACH were used to compile the information on the behaviours identified as contravening the obligations of REACH in the twenty-nine countries under study, as follows:

- Registration and evaluation,
- Authorisation and restrictions,
- Supply chain,
- Downstream users.

These tables, which can be found in Annex I to this report, compare the types of offences for the infringement of REACH provisions across Member States, be they criminal or administrative.

This study focuses on the provisions that specifically enforce the obligations set by the REACH regulation. Therefore, provisions in the national legislation containing general obligations that could impact on the implementation of REACH have not been reflected in the tables of Annex I on the types of offences.

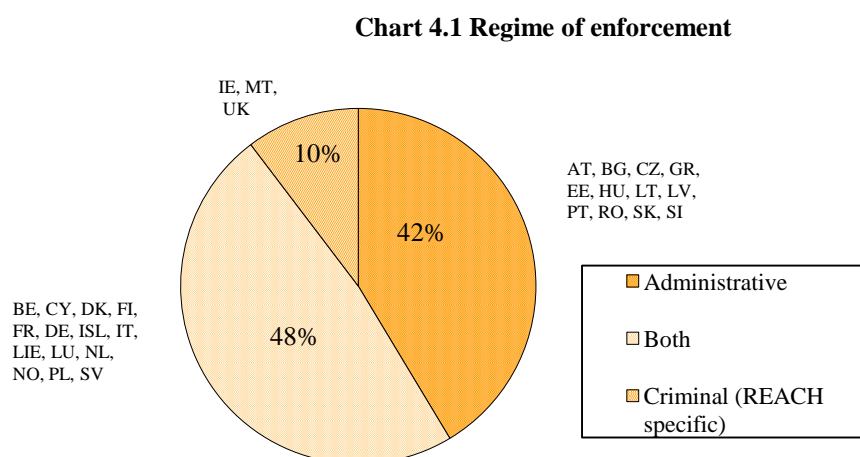
#### ***Distinction between administrative and criminal enforcement regimes***

The nature of the offence, whether administrative or criminal, varies among Member States depending upon existing practices and cultural interpretations.

In Europe, and in the countries under study, a first distinction can be made between countries with a continental system, and those with a common law system (UK, Ireland) or with a common law influence (Malta). Continental systems clearly define whether the enforcement regimes for the protection of the environment are criminal or administrative, and offences will be classified accordingly. In the common law countries, the protection of the environment is mainly ensured through criminal law.

Whilst common law systems enforce REACH obligations mainly through enforcement notices and criminal law<sup>32</sup> (Ireland, UK, but also Malta), in the continental systems, REACH obligations are enforced either through administrative law alone (Austria, Bulgaria, Czech Republic, Greece, Estonia, Hungary, Lithuania, Latvia, Portugal, Romania, Slovakia and Slovenia) or combined with criminal law (Belgium, Cyprus, Denmark, Finland, France, Germany, Iceland, Italy, Liechtenstein, Luxembourg, the Netherlands, Norway, Poland, Sweden).

The pie chart below shows with which types of regime Member States have chosen to address the infringement of REACH obligations:



Despite the classification established for this chart, the distinction between the different choices of regimes is more subtle. In particular, under the countries classified as having a combined approach, a few countries let their enforcement policy rely more heavily on one regime than the other. For instance, France and Germany put a stronger emphasis on administrative sanctions, while Denmark, Finland, Sweden and Iceland, but also Poland, address most of the offences, particularly the most significant ones, under criminal law. Sweden provides for administrative sanctions only regarding the language of the safety datasheet.

The line between administrative and criminal enforcement is also blurred in the case of Austria and Germany, as they use a so-called “quasi-criminal” (or administrative-criminal) approach. This is a hybrid concept which combines administrative responses (sanctions imposed by the administrative authorities) and the guarantees of the criminal process (notably due to the nature of the sanctions that can be imposed, i.e. deprivation of freedom). While under this system the Austrian approach is closer to the administrative law regime, Germany’s enforcement policy combines administrative criminal and criminal tools.

### ***Link between enforcement regime and types of offences***

Among the three categories of enforcement regime identified above, the countries having opted for the development of a criminal enforcement regime consider any breach of the obligations imposed on a stakeholder as an offence. In the UK and Ireland, even though criminal offences are mostly identified,

<sup>32</sup> In the UK, as shown in Section 4.2, the first measures are administrative but due to the fact that the violation of the administrative measure is considered a crime, in the end criminal law is applied to enforce environmental legislation. Furthermore, the main breaches of environmental law are criminal offences. Ireland also provides for the possibility of a summary prosecution, where inspectors can impose a fine, which, when paid, puts an end to the prosecution.

a great importance is also given to administrative measures to bring the offender in compliance with legal requirements, and the policy is very much oriented towards informing the offender. This is also the approach adopted in some Nordic countries and in the quasi-criminal law countries, which only consider as criminal the intentional or grossly negligent breach of the REACH obligations (Finland, Sweden and Germany and Liechtenstein). In Denmark and Finland, the policy is geared towards bringing the offender in compliance, and the criminal procedure will only take place once this method has failed.

In the countries that have opted for an enforcement regime oriented towards administrative sanctions, without use of a catch-all provision, the offences can usually be distinguished between major and minor offences. Major offences will then usually correspond with the main requirements of REACH while other offences are minor. This is the case in Bulgaria, Greece, Hungary and Romania. Portugal categorises the administrative offences under “serious offences” and “very serious offences”.

In these countries, only offences characterised by a serious endangerment of health or the environment will be considered as punishable under criminal law. Thus, in Romania, applicable criminal sanctions are in the Law of the Environment and are not specifically linked with REACH. There is also one paragraph in the Criminal Act stating that crimes concerning the environment are to be punished with imprisonment, which is also of a very general nature and is about to be amended.

In Hungary, certain provisions of the Penal Code may become relevant as an indirect result of infringing of REACH provisions. They deal with the endangerment of the human health and the environment, but also forgery of documents, professional misconduct or economic crimes. In Slovakia and Estonia, the legislation provides for obligations in relation with chemicals. The Slovakian legislation prohibits the illegal manufacturing, import, export, transfer, purchase, sale, exchange, modification, use, or procuring highly dangerous chemical substances without permission. Estonia bans the handling of chemicals or waste dangerous to human health or the environment, if such violation causes a danger to human life or health or to the environment. These provisions are usually of a very general nature and are not specifically linked to REACH, and therefore, are not reflected in the Annex I tables.

It should be noted that in Denmark, REACH penalties are part of “the consolidated act No. 1755 on Chemical Substances and Products”, which apply to chemicals in general without specific provisions concerning REACH. Therefore, the only offence applicable to REACH is of a very general nature, and refers to “any violation of the European Community regulations regarding chemical substances, products and articles”. In that specific situation, this general provision was taken into account in the study. The Italian legislation has also adopted a particular approach, as it mentions that REACH specific provisions shall apply “unless it constitutes a criminal offence”. What is considered as a criminal offence shall be analysed on a case-by-case basis, in case more general provisions of criminal law could be considered as applicable to the situation of infringement.

Regarding the countries that have established both a criminal and administrative enforcement system for REACH, the types of offences defined under administrative and criminal offences in the different countries can be separated into two main groups.

In a few countries, the situations described as criminal and administrative offences are to some extent similar (Belgium and Luxembourg) or overlapping (Cyprus and the Netherlands). In the four countries, the accumulation of the administrative and the criminal procedures is then possible. In Belgium, on a case-by-case basis, depending on the seriousness of the offence, the administrative authority or the inspector will decide to bring the case before the public prosecutor if he considers that the offence would constitute a crime.

In most countries however, the behaviours designated as administrative and criminal offences describe very different situations (different types of offences, different types of offenders, etc.). Other countries, such as France, even refer to one category as exclusive from the other (all offences that are

not considered criminal are administrative). It can be noted that, in these cases, depending on the behaviour identified, the procedure will either be administrative or criminal, without there being a problem of accumulation.

Where different offences are identified under the criminal and the administrative regimes, what is considered as a criminal or an administrative offence varies quite a lot from one country to another. However, the common point is that the criminal offences designate what are considered as more serious breaches, and the aim is to punish the offender. Criminal offences relate to the violations of the main requirements of REACH, or more generally to intentional breaches of REACH obligations that may result in the impairment of health and of the environment.

In Denmark, Finland and Sweden, most administrative offences refer to minor obligations of REACH (e.g. language of a document) and a first breach of the legal obligations. In France and Poland, the most important obligations of REACH are covered by criminal law.

The intentional element also plays a determining role in defining an offence as criminal or not. In Finland, Sweden, Norway, and to some extent in France, the breach of an obligation has to be wilful and negligent to be qualified as a criminal offence. This is also the criteria to determine if behaviour falls under criminal-administrative and criminal law in Germany and Liechtenstein. This indicates that, given the complexity of REACH and the possibility that companies might not be aware of all of their obligation under the Regulation, these Member States preferred to focus their enforcement policy on informing the registrants rather than punishing them.

### ***Identification of the offences***

In a few countries, the list of situations that will be regarded as an offence is very extensive, and aim at listing exhaustively the cases constituting an infringement of the REACH regulation. This is the case in Belgium, Bulgaria, Cyprus, Greece, Hungary, Italy, Lithuania, Portugal, Romania, Slovakia, Slovenia and the United Kingdom. Other countries, such as Austria, Finland, France, Germany, Luxembourg, the Netherlands, Poland and Sweden, have made use of general terms reflecting the main obligations under REACH. A few countries have used catch-all provisions (i.e. Austria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Malta and Norway), meaning that the situations regarded as being in violation with REACH are not exhaustively defined in the text of the enforcement legislation, which rather includes a more general reference to violations of the Regulation<sup>33</sup>.

In countries where enforcement is primarily done via criminal law, two countries have used a catch-all provision (Ireland and Malta). Where the legislation is mainly (or only) enforced through administrative law, the national legal provisions describing breaches of the REACH obligations contain a catch-all provision less frequently (i.e. Austria, Czech Republic, Hungary, Latvia).

The use of the catch-all provision has taken two different forms. In some cases (i.e. Czech Republic, Denmark, Estonia, Iceland, Ireland, Liechtenstein, Malta, Norway) the legislation has provided only a catch-all provision, while other countries (Austria, Cyprus, France, Germany, Hungary and Latvia) have provided a residual catch-all provision, allowing the sanctioning of any other breach of legislation not expressly mentioned.

Given the extensive amount of REACH obligations considered as enforceable by Member States, many countries used a so-called “by-reference provision”. This is not to be confused with a catch-all

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<sup>33</sup> To illustrate the concept of “catch-all provision”, the example of Ireland can be quoted. The Irish Chemicals Act of 2008 states in its Article 29: “Where—(a) a distributor, (b) a downstream user, (c) an importer, (d) a manufacturer, (e) a person appointed in accordance with Article 8 of the REACH Regulation, or (f) a producer of an article, contravenes a provision of the REACH Regulation that applies to him or her, that person shall be guilty of an offence”.

provision, as it tends to list the provisions of REACH, infringements of which will be considered as an offence. Such a provision was used in Belgium, Bulgaria, Finland, Greece, Hungary, Italy, Latvia, Luxembourg, the Netherlands, Poland, Romania, Slovenia, Sweden and the United Kingdom<sup>34</sup>.

### *Types of offences*

More generally, the behaviours that may constitute offences or that may lead to an enforcement reaction can be acts or omissions of either a substantial or of a more technical nature<sup>35</sup>; the latter will be the main types of offences applicable to REACH. Offences of a technical nature can be divided into different types of offences:

- *Registration* related offences: As registration is a pillar of REACH, placing on the market without being registered is obviously an offence which is considered as major in all countries. The absence of registration or pre-registration when applicable will also be considered as serious breaches of legislation.
- *Authorisation*: the offences will range from the absence of authorisation, to the failure to comply with the conditions attached to the authorisation. Behind these types of offences is not only the aim of controlling the companies' activity with regard to the most dangerous substances, but also to ensure that endangerment of health and/or the environment have or will not occur. Conditions are set to ensure that certain activities, which are known to be a risk to the environment, affect the environment to the least possible extent, and the administration shall ensure that this is well respected. For this reason, in serious cases of endangerment or where the activity has resulted in damages to the environment, these types of offences can constitute crimes.
- *Document-related infringement*: this type of offence is very relevant to REACH. It includes cases where persons hide or alter documentation that has to be provided to the administration. Falsification, alteration or hiding of documents is often considered as a crime (France), as well as the refusal to communicate information (SDS) or provision of false information to the other actors in the chain. The detection of this type of offence relies on good communication between ECHA and the national authorities<sup>36</sup>.
- *Obstruction to controls and inspections carried out by authorities*: obstruction has also been considered as an offence in the legislation under study. However, as this is not directly linked to the enforceable articles of REACH, they have not been further analysed in this report. However, it will be considered as an offence since operators and citizens in general have the obligation to collaborate with the administration.

In addition to technical infringements, substantive infringements may also occur. It is possible to find some acts that could constitute typical crimes against the environment since they affect or may affect elements of the environment. These include the illegal traffic of substances.

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<sup>34</sup> As an example, Article 1(2)(a) of the Hungarian Government Decree No. 224/2008. (IX.9.) on the detailed rules of the penalties applicable for infringement of the provisions of the REACH Regulation can be quoted: "A penalty of 2 000 000 to 20 000 000 HUF may be issued, if a natural person, a legal person or an organization without legal entity: a) does not respect or intentionally infringes the obligations relating to the registration of substances, thus especially those laid down in Articles 5, 6, 7(1), 10, 11, 12, 17, 18, 19, 21 and 38 (1) of the Regulation 1907/2006/EC".

<sup>35</sup> Substantial infringements, as opposed to technical infringements, refer to actions of the infringer that directly impairs the environment or health (dumping of substance into the environment, discharge of dangerous chemicals into water, etc.). Technical infringements on the other hand refer to the non respect by the infringer of technical (or formal) requirements that he/she is supposed to follow according to the law.

<sup>36</sup> See on this point p. 7 of the report

## 4.2. Comparative analysis of the level of penalties

A range of penalties has been adopted, including administrative penalties such as fines, injunctions, and name-and-shame, as well as criminal penalties such as prison sentences. Financial penalties are however the most common penalties.

### Scope of liability

Penalties may vary depending on whether they apply to legal or natural persons. Liability of legal persons is possible in all Member States under study, except in Austria, Lithuania, Luxembourg and Sweden, as well as in Slovakia for criminal liability. But even in cases where the legal person is not liable, the managers and directors can be liable for *culpa in custodiendo* and *culpa in eligendo*. Some accessory measures (such as closure of the establishment) are clearly directed towards companies. On the other hand, in Iceland, REACH penalties are applicable exclusively to legal persons. In the latter case, the law mentions that the company, as a legal person, shall be responsible for the wrongful behaviour of its employees. In Cyprus, Germany, Hungary, Poland and Portugal, fines can also be imposed on entities without legal personality, and in Liechtenstein on limited and collective partnerships.

The level of the financial penalty varies particularly in some countries, depending on whether the offender is a natural or a legal person, while in other countries, there is no distinction between natural and legal persons (in Bulgaria, Belgium, Cyprus, Czech Republic, Ireland, Italy, Malta, Romania, Slovakia, UK, and Germany for “*Ordnungswidrigkeiten*”). In the countries where fines imposed on legal persons are different to those imposed on natural persons, the fines will in any case be higher, and in a few cases, specific criteria will apply for the calculation of the fine. For instance, in France, the law sets out that the fine for legal persons shall be multiplied by five. In Slovenia, the fine is usually twice as high for legal persons as for natural persons. In the Netherlands, the fine applied to legal persons is one category higher than the one imposed on natural persons.

**Table 4.2.1 Sanctions applicable to legal persons**

	Sanctions applicable to legal persons	Criteria	Sanctions applicable to other groups
<b>Austria</b>	Y	Y- Legal persons are liable for the payment of fines which are imposed on the representative of a legal person which has committed an offence	Y (registered partnerships)
<b>Belgium</b>	Y	Identical to natural persons	N
<b>Bulgaria</b>	Y	Identical to natural persons <sup>37</sup>	N
<b>Cyprus</b>	Y	Identical to natural persons	Y (anyone)
<b>Czech Republic</b>	Y	Identical to natural persons (with a business licence)	N
<b>Denmark</b>	Y	Specific to legal persons	N
<b>Estonia</b>	Y	Specific to legal persons	N
<b>Finland</b>	Y	Specific to legal persons	N
<b>France</b>	Y	Fine multiplied by 5.	N
<b>Germany</b>	Y	-“ <i>Ordnungswidrigkeiten</i> ”: Identical to natural persons -Criminal offences: Special provisions	Y (Associations without legal personality)
<b>Greece</b>	Y	Specific to legal persons	N
<b>Hungary</b>	Y	Identical to natural persons	Y (Organisation without legal personality)
<b>Iceland</b>	Y	Specific to legal persons (only a fine)	N
<b>Ireland</b>	Y	Identical to natural persons	N

<sup>37</sup> Under Bulgarian legislation ‘*fine*’ refers to a natural person while ‘*pecuniary sanction*’ refers to a legal person. Despite some opinions in the legal doctrine that the ‘*pecuniary sanction*’ does not belong to the system of the administrative measures as only natural persons may hold administrative liability it should be noted that in both cases the penalty is of economic nature.

Italy	Y	Identical to natural persons	N
Latvia	Y	Specific to legal persons (higher fine)	N
Liechtenstein	Y	Joint liability of legal and natural persons <sup>38</sup>	Y (Collective and limited partnerships)
Lithuania	N	N/A	N
Luxembourg	N <sup>39</sup>	N/A	N
Malta	Y	Identical to natural persons	N
The Netherlands	Y	Fine one category higher than for natural persons	N
Norway	Y	Specific to legal persons (only a fine)	N
Poland	Y	Specific to legal persons	Y (organisation without legal personality to which separate regulations confer legal capacity)
Portugal	Y	Specific to legal persons (Higher than for natural persons depending on the type and nature of the infringement but without a fixed rate) <sup>40</sup>	Y (partnerships and organisations without legal personality)
Romania	Y	Identical to natural persons	N
Slovakia	Y	Y – identical to natural persons, Not for criminal penalties	N
Slovenia	Y	Specific to legal persons In general, multiplied by 2	N
Sweden	N	N/A	N
United Kingdom	Y	Identical to natural persons	N

### Analysis of the level of penalties

The tables in Annex II serve to compare the level of penalties foreseen in the national legislation across Member States based on the type of obligations under the Regulation. The tables are articulated on the same model as the tables on the types of offences above: registration and evaluation, authorisation and restrictions, supply chain, downstream users. The tables include fines, as well as other penalties which are entered into the table as qualitative data.

### Definition of penalties

Article 126 of REACH refers to the obligation for Member States to impose “penalties”. In the context of this provision, this term is understood as equivalent to “sanctions”. The sanctions are characterised by their punitive or repressive character. However, this repressive character does not prevent a sanction from having a preventive dimension, due to the deterrent effect that a sanction usually has. Sanctions are one of the most important enforcement measures taken in order to ensure compliance with the legislation by preventing or by restoring the legality of a situation.

During the course of this project, other measures than sanctions were identified. These are mostly *coercive measures*, imposed at the administrative level, which intend to compel the offender to comply with a decision of the competent authority, including a decision imposing a sanction. Some systems, such as in the Nordic Countries, are based mainly on coercive measures or the threat to impose certain measures if non-compliance occurs. There are two main types of coercive measures: coercive or conditional fines, and coercive actions. In the first case a fine will be imposed if the offender does not comply with the administrative decision, order or prohibition. If the offender does not comply with the administrative decision within the time limit set forth by the administration, the competent authority will fix an amount of money to be paid for every day of non-compliance. Coercive actions include the threat of suspension of the activity or withdrawal of the permit as well as forced execution or substitutive/subsidiary execution at the expense of the offender.

<sup>38</sup> Art. 12, Act on the marketability of goods.

<sup>39</sup> A law proposal has been submitted to the Parliament but has not been adopted yet.

<sup>40</sup> Fine multiplied by 5 applies also in Portugal, but only for infringement of the Biocides legislation.

In Finland, the authorities can prohibit persons from continuing or repeating a procedure infringing REACH. The prohibition can also be combined with a coercive fine. A coercive fine is imposed on a daily, weekly or monthly basis if the regulations or decisions made pursuant to them have not been complied with within a specified time limit, and shall continue until the regulations or decisions are complied with. A coercive fine may alternatively be imposed as a single payment. However, coercive fines are not considered a penalty or punishment but are used as a measure to ensure that the regulations or decisions made pursuant to them are complied with. The superior authority can alternatively impose an order to interrupt the activity. The coercive fine is also used in Norway and in Iceland. In Iceland, it is used together with the possibility of putting a stop to the marketing of a product, or the requirement by the inspectors to dispose of the product, withdraw it or store it until any mishandling has been corrected.

At a certain extreme, criminal law is a coercive measure with regard to administrative measures. In some countries, such as the UK or Ireland, this is clearly due to the relation between breaches of administrative decisions and criminal law. If the offender does not comply with the administrative decision, the conduct will be regarded as a crime. Administrative measures also have a coercive role in France. If the infringer does not comply with the “*mise en demeure*” (formal notice) in the specified time, a sanction will likely be applied.

In Germany, the competent authorities of the Federal States may issue administrative acts to eliminate actual or prevent future infringements of all REACH provisions. If the offender does not comply with these administrative acts, the competent authority may enforce them according to the Administrative Enforcement Laws of the Federal States. At the same time, non-compliance with administrative acts issued to put an end to an infringement of REACH provisions constitutes an “*Ordnungswidrigkeit*”.

Where the countries have mentioned coercive measures when notifying the penalties adopted in their national legislation, this is indicated in the tables of Annex II via the use of the expression “*coercive measures*”, with the explanation of the type and if available the level of these measures in each country using it.

### ***Types and level of penalties***

In general, the Member States under study have included fines in their penalty systems, as a continuation of their existing systems. Other types of penalties include injunctions (including market withdrawal), prison sentences, and name-and-shame methods where non-compliance is made public.

With regards to **administrative measures**, the main type of sanction is economic, through fines and deposits. Fines are a very flexible instrument and considered especially appropriate for environmental offences where the main offender is a legal person. In some countries, although there is a possibility to apply fines, these are rarely used as their systems are mostly based on initial warnings and formal notices and a fine is imposed only as an *ultima ratio*.

Fines are the only instrument foreseen at the administrative level in Bulgaria, Cyprus, Estonia, Hungary, Italy, Latvia, Liechtenstein and Romania.

Two types of fines can be found: lump sums (in all countries using the administrative fine) and daily fines (Cyprus, France). Lump sums are determined by the authority according to the minimum and/or maximum limits set forth by the law. Belgium, Bulgaria, Greece, Hungary, Italy, Latvia, Lithuania, Portugal, Romania, Slovakia and Slovenia have adopted a range of fines, with a minimum and a maximum sentence, while other countries has chosen to provide for a maximum fine only. Both systems allow for the nuancing of the severity of the penalty to reflect the seriousness of the violation. In the case of daily fines, the competent authority will fix the quantity of the fine to be paid per day during the period laid down in the decision.



In the Netherlands, the *Dwangsom* is a conditional fine: following the period during which the offender can correct the situation, the wrongdoer has to pay a fine for every time an offence is observed or for every period an illegal situation continues. When possible, it is common to set the maximum *dwangsom* at twice the amount of the financial advantage obtained from the illegal behaviour. It should be proportionate to the violation and the aimed effect of the penalty imposed.

The amount of the administrative fine can vary significantly from one system to another, from a maximum of less than 1000 EUR in some countries for certain types of minor offences (Latvia, Greece, Cyprus) to a maximum of 2 500 000 EUR (in Poland for very serious offences with a fault from the offender). Usually, the countries have provided different categories or classes of fines, depending on the seriousness of the infractions (Belgium, Bulgaria, Cyprus, Greece, Hungary, Latvia, Liechtenstein, Lithuania and Romania), rather than one range of fines applying to all types of offences (Czech Republic, Estonia, France, Poland and Slovenia).

Other pecuniary measures used in the countries under study include the payment of costs for the accomplishment of formalities linked to REACH as required by the Regulation (establishment of data, tests, etc.) in France.

Complementary measures can include:

- Suspension of a business licence or partial or total suspension of the activity (Czech Republic, Luxembourg, Portugal)
- Closure of the premises partly or totally (Luxembourg, Portugal)
- Withdrawal of a permit (The Netherlands, Portugal)
- Suspension or ban on the use of the substance or mixture (Czech Republic, Poland)
- Suspension of placing on the market, placing into circulation or distribution and selling of mixtures that are suspected to be dangerous or obligation to withdraw from the market (Czech Republic, Denmark, Poland, Slovakia)
- Seizure, confiscation or deprivation of assets or objects (Belgium, Germany, Portugal, Slovenia)
- Destruction of the substance, mixture or article when the legislation on registration or authorisation has not been respected (Belgium, France, Czech Republic, Denmark)

On the last aspect, it should also be noted that the recent European Regulation 765/2008/EC on Market Surveillance relating to the Marketing of Products also foresees the possibility to destroy a product (including a substance)<sup>41</sup>. As a European Regulation, this allows market surveillance authorities in every Member States to “destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary”, applicable from 1 January 2010.

Portugal provides for a wide range of administrative sanctions that may also be useful either to bring the offender into compliance or to punish him. They cover, in addition to the penalties mentioned above, the suspension of the right to obtain subsidies or other benefits issued by public authorities (at national or EC level), the suspension of the right to participate in exhibitions or events at national or international level aimed at selling or marketing the products or activities of the agent, the suspension of the right to participate in public tenders for providing public services or the right to be issued permits; - Loss of fiscal and credits benefits, the application of measures aimed at preventing

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<sup>41</sup>Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, article 19.

environmental damage, the administrative conviction/decision being made public and the confiscation of the animal with regard to offences concerning animal testing.

With regards to **criminal sanctions**, three main types of measures - pecuniary, deprivation of rights and prohibitions and orders - can be identified.

Fines and prison sentences are the main criminal sanctions in all countries where criminal law is applied. The fine can go up to 55 000 000 EUR in Belgium, while on conviction on indictment, the fine is unlimited in the United Kingdom. The most serious breaches of the REACH regulation are punished with imprisonment in all countries with criminal sanctions, except for Poland. In Belgium, the most serious offences can lead to up to eight years of prison, while the maximum is of three months in Norway. However, in most cases, prison sanctions are from 6 months to five years.

A few countries also provide a range of complementary measures, such as:

- Closure of establishment: total or partial, temporary or permanent, including cessation or suspension of activities or the prohibition to use the premises where the infringement was committed (Belgium, France)
- Deprivation or suspensions of rights: incapacitation to carry out an activity, to offer financial titles on the regulated market, to be contractor for the administration, to use public subsidies, suspension or withdrawal of authorisation (Belgium, France, Malta, Poland).
- Actions on goods: confiscation, and in some cases, destruction of the substance, article or mixture on the costs of the offender, as well as withdrawal from the market (Belgium, France, Iceland, Poland)
- Actions on financial assets: confiscation of any economic gain from the violation of REACH (Denmark, Iceland, Poland)
- Publication of the judgment (Belgium, France, Poland)

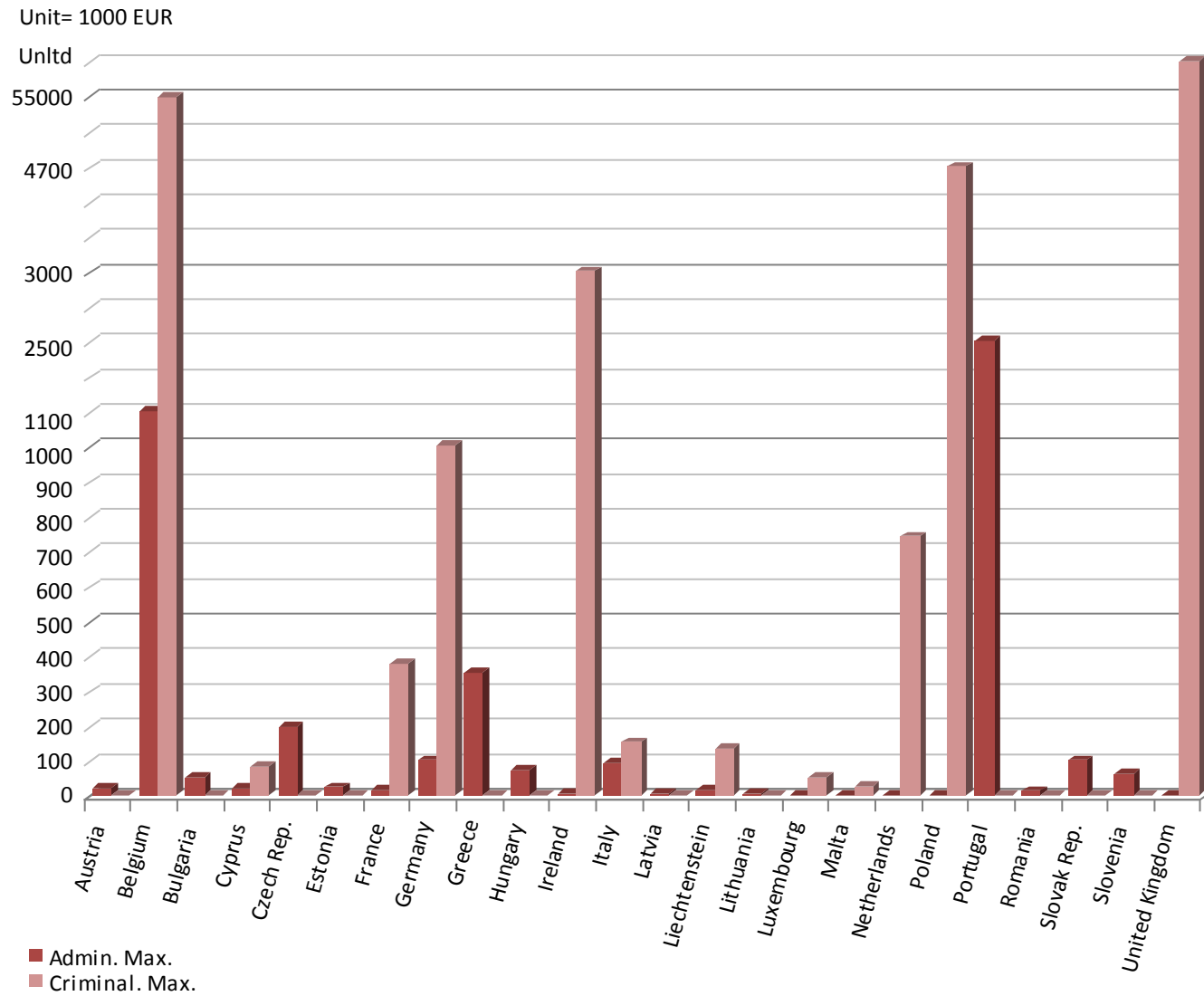
When a range of sanctions is foreseen in the legislation, the authorities and/or the courts have the possibility to adjust and to choose the most appropriate sanctions. Normally, when imposing the sanction and fixing the level of the fine, elements such as the benefit obtained from the offence, the economic situation of the offender, the damage caused, and recidivism are taken into account. However, in cases where there is no express reference, the principle of proportionality tends to produce the same effect. In any case, the discretion of the judge to decide on the level of the sanction is very important.

The bar on the next page demonstrates the variation in the level of fines employed by the countries under study where fines are set in the legislation<sup>42</sup>. It only takes into account the fines imposed on the first infringement.

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<sup>42</sup> This excludes Denmark, which does not provide for fines, as well as Finland, Iceland, Norway and Sweden, for which there is not fix amount in law.

Chart 2 Level of administrative and criminal fines



It should be noted that this is based on the nominal level of penalties in the Member States and EEA countries (converted into Euros when the country is using another currency). In order to make the penalty levels comparable with regard to the value of money in the different countries, it may be relevant to make some adjustments for purchasing power parity (in particular with regards to the new Member States). We provide in Annex III a table comparing the nominal level of fines used in the countries under study (.e.g, the level of fines as provided in the relevant pieces of national law) with an adjusted level of fines based on the purchasing power parity. The purchasing power parity used is based on consumers' prices<sup>43</sup>. This is not the most appropriate information for comparison, as it is calculated on the consumption of a household, which is quite different from the prices that are applicable in the industry. However since no purchasing power parity index based on industry prices could be found by the contractor, it was decided to base the adjustment on consumer prices. Because consumer and industry prices are quite different, the information provided in Annex III only gives an indication of the orientation of the value of the fine from one country to another.

### **4.3. Quantitative assessment of penalties against compliance costs**

The penalties imposed under REACH need to be effective, proportionate and dissuasive, to ensure that manufacturers, importers, downstream users, distributors and article producers fulfil their respective duties. In assessing whether the proposed levels of penalties will achieve this goal, the study compared the sanctions imposed on non-compliant with the costs of complying with the relevant REACH provisions.

#### **4.3.1. Methodology for determining compliance costs**

First, standard cost values for compliance with the relevant REACH provisions were prepared to allow assessment of significant differences between the penalty and the cost of compliance for specific provisions and in general. The calculation of such standard cost values is only approximate as, in individual cases, the specific duty holder and substance may not be subject to all the different elements included in the calculation. Thus, only an average costing is possible. For the purposes of this calculation, and following the logic of the previous sections, comparison is structured according to the four main elements of REACH:

- Registration and evaluation
- Authorisation
- Supply chain
- Downstream users

#### ***Registration and evaluation***

During the preparation of the REACH proposal, the Commission prepared an extended Impact Assessment<sup>44</sup> which estimated the costs for industry to be between 2.8 and 5.2 billion Euros over 11 years. However, this does not allow for the calculation of average compliance costs. The costing carried out by the JRC on the 'Assessment of additional testing needs under REACH: effects of (Q)SARS, risk based testing and voluntary industry initiatives'<sup>45</sup> proves to be more useful for this purpose. This study estimated the average testing costs per substance as follows:

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<sup>43</sup> The index is based for OECD countries on the OECD comparative price levels of September 2009, with the base of a value 100 for Germany (see <http://www.oecd.org/dataoecd/48/18/18598721.pdf> ). No data could be found for the non OECD countries.

<sup>44</sup> Commission Staff Working Paper, Extended Impact Assessment, SEC (2003) 1171/3 available from: [http://ec.europa.eu/environment/chemicals/reach/background/docs/eia-sec-2003\\_1171.pdf](http://ec.europa.eu/environment/chemicals/reach/background/docs/eia-sec-2003_1171.pdf)

<sup>45</sup> Pedersen, F., de Bruijn, J., Munn, S. and van Leeuwen, Kees. (2003), Assessment of additional testing needs under REACH: Effects of (Q)SARS, risk based testing and voluntary industry initiatives.

Tonnage	Testing costs per substance (kEURO)	
	Average	Range
1-10 tonnes/year	12.1	8.6 - 16.4
10 – 100 tonnes/year	40.5	73.1 – 152
100 – 1000 tonnes/year	163	128 - 244
1000 tonnes/year	208	185 - 278

These costings provide an initial basis for the calculation of standard cost values. They do not take the following cost pressures into account:

- Costs related to product inventories, pre-registration and SIEF costs.
- Costs related to development of the Chemical Safety Assessment and compilation of the technical dossier.
- Registration fees.
- Costs related to changed SDS and increased communication with customers and suppliers.
- Potential cost of evaluation.

The fees to be paid for registration<sup>46</sup> depend on both the tonnage manufactured or imported per year and whether or not there is a joint registration:

Tonnage	Registration fee (Euro)	
	Individual submission	Joint submission
1-10 tonnes/year	1 600	1 200
10 – 100 tonnes/year	4 300	3 225
100 – 1000 tonnes/year	11 500	8 625
1000 tonnes/year	31 000	23 250

The fees set out above are further subject to a reduction of 30% for medium sized enterprises, 60% for small enterprises and 90% for micro-sized enterprises.

The costs of dossier preparation and submission have been previously estimated with regard to the 'Internet version' of REACH; an additional 10% of the full testing costs was added to equate to the full registration costs reflecting differences in the level of testing required by tonnage and by hazard potential (and associated differences in the level of effort required to compile dossiers)<sup>47</sup>.

Taking into account the testing costs, registration fees (assuming a joint registration from a small enterprise) and the costs of dossier preparation, this would equate to:

Tonnage	Lowest range of testing costs (kEURO).	Joint registration fee for small enterprise (Euro).	Costs of dossier preparation (Euro).	Total (Euro)
1-10 tonnes/year	8.6	720	860	10 180
10 – 100 tonnes/year	73.1	1 935	7 310	82 345
100 – 1000 tonnes/year	128	5 175	12 800	145 975
1000 tonnes/year	185	13 950	18 500	217 450

The compliance cost range used for registration and evaluation will therefore be **10 180 Euros to 217 450 Euros**.

46 Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency.

47RPA and Statistics Sweden (2002) Assessment of the Business Impact of New Regulations in the Chemicals Sector available at [http://ec.europa.eu/enterprise/reach/reach/archives/white\\_paper/business\\_impact/index\\_en.htm](http://ec.europa.eu/enterprise/reach/reach/archives/white_paper/business_impact/index_en.htm).

### **Authorisation**

The fee for an authorisation application, as set out in the Fees Regulation<sup>48</sup>, is 50 000 Euros per application plus 10 000 Euros per additional substance or use applied for and 37 500 Euros for each additional applicant. A reduced fee has been set for producers of small quantities with a 20% reduction for medium sized companies, a 50% reduction for small companies and an 85% reduction for micro sized companies.

The direct costs of authorisation were estimated during the original BIA<sup>49</sup> and include liaison with authorities and, if required, preparing a socio-economic justification for the proposed uses. No costs were included for dossier preparation, i.e. production of the Chemical Safety Report, as this was already assumed to have taken place when registering the substance. The costs entailed:

- 15 000 Euros for liaison with authorities (assuming 15 person days at 1 000 Euros per day); and
- 35 000 Euros for preparation of the socio-economic justification and information on substitute substances or technologies.

The REACH Regulation offers two ways to obtain an authorisation: either by demonstrating adequate control or through socio-economic analysis. It is only the latter route to authorisation that requires a SEA. There is no indication of proportions of these two routes so an adequate control route is assumed for the purposes of this study.

A compliance cost of **65 000 Euros** is therefore assumed to take into account a minimum authorisation of one application plus liaison with the authorities.

### **Downstream users**

There is little concrete information on costs to downstream users that would allow an adequate analysis of compliance costs. However, the assessment of the business impact of new regulations in the chemicals sector<sup>50</sup>, carried out for the Commission's internet version of REACH, did attempt to estimate costs to downstream users. That evaluation was based on the requirements of the Regulation at that time, specifically that a registration dossier should cover 90% of uses for phase-in substances but, where this is not the case, any information on the use of a substance of more than 250 kg per year should be reported to the Agency. They must also provide information up the supply chain to manufacturers and importers to assist in the registration process and in relation to the appropriateness of risk management measures. The cost of submitting an unintended use report was estimated as 8 963 Euros, plus an additional 1 793 Euros (20%) for re-reporting as downstream users will regularly change their usage of chemicals in response to changing customer demands, a desire to innovate, etc. The total costs are lower than those assumed in the original BIA, where a value of 15 000 Euros per "postcard notification" was calculated based on an assumed 15 days of effort (at 1000 Euros per day) and required pulling together use, exposure, control data, and a risk assessment.

The requirements of the Regulation have changed since the Internet version, in that downstream users may now indicate their uses to their supplier, who then should take those uses in their Chemical Safety Assessment. If their use is not included in the CSA, then they should develop an exposure scenario for their use and report to the Agency. These changes make the costs in the BIA difficult to relate to the current requirements.

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<sup>48</sup> Commission Regulation (EC) No 340/2008 of 16 April 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)

<sup>49</sup> RPA and Statistics Sweden (2003) "Assessment of the Business Impact of New Regulations in The Chemicals Sector" available at [http://ec.europa.eu/enterprise/reach/docs/reach/rev\\_bia-2003\\_10\\_29\\_en.pdf](http://ec.europa.eu/enterprise/reach/docs/reach/rev_bia-2003_10_29_en.pdf)

<sup>50</sup> Idem.

For downstream users, the costs (staff time, etc.) of providing information for use in the registration dossiers is equivalent to 30% of the dossier preparation costs incurred by manufacturers/importers.

Due to the difficulty of obtaining good quality information on the costs to downstream users, no compliance cost for downstream user requirements will be used.

### ***Supply chain***

The UK, in its Impact Assessments for legislation implementing the Dangerous Substances Directive and Dangerous Preparations Directive, has assessed the cost of revising a SDS as between 130£ (approx. 150 Euros) to 300£ (approx. 340 Euros) at 2001/2002 prices<sup>51</sup>.

The low cost of this requirement compared to the other prices, even if updated to 2009 prices, means it will not be further considered in this study.

#### 4.3.2. Comparison by country

For each Member State a comparison of the financial penalties (quantitative) and other measures (qualitative), is developed in more detail and assessed in the table of Annex IV.

On the next page is a summary table indicated the percentage of the fines in relation with the cost of compliance with regard to registration and to authorisation. For authorisation, it is distinguished between low tonnage (1-10 tonnes) and high tonnage (more than 1000 tonnes). A percentage higher than 100 % means that the penalties are more important than the costs of compliance. In the countries where several ranges of fines are applicable, the calculation was made for the maximum in each range, and the highest result is highlighted in bold. In the countries which have not set a fixed amount for penalties in the legislation, the table indicates “no data”.

The level of the sanctions considered in all cases only take into account the monetary amount set out in the relevant legislation and do not take into account other consequential costs of non-compliance. Two other types of measures shall be distinguished here. Firstly, concrete measures, such as the closure of an establishment or the destruction of the substance, article or mixture have financial consequences which can be quite severe. However, these can only be estimated on a case-by-case basis. Secondly, the costs of other measures resulting in a loss of reputation or business or in more extreme cases as the deprivation of rights or of liberty cannot be quantified. However, in terms of quality, these types of sanctions can have a much more important impact on the offender than pecuniary measures.

Almost all countries have set quantitative sanctions (*i.e.*, fines) for failure to comply with the provisions of REACH. Only in a few countries, the fines are not set by law, since they are either calculated on a case-by-case basis (based on the income or the size of the company infringing the law, in Denmark, Iceland, Norway and Sweden), or are unlimited fine (UK). For these countries, no comparison could be carried out. For the other countries, as mentioned under Section 4.2, the fines are much variable and can amount up to 55 000 000 Euros (in Belgium). The maximum penalty in Belgium is thus equivalent to 540 275% of the compliance costs for registration in the 1-10 tonnage range, 25 293% for the 1000 tonnes plus tonnage range, and 84 615% for authorisation.

In countries where the fine is very high, as is the case for Belgium, the penalties are proportionally much higher than the costs of compliance, and are a strong incentive for the companies to comply with their obligations, rather than to avoid the costs of registration and/or authorisation. However, the category of countries which provided for a maximum fine below 200 000 Euros, even if they impose

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<sup>51</sup> New Chemicals (Hazard Information and Packaging for Supply Regulations (CHIP 3): Regulatory Impact Assessment (Post consultation) available from <http://www.hse.gov.uk/ria/chemical/chip3.pdf>.

penalties higher than the costs of compliance in most cases, do not sufficiently high fines to override the costs of compliance of the highest tonnage range (1000 tonnes per year and more). This is quite problematic as this would have a discriminatory impact on producers of small quantities.



*Report on the penalties applicable for infringement of the provisions of the REACH Regulation*

Registration	AT	BE	BG	CY	CZ	DK	EE	FI	FR	DE	GR	HU	ISL	IE	IT
1-10 tonnes/year	186 %	Admin. fine : Major offence <b>1080 %</b> Minor offence 324% Crim. fine: Major <b>216110 %</b> Minor 6 483%	Admin. fine: <b>502.25%</b> 251.13%	Admin. fine: 49.12% <b>196.46%</b> Crim. fine: <b>785.85%</b>	<b>1922.35%</b>	No data	13.1% <b>219.69 %</b>	No data	Admin. fine: <b>147%</b> Crim. fine: <b>736%</b>	Admin. fine: <b>491 %</b> 98.2% Crim. fine: <b>982%</b>	Admin. fine: 343.8% 147.3% 196.4% <b>3438.9%</b>	Admin. fine: <b>691.8%</b> 345.9%	No data	SP <b>49.12%</b> CI: <b>29469%</b>	<b>884%</b> 589.39%
Plus 1000 tonnes/year	9%	Admin. fine : Major <b>506 %</b> Minor 10805% Crim. fine: Major <b>10117%</b> Minor 303%	Admin. fine: <b>32.4%</b> 23.51% 11.76%	Admin. fine: 2.30% <b>920%</b> Crim. fine: <b>36.79%</b>	<b>90%</b>		0.62% <b>10.28 %</b>		Admin. fine: <b>6.9%</b> Crim. fine: <b>34.5%</b>	Admin. fine: <b>23</b> 4.6% Crim. fine: <b>46%</b>	Admin. fine: 16.10% 6.90% 9.20% 2.30% <b>160.96%</b>	Admin. fine: <b>32.4%</b> 16.3%		SP: 2.3% CI: <b>1379.63 %</b>	<b>41.39%</b> 27.59%
Authorisation	AT	BE	BG	CY	CZ	DK	EE	FI	FR	DE	GR	HU	ISL	IE	IT
Cost of compliance	29%	Admin. fine : Major <b>1692%</b> Minor 50.77% Crim. fine: Major 33846% Or <b>84615%</b> Minor 1015%	Admin. fine: <b>78.66%</b> 39.33%	Admin. fine: <b>30.77%</b>	<b>301.07%</b>		2.06% <b>34.41 %</b>		Admin. fine: <b>23.1%</b> Crim. fine: <b>115%</b>	Admin. fine: <b>76.92%</b> Crim. fine: <b>154%</b>	Admin. fine: 23.08% 7.69% 1.54% <b>538.46%</b>	Admin. fine: <b>108%</b> 54.1%		SP: <b>7.69%</b> CS: <b>4615.38 %</b>	<b>230.77%</b> 92.31%
Registration	LV	LI	LT	LU	MT	NL	NO	PL	PT	RO	SK	SI	SE	UK	
1-10 tonnes/year	9.78%	129.53% <b>1295.1%</b> 647.65%	17.09% 14.24% 11.39% 8.55% <b>22.79%</b>	<b>491.16%</b>	<b>114.41%</b>	726.92% <b>7269 %</b> 340.31% 181.73%	No data	11.7 % 1 683% <b>47 891%.</b>	368.37% <b>24558%</b>	35.01% 70.02% <b>116.79%</b>	293.46% 423.89% <b>978.21%</b>	589.39% 314.34%	No data	SC : <b>41%</b>	
Plus 1000 tonnes/year	0.46%	6.06% 3.03% <b>60.64%</b> 30.32%	0.40% to <b>1.07%</b>	<b>22.99%</b>	<b>5.36%</b>	34.03% <b>340.31%</b> 8.51%		0.55 % 78,84% <b>5 950%</b>	17.25% <b>1149.7</b>	1.64% 3.28% <b>5.47%</b>	13.74% 19.84% <b>45.80%</b>	<b>27.59%</b> 14,72%		SC : <b>2.1%</b> CI : Fine <b>unlimited</b>	
Authorisation	LV	LI	LT	LU	MT	NL	NO	PL	PT	RO	SK	SI	SE	UK	
Cost of compliance	6.57%	20.29% 10.14% <b>202.87%</b> 101.43%	1.78% <b>6.69%</b> 4.46%	<b>76.92%</b>	17.92%	113.85% <b>1138.4%</b> 28.46%		263.74% <b>7500%</b>	57.69% <b>3846.15 %</b>	10.97% <b>18.29%</b>	45.96% <b>153.20%</b>	<b>92.31%</b> 49.23%		SC: <b>8.3%</b> CI: fine <b>unlimited</b>	

In **Austria**, the sanctions for breaches of the registration requirements amount to a maximum of 186.64% of the cost of compliance at the 1-10 tonnes level and to a maximum of 8.74% of the cost of compliance at the 1000 tonnes and above level. The sanctions for repeated infringements of the registration provisions amount to a maximum of 373.28% of the compliance cost for the 1-10 tonnage range and a maximum of 17.48% for the 1000 tonnes plus tonnage range. The sanctions for breaches of the authorisation provisions amount to a maximum of 29.23% of the calculated compliance cost. The sanctions for repeated infringements of the authorisation provisions amount to a maximum of 58.46% of the compliance cost.

In **Belgium**, the quantitative criminal sanctions for breaches of major registration offences amount to a maximum of 216110.02% of the cost of compliance at the 1-10 tonnes level and a maximum of 10117.27% of the cost of compliance at the 1000 tonnes and above level. The criminal sanctions related to minor registration offences amount to a maximum of 6483.30% of the compliance cost for the 1-10 tonnage range and a maximum of 303.52% of the compliance cost for the 1000 tonnes plus tonnage range. The quantitative criminal sanctions for major authorisation offences amount to a maximum of 33846.15% of calculated compliance cost. The maximum increased fine amounts to a maximum of 84615.38% of the compliance cost. The criminal sanctions related to minor authorisation offences amount to a maximum of 1015.38% of the compliance cost.

The quantitative administrative sanctions related to major registration offences amount to a maximum of 10805.50% of the compliance cost for the 1-10 tonnage range and a maximum of 505.86% for the 1000 tonnes plus tonnage range. The minor registration offences amount to a maximum of 324.17% of the compliance cost for the 1-10 tonnage range and a maximum of 15.18% for the 1000 tonnes plus tonnage range. The administrative fines related to major Authorisation offences amount to a maximum of 1692.31% of the compliance cost and for minor Authorisation offences amount to a maximum of 50.77% of the compliance cost.

In **Bulgaria**, the sanctions for breaches of registration amount to a maximum of 502.25% of the cost of compliance at the 1-10 tonnes level and a maximum of 23.51% of the cost of compliance at the 1000 tonnes and above level. The second set of sanctions for registration amounts to a maximum of 251.13% of the compliance cost for the 1-10 tonnage range and a maximum of 11.76% for the 1000 tonnes plus tonnage range. If the penalties are doubled then the compliance costs will also be doubled. The sanctions for authorisation amount to a maximum of 78.66% of calculated compliance cost and the second set of sanctions amount to a maximum of 39.33%.

In **Cyprus**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 49.12% and 196.46% of the cost of compliance at the 1-10 tonnes level and between a maximum of 2.30% and 9.20% of the cost of compliance at the 1000 tonnes and above level. For criminal sanctions related to registration the maximum fine is equivalent to 785.85% of the compliance cost for the 1-10 tonnage range and 36.79% for the 1000 tonnes plus tonnage range. The additional maximum 80 000 Euros fine on a second condemnation would double the percentage of the compliance cost. The sanctions for breaches of the authorisation provisions amount to a maximum of 30.77% of the calculated compliance cost. The percentage of the compliance cost for the sanction related to the daily fine of 100 and 500 Euros is difficult to quantify as is the fine in case of continual infringement. But in the former case the infringement would have to continue for 130 or 650 or days until it reached 100% of the compliance cost.

In the **Czech Republic**, the sanctions for breaches of registration amount to a maximum of 1922.35% of the cost of compliance at the 1-10 tonnes level and a maximum of 90% of the cost of compliance at the 1000 tonnes and above level. The sanctions for authorisation amount to a maximum of 301.07% of the calculated compliance cost.

In **Denmark**, there is no fine. The sanctions regarding imprisonment and confiscation of economic gains are difficult to quantify but may be significant.

In **Estonia**, the sanctions for breaches of registration amount to a maximum of 13.18% of the cost of compliance at the 1-10 tonnes level and a maximum of 0.62% of the cost of compliance at the 1000 tonnes and above level. With regard to legal persons, the higher maximum fine is equivalent to a maximum of 219.69% of the compliance cost for the 1-10 tonnage range and a maximum of 10.28% for the 1000 tonnes plus tonnage range. The sanctions for authorisation amount to a maximum of 2.06% of the calculated compliance cost. With regard to legal persons, the maximum fine is equivalent to 34.41% of the compliance cost.

In **Finland**, the corporate fine for breaches of registration amount to a maximum of 8349.71% of the cost of compliance at the 1-10 tonnes level and a maximum of 390.89% of the cost of compliance at the 1000 tonnes and above level. The sanctions for authorisation amount to a maximum of 1307.69% of the calculated compliance cost. The proportional fine and also the additional sanctions of imprisonment cannot be easily quantified but may be significant.

In **France**, the criminal sanctions for breaches of registration and evaluation amount to 736% of the cost of compliance at the 1-10 tonnes level and 34.5% of the cost of compliance at the 1000 tonnes and above level. However, this does not take into account the custodial sentence that forms part of the sanctions. The criminal sanctions for authorisation amount to 115% of calculated compliance cost but again, this does not take into account the concurrent custodial sentence, which would certainly be considered a punitive and dissuasive penalty. Regarding the analysis of the quantitative administrative sanctions for offences related to registration and evaluation, the maximum fine of 15000 Euros is equivalent to 147% of the compliance cost for the 1-10 tonnage range and 6.9% for the 1000 tonnes plus tonnage range. This will be increased by the daily periodic penalty payments of 1500 Euros. For administrative fines related to authorisation, the maximum fine of 15 000 Euros is equivalent to 23.1% of the compliance cost. This will be increased by the daily periodic penalty payments of 1500 Euros.

In **Germany**, the administrative sanctions for breaches of the registration amount to between a maximum of 98.23% and 491.16% of the cost of compliance at the 1-10 tonnes level and between a maximum of 4.60% and 22.99% of the cost of compliance at the 1000 tonnes and above level. The criminal sanctions for breaches of registration amount to a maximum of 982.32% of the compliance cost for the 1-10 tonnage range and a maximum of 45.99% for the 1000 tonnes plus tonnage range. The administrative sanctions for breaches of the authorisation provisions amount to between a maximum of 15.38% and 76.92% % of the calculated compliance cost. The criminal sanctions for breaches of the authorisation provisions amount to a maximum of 153.85% of the calculated compliance cost.

In **Greece**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 9.82% and 343.81% of the cost of compliance at the 1-10 tonnes level and between a maximum of 0.46% and 16.10% of the cost of compliance at the 1000 tonnes and above level. The maximum fine for non-compliance with an order from the State General Laboratory is equivalent to 3438.11% of the compliance cost for the 1-10 tonnage range and 160.96 % for the 1000 tonnes plus tonnage range. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 1.54% and 23.08% of the calculated compliance cost. The maximum fine for non-compliance with an order from the State General Laboratory is equivalent to 538.46% of the compliance cost.

In **Hungary**, the sanctions for breaches of registration and evaluation depend on the relevant article of the legislation that has not been complied with. For the first set of articles, the sanctions amount to 691.8% of the cost of compliance at the 1-10 tonnes level and 32.4% of the cost of compliance at the 1000 tonnes and above level. For the second set of articles, where the fine is lower, the sanctions amount to 61% of the cost of compliance at the 1-10 tonnes level and 3.2% of the cost of compliance at the 1000 tonnes and above level. The sanctions for authorisation amount to between 0.5% and 54.2% of calculated compliance cost for the higher level of fines and between 10.8% - 1.1% for the lower level of fines.

In **Iceland**, the proportional fine cannot be quantified but may be significant. The additional sanctions of imprisonment or confiscation of products or profits are difficult to quantify but may also be significant.

In **Ireland**, the sanctions for breaches of registration on summary prosecution amount to a maximum of 49.12% of the cost of compliance at the 1-10 tonnes level and a maximum of 2.3% of the cost of compliance at the 1000 tonnes and above level. The maximum fine for conviction on indictment is equivalent to a maximum of 29469.55% of the compliance cost for the 1-10 tonnage range and a maximum of 1379.63% for the 1000 tonnes plus tonnage range. The sanctions for breaches of authorisation on summary prosecution amount to a maximum of 7.69% of the calculated compliance cost and the maximum fine for conviction on indictment is equivalent to a maximum of 4615.38% of the compliance cost.

In **Italy**, the sanctions for breaches of the registration requirements amount to a maximum of between 589.39% and 884.09% of the cost of compliance at the 1-10 tonnes level and to a maximum of 27.59% and 41.39% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions amount to a maximum of between 92.31% and 230.77% of the calculated compliance cost.

In **Latvia**, the administrative sanctions for natural persons for breaches of registration amount to a maximum of 4.19% of the cost of compliance at the 1-10 tonnes level and a maximum of 0.20% of the cost of compliance at the 1000 tonnes and above level. The administrative sanctions for legal persons for breaches of registration amount to a maximum of 13.98% of the cost of compliance at the 1-10 tonnes level and a maximum of 0.65% of the cost of compliance at the 1000 tonnes and above level. The additional sanctions for registration amount to a maximum of 9.78% of calculated compliance cost for the 1-10 tonnage range and a maximum of 0.46% for the 1000 tonnes plus tonnage range. The additional sanctions related to Authorisation amount to a maximum of 6.57% of the compliance cost. The administrative sanctions for natural persons for breaches of authorisation amount to a maximum of 0.66% of the cost of compliance. The administrative sanctions for legal persons for breaches of Authorisation amount to a maximum of 2.19% of the cost of compliance.

In **Lithuania**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 8.55% and 22.79% of the cost of compliance at the 1-10 tonnes level and between a maximum of 0.40% and 1.07% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 1.78% and 6.69% of calculated compliance cost.

In **Liechtenstein**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 64.76% and 1295.1% of the cost of compliance at the 1-10 tonnes level and between a maximum of 3.03% and 60.64% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions amount to between a maximum of 10.14% and 202.87% % of the calculated compliance costs.

In **Luxembourg**, the criminal sanctions for breaches of registration amount to a maximum of 491.16% of the cost of compliance at the 1-10 tonnes level and a maximum of 22.99% of the cost of compliance at the 1000 tonnes and above level. The criminal sanctions for authorisation amount to a maximum of 76.92% of the calculated compliance costs.

In **Malta**, the sanctions for breaches of registration amount to a maximum of 114.41% of the cost of compliance at the 1-10 tonnes level and a maximum of 5.36% of the cost of compliance at the 1000 tonnes and above level. The sanctions for authorisation amount to a maximum of 17.92% of the calculated compliance costs. If the fines are doubled due to second or subsequent offences then the % of compliance costs will also double.

In **the Netherlands**, the sanctions for breaches of the registration provisions amount to between a maximum of 181.73% and 7269.16% of the cost of compliance at the 1-10 tonnes level and between a maximum of 8.51% and 340.31% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions amount to between a maximum of 28.46% and 1138.46% of calculated compliance costs.

In **Norway**, no quantitative analysis of fines was possible.

In **Poland**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 11.69% and 6080.99% of the cost of compliance at the 1-10 tonnes level and between a maximum of 0.55% and 284.68% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 263.74% and 952.38% of calculated compliance cost. In addition the forfeiture of objects, property benefits or their value for legal persons are difficult to quantify but could be significant. In addition, the prohibition of various promotions, financial support, assistance, seeking public orders etc. could also be significant.

In **Portugal**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 368.37% and 24557.96% of the cost of compliance at the 1-10 tonnes level and between a maximum of 17.25% and 1149.69% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 57.69% and 3846.15% of calculated compliance cost.

In **Romania**, the sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 35.01% and 116.79% of the cost of compliance at the 1-10 tonnes level and between a maximum of 1.64% and 5.47% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 10.97% and 18.29% of calculated compliance cost.

In **Slovakia**, the sanctions for breaches of the registration provisions amount to between a maximum of 293.46% and 978.21% of the cost of compliance at the 1-10 tonnes level and between a maximum of 13.74% and 45.80% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions amount to between a maximum of 45.96% and 153.20% of calculated compliance cost.

In **Slovenia**, the administrative sanctions for breaches of the registration provisions depend on the article that is breached and amount to between a maximum of 314.34% and 589.39% of the cost of compliance at the 1-10 tonnes level and between a maximum of 14.72% and 27.59% of the cost of compliance at the 1000 tonnes and above level. The sanctions for breaches of the authorisation provisions depend on the article that is breached and amount to between a maximum of 49.23% and 92.31% of calculated compliance cost.

In **Sweden**, the proportional fine cannot be quantified. The environmental sanction fee related to registration is equivalent to a maximum of 4.80% of the compliance cost for the 1-10 tonnage range and a maximum of 0.22% for the 1000 tonnes plus tonnage range. The environmental sanction fee related to authorisation is equivalent to a maximum of 0.75% of the compliance cost.

In the **United Kingdom**, the maximum lower level of fine is equivalent to between 41% and 2.1% of the compliance costs for registration and evaluation, and 8.3% of the compliance costs for authorisation. The maximum fine on conviction by indictment is unlimited so it could be at the higher level of both compliance costs.

#### 4.4. Comparison with comparable offences

A review of the penalties imposed under comparable offences gives us an insight into the proportionality of penalties. It also provides an indication of the value that society places on the specific goods that the Regulation is trying to protect, namely human health and the environment.

For this comparison, EU legislation where obligations might be considered comparable to those foreseen under REACH were selected:

- Directive 98/8 Biocides<sup>52</sup>
- Directive 2001/83 Medicinal products<sup>53</sup>
- Directive 91/414 Plant protection products<sup>54</sup>
- Directive 96/61 and 2008/1 IPPC<sup>55</sup>

For this step in the analysis, information was on the types and levels of penalties imposed for comparable offences in the legislation listed above for each Member State. This information is presented in the tables in Annex V, for each of which one specific requirement has been analysed.

##### 4.4.1. Obligation to register or to apply for authorisation

The obligation to register, or the “no data, no market” rule, is at the heart of the REACH system. In other legislation, placing a product on the market or carrying out an activity without an authorisation is also punishable if expressly prohibited by the European legislation. For each of the Directives listed above, one or more provisions have been identified as creating a comparable obligation as that under REACH. They are<sup>56</sup>:

- **REACH:** Article 5 for registration, and Article 56(1) for authorisation;
- **Directive 98/8 Biocides:** Article 3.1(I) (i) for registration, and Article 3.1 for authorisation;
- **Directive 2001/83 Medicinal products:** Article 6.1;
- **Directive 91/414 Plant protection products:** Article 3(1);
- **Directive 96/61 IPPC (or Directive 2008/1/EC)** Article 4.

The first table in Annex V presents the corresponding penalties in each Member State, thereby allowing for comparison of the level of the sanction for the illegal placing on the market or operating without a permit under different legislation at the national level.

The table shows that in most countries, there is no uniformity as to the sanctions provided by national law when a breach of the obligation to register or to apply for authorisation occurs under each of the five pieces of legislation under study. Some similarities have however been noticed with regards to sanctions imposed under REACH and the Biocides Directive. In eight countries (Bulgaria, Belgium, France, Denmark, Finland, Liechtenstein, Luxembourg and the UK), identical sanctions are provided for the breach of the obligation to register under REACH and under Directive 98/8/EC. This is partly due to the fact that in these countries (e.g France), the Regulation and the Directive are enforced in national law by the same piece of legislation.

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<sup>52</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

<sup>53</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

<sup>54</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

<sup>55</sup> Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, repealed by Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control

<sup>56</sup> The provisions are quoted in Annex V under Table Va.

However, overall, some major differences have been observed in the level of fines or imprisonment imposed under the transposing pieces of legislation in most countries. For example, in Greece, the infringements of the obligation to apply for authorisation under Directive 2008/1/EC lead to a fine of up to 500 000 euros while the infringements of the obligation to register under REACH lead to a fine of only up to 35 000 Euros. Furthermore, only the infringements of the obligation to apply for an authorisation under Directive 98/8/EC and Directive 91/414/EC lead to imprisonment penalties.

Sanctions related to the infringement of the obligation to register under REACH are more severe than equivalent offences under other laws in a few countries (Estonia, Hungary, Germany, Italy, Portugal and Latvia). This is notably reflected in the regime of sanctions chosen to enforce the obligation. Thus, in Estonia, the breach of the obligation to register under REACH leads both to administrative and criminal sanctions (with imprisonment penalties) while the infringements of the relevant obligations of the other four EC acts only lead to administrative sanctions. In seven countries (Bulgaria Czech Republic, Hungary, Latvia, Lithuania, Slovenia, Austria) the infringements of the obligation to register or to apply for authorisation of the five EC legislations only lead to administrative sanctions. The infringements of these obligations might, however, indirectly trigger more general criminal procedures for instance in case they endanger the state of the environment or human health.

Conversely, sanctions related to the breach of the obligation to apply for an authorisation under the IPPC Directive are more severe in five countries (Ireland, Czech Republic, Lithuania, UK, and Austria). For example, in the UK, the breach of this obligation leads to an imprisonment penalty of five years while infringements of the obligation to register under REACH or to apply for authorisation under Directive 98/8/EC or 2001/83/EC only lead to two years of imprisonment, and finally the breach of the obligation to apply for an authorisation under Directive 91/414/EEC only leads to a penalty fine. Sanctions related to the breach of the obligation to apply for an authorisation under Directive 2001/83/EC are more severe in six countries (Malta, Slovenia, Norway, Latvia, Romania, and Slovakia). In Malta, for instance, the breach of that obligation leads to a maximum fine of 116 468 Euros and two years imprisonment.

#### 4.4.2. Obligation to supply information for registration/authorisation

To be granted an authorisation or to be registered in order to put a product on the market implies the submission of some information to the competent authorities. For REACH, Article 10 mainly, but also in other provisions, lists the information to be provided for registration and authorisation. The same type of enumeration exists for the other acts selected for this study. The provisions identified as relevant are the following<sup>57</sup>:

- **REACH:** Article 10 for registration;
- **Directive 98/8 Biocides:** Article 8;
- **Directive 2001/83 Medicinal products:** Article 11;
- **Directive 91/414 Plant protection products:** Article 4(6)(b);
- **Directive 96/61 IPPC:** Article 6.

These articles may be considered as self-enforcing, as the lack of any elements will lead to the rejection of the application. However, supply of false information (fraud) would be punished under these requirements. The penalties in place to sanction this behaviour are observed in the second table in Annex V.

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<sup>57</sup> The provisions are quoted in Annex V under Table Vb.

The breach of the obligation to supply information for registration or for authorisation under the five EC acts mentioned above lead to comparable sanctions in nine countries (Norway, Sweden, Finland, Iceland, Denmark, France, UK, Slovakia, and Bulgaria). For example, in Norway, for most acts, sanctions take the form of an administrative coercive fine or a criminal fine and/or an imprisonment penalty for a term not exceeding three months, and the fines are calculated by judges on the basis of the daily income of the offender.

As for the sanctioning of authorisation requirements, the similarities between the Biocides and the REACH sanctions for the supply of false information are noticeable. Nine countries (Belgium, Denmark, France, Liechtenstein, Luxembourg, Bulgaria, Czech Republic, Hungary and the UK) provide the same sanctions for the breach of the obligation to supply information for registration under REACH and under Directive 98/8/EC. For example in Bulgaria, the infringement of these obligations under Directive 98/8/EC and REACH can both lead to an imprisonment of up to three years or a fine of 51 to 153 Euros. In six countries (Bulgaria, Czech Republic, Hungary, Latvia, Lithuania, Austria), infringements of the obligation to supply information for registration or authorisation under the five EC acts only lead to administrative sanctions.

Sanctions related to the breach of the obligation to supply information for registration under REACH are more stringent than under other legislation in seven countries (Estonia, Latvia, Portugal, Austria, Germany, and Netherlands, Slovakia). In Portugal, for example, infringements of the obligation to supply information for registration under REACH lead to a fine up to 250 0000 Euros while the infringements of the same obligations under the other four EC legislations lead to less significant fines (10 000 Euros, 30 000 Euros, 44900 Euros, 45 000 Euros). The sanctions related to the infringements of the obligation to supply information for authorisation under the IPPC Directive are the most severe in four countries (Czech Republic, Lithuania, Liechtenstein and Ireland). In Ireland, for instance, infringements of this obligation can lead to a fine of up to 15 000 000 Euros and 10 years imprisonment. The infringement is more strongly sanctioned if under the Medicinal Product Directive in three countries (Malta, Slovakia and Norway).

Finally, in Slovenia and Poland no sanctions are provided for the infringements of the obligation to supply information for registration or for authorisation under the five EC legislations.

#### 4.4.3. Requirement to update information

The approval of placing on the market or of the exercise of an activity is based on information provided to the authorities who issued the authorisation. However, the information may for some reason change in time, which may require a revision of the terms of authorisation. Therefore, the authorisation/permit holders are required to update the information they have provided under certain circumstances. The following provisions reflect this obligation in the selected pieces of legislation under comparison<sup>58</sup>:

- **REACH:** Article 22(1);
- **Directive 98/8 Biocides: Article 14 (1);**
- **Directive 91/414 Plant protection products: Article 4(5);**
- **Directive 96/61 IPPC:** Article 12(1);

The third table in Annex V provides information on the penalties in case of breach of these provisions.

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<sup>58</sup> The provisions are quoted in Annex V under Table Vc.



Infringements of the obligation to update information imposed under the provisions of the five acts listed above lead to almost identical types of sanctions under the different legislation under study in twelve countries (Denmark, Finland, Hungary, Iceland, Norway, Sweden, the UK, France, the Netherlands, Estonia, Slovakia and Hungary). The enforcement level is particularly well harmonised in the Nordic countries. As for the other obligations assessed, thirteen countries (France, Hungary, Latvia, UK, Denmark, Finland, Hungary, Latvia, Liechtenstein, Norway, Sweden, Belgium, and Luxembourg) provide the same level of sanctions for the breach of the obligation to supply updated information under REACH and under Directive 98/8/EC. For example, in Latvia, the breach of these obligations leads to a fine of up to 996 Euros for legal persons.

Moreover, in six countries (Lithuania, Romania, Slovakia, Slovenia, Czech Republic and Austria) infringements of the obligation to supply updated information under the five EC legislations only lead to administrative sanctions.

The breach of the obligation to supply updated information is more severely sanctioned under the legislation enforcing REACH than under the pieces of legislation transposing the EC Directives in nine countries (the Netherlands, Poland, Slovakia, Estonia, Austria, Malta, Slovenia, Italy, and Portugal). For example, in Poland the breach of this obligation leads to a fine of up to 1 190 Euros while there is no sanction for the breach of similar obligations in the other four EC acts. The sanctions related to infringements of the obligation to supply updated information under the IPPC Directive are more stringent in four countries (Ireland, Greece, Romania, and Lithuania). In Romania, for example, the breach of that obligation can lead to a fine of up to 23 435 Euros while the breach of similar obligations under the other four EC acts leads to less significant fines.

#### 4.4.4. Obligation to follow the conditions included in an authorisation

Authorisations issued by the authorities are often accompanied by conditions or restrictions to be respected by its holder. The obligation to follow any restrictions attached to the authorisation can be found in all pieces of legislation being compared under this Section<sup>59</sup>:

- **REACH:** Article 60(8);
- **Directive 98/8 Biocides:** Article 5(3) (4);
- **Directive 2001/83 Medicinal products:** Article 22;
- **Directive 91/414 Plant protection products:** Article 4(2);
- **Directive 96/61 IPPC:** Article 9(2).

Enforcement measures for the conditions set in these provisions are presented in the fourth table of Annex V.

Infringements of the obligation to follow the conditions included in an authorisation under the five pieces of EC legislation listed above lead to very different types of sanctions in nineteen of the countries assessed while these infringements lead to almost the same level of sanctions in the other ten countries (Denmark, Finland, Iceland, Norway, Bulgaria, France, the Netherlands, Slovenia, the UK, Slovakia.). Here again, the sanctions are well harmonised in Nordic countries, and sanctions under the REACH and the Biocides legislation are similar in seven countries (Belgium, Czech Republic, France, Portugal, Germany, Liechtenstein, Latvia). In some cases, this is due to the fact that the same piece of legislation enforces the Regulation and the Directive.

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<sup>59</sup> The provisions are quoted in Annex V under Table Vd.

Sanctions related to the breach of the obligation to follow the conditions included in an authorisation under REACH are more stringent than the national legislation transposing the EC Directives with comparable provisions in eight countries (Bulgaria, Estonia, Liechtenstein, Latvia, Hungary, Portugal, Luxembourg and Netherlands). For example, in Bulgaria the breach of this obligation leads to a fine of 51 129 Euros while infringements of the similar obligations in other legislation lead to fines from 614 to 25 565 Euros. Comparatively, infringements of the obligation to follow the conditions included in an authorisation under the IPPC Directive have been more severely sanctioned offences in eight countries (Czech Republic, Ireland, Lithuania, Slovakia, Liechtenstein Greece, Slovenia and the UK). In three countries (Romania, Austria and Norway), the sanctions related to infringements of the equivalent obligation under the Medicinal Products Directive are more severely sanctioned than under REACH and the other pieces of legislation under study. In Austria, for example, the breach of that obligation can lead to a fine of a maximum fine of 25 000 Euros while infringements of similar obligations under REACH incur fine of 19 000 Euros for the first condemnation.

In five countries the breach of the obligation to follow the conditions included in an authorisation only lead to administrative sanctions (Bulgaria, Czech Republic, Hungary, Latvia, and Austria).

### **Conclusions**

In two thirds of the countries assessed, infringements of the obligations under REACH lead to the application of very different levels of sanctions than comparable obligations under Directive 98/8/EC on biocides, Directive 96/61/EC (or 2008/1/EC) concerning integrated pollution prevention and control, Directive 2001/83/EC on medicinal products and Directive 91/414/EEC on the placing of plant products on the market. In the remaining one third of the countries assessed, infringements of the obligations (mentioned above) of these five EC acts are sanctioned similarly. This is particularly true in the Nordic countries.

Where the analysis of the different sanctions in place has shown significant disparities, different explanations can be given. Firstly, even though the types of obligations are more or less equivalent, and they stem from fields of law linked to REACH (chemicals and health legislation), the pieces of legislation selected are quite different from REACH, as in practice they address very different issues and have different implications. This is particularly obvious for the Medicinal Products Directive, which is probably least similar to REACH, and for which the sanctions adopted are the less comparable. On the contrary, the Biocides Directive and REACH are closely linked. The fact that in a few countries, the transposition of the Biocides Directive and implementation of the REACH requirements are covered in the same legal acts is quite significant in this regard. In many cases, the level of sanctions provided under the two pieces of legislation was very similar, if not identical.

Secondly, another ground for disparity lies in the actual degree of comparability of the obligations selected under the Directives and the Regulation. The analysis above has highlighted a particularly low level of harmonisation where the obligations are more difficult to compare, *i.e.*, where the REACH obligations are very distinctive from the requirements established in other pieces of legislation. This is the case for the obligations linked to authorisation and to conditions. These two elements are characteristic of REACH, whereas the obligations of authorisation under the Plant Protection Products Directive and issuance of a permit under the IPPC Directive pursue very different aims. For these two obligations in particular, the level of consistency between the sanctions under REACH and the other pieces of legislation is low.

Even though REACH is distinct from the other pieces of legislation, and constitutes undoubtedly a core element of the environmental legislation, with a potentially strong impact on the overall legal framework of protection of the environment and health at the national level, the enforcement of REACH does not have noticeably more severe sanctions in comparison with the sanctions imposed under other legislation. On the other hand, REACH sanctions are almost never the less stringent ones.

Finally, the types of measures adopted to enforce REACH are not particularly innovative when compared to those imposed under other legislation. In most countries, both criminal and administrative sanctions are used. It is however worth noticing that Cyprus made use of administrative sanctions for the first time with the enforcement of REACH.

#### **4.5. Major Discrepancies between Member States and Regions**

##### *Discrepancies based on the choice of enforcement regime*

The countries under study have developed very different enforcement regimes, based on their national approaches towards sanctions with regards to environmental, and in particular chemicals, legislation.

The common law countries and countries with a common law influence (United Kingdom, Ireland and Malta) distinguish themselves by a focus on administrative notices backed up by criminal sanctions. This is also true for the Nordic Countries, which clearly put the priority on coercion, and aim first at compelling the offender to comply with the legislation through the issuance of notices or coercive fines, rather than to punish the breach of law. Under these systems, penalties with a repressive character as the punitive instruments will only be used as the last resort.

The remaining countries are divided between countries enforcing REACH mostly at the administrative level (Austria, Bulgaria, Czech Republic, Greece, Estonia, Hungary, Lithuania, Latvia, Portugal, Romania, Slovakia and Slovenia) and those combining the administrative and the criminal approach (Belgium, Cyprus, Denmark, Finland, France, Germany, Iceland, Italy, Liechtenstein, Luxembourg, The Netherlands, Norway, Poland and Sweden).

The countries of the first category have a very limited use of criminal penalties or use exclusively administrative sanctions.

Countries with a combined approach have usually distinguished administrative from criminal offences. It is done with the insertion of an element of intentional infringement or of endangerment to justify the use of criminal sanctions. This is for instance the case in Finland, Sweden and Norway, and in the quasi-criminal law countries (Germany and Liechtenstein) where the breach of an obligation has to be wilful and negligent to be considered a criminal offence. In Denmark on the other hand, first breach and minor offences are considered as administrative offences, while all others are criminal. In these countries, this is the behaviour of the offender towards infringement that will lead or not to criminal prosecution.

In other countries the distinction is made simply as the infringements considered as administrative or as criminal offences are not the same. In Poland, the most important obligations of REACH are covered by criminal law. In France, all offences that are not considered criminal are administrative.

In the remaining countries, the administrative and criminal offences are exactly (Belgium and Luxembourg) or partially (Cyprus, the Netherlands and to a certain extent Italy) similar. In Belgium, it is, on a case-by-case basis, and depending on the severity of the infringement, for the administrative authorities to decide to bring the case before the Court if they consider that the offence could constitute a crime. In Italy, it is also checked on an individual basis whether an offence can fall under criminal law, if not, administrative law will apply.

However, despite these differences, it seems that in all countries under study, due to the complexity of the Regulation and the extent of the obligations, the use of warnings and formal notices are widely used by the inspectors to bring the offender in compliance and the administrative procedure is preferred as more simple and having a greater flexibility.

### *Discrepancies based on the types and level of penalties adopted in the different countries*

Regarding the types of penalties in place, fines are the most commonly used tool in all countries under study, and is as such a very useful point of comparison regarding discrepancies in the level of enforcement.

Countries which have adopted criminal sanctions have usually adopted consequently higher fines than other countries, as can be explained by the repressive nature of such fines. The United Kingdom and Ireland, with respectively fines that can be unlimited and up to 3 000 000 Euros, ensure that the infringement is strongly punished.

Among the countries with a combined approach, Poland has also put a strong emphasis on punishment by way of criminal law, and has adopted fines of more than 4 500 000 Euros. Belgium, which provides for extremely high fines at the criminal level (up to 55 000 000), but also at the administrative level (up to 1 110 000 Euros) compared to the level of fines provided in other countries is also noteworthy. Portugal, although having only administrative sanctions in place, provides for fines up to 2 500 000 Euros.

Other countries can be classified in different ranges:

- five countries under study have set a maximum fine below 50 000 Euros (Austria, Latvia, Lithuania, Malta and Romania)<sup>60</sup>
- six countries have set a maximum fine between 50 000 and 100 000 Euros (Bulgaria, Cyprus, Hungary, Luxembourg, Slovakia and Slovenia)
- seven countries have set a maximum fine between 100 000 and 1 000 000 Euros (Czech Republic, Italy, Liechtenstein, France, Greece, Germany and the Netherlands).

The countries with the lower fines could consider adapting their level of fines to the higher levels set in other countries. In particular, a few countries have set a maximum fine below 5 000 Euros (Latvia and Lithuania), which is very low in comparison with what is adopted in the other countries<sup>61</sup>.

Nevertheless, it can be noted that in a few countries, other instruments have been adopted to complement the fine. They can potentially also have a very strong economic impact (closure of the establishment, withdrawal from the market), and could possibly balance lower fines. In the countries with the lowest fines, however, only Austria provides for the possibility to confiscate substances, while Malta foresees the possibility to suspend the licence of a company. On the other hand, the countries with the highest rates of fines also have the broadest range of penalties. For instance, Belgium, Poland and Portugal provide for a whole set of complementary penalties, in addition to their high level of fines. France and the Czech Republic also use a particularly wide range of administrative sanctions (deprivation of rights, destruction of the substance, etc.). Quite a few countries have also adopted imprisonment penalties, which can have a powerful deterrent effect (this is the case in all countries with criminal sanctions, except for Poland).

At the national level, for most countries, the appropriateness and consistency of the sanctions foreseen for the violation of REACH are quite arguable.

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<sup>60</sup> Estonia also provides for administrative fines of up to 22 000 Euros. However, the law also foresees the possibility of a criminal fine, of which the amount is not provided in the law.

<sup>61</sup> It should be noted that this review does not take into account the possibility to cumulate sanctions where several different infringements have been noted. The pecuniary sanctions can usually be cumulated, while other sanctions (such as prison) cannot. The possibility to cumulate sanctions can make the maximum level of fine in one country raise substantially where an offender has committed several offences at the same time. It is however difficult to calculate for each country a maximum amount that could be used in the framework of this study, as the cumulation will depend in each case on the type and the number of the infractions observed.

On the one hand, when comparing the costs of compliance with the sanctions, for all “mid-level enforcement” countries (Bulgaria, Cyprus, Hungary, Luxembourg, Slovakia and Slovenia), the sanctions are efficient only up to a certain tonnage (usually below 1 000 tonnes). When the tonnage is above, the costs of compliance are higher than the level of penalties, which provides little incentive for big producers or importers to comply, even though these companies will have in most cases a significant share of the market, and a potentially stronger impact on the environment and health. *A fortiori*, in the countries with the lowest level of penalties, the incentives for an offender to comply with the legislation rather than to pay a fine are very weak. It seems that only countries with a high level of fine and a well-developed panel of other instruments with a strong deterrent effect can impose sanctions that are high enough to compete with the important costs implied by the respect of REACH obligations.

On the other hand, when sanctions for infringements of REACH are compared to the sanctions of comparable offences under other legislation, the sanctions for REACH are more or less equivalent to the sanctions imposed in other environmental and health legislation. This is in particular the case when the obligations are similar and enforced under the same national acts. In this respect, REACH and the biocides legislation are strongly connected. In conclusion, the enforcement regime under REACH is not significantly more stringent or more creative than what is provided in neighbouring fields of law.

#### 4.6. Short Descriptions

This section provides short descriptions of the level and type of penalties employed for each Member State under study.

##### *Austria*

On the 18th August 2009 the Law on the Execution of REACH (*Bundesgesetz zur Durchführung der REACH Verordnung, REACH-Durchführungsgesetz*) came into force (Federal Law Gazette I No. 88/2009), laying down, inter alia, administrative criminal sanctions for REACH infringements, including a “catch-all” provision.

Serious infringements of REACH mentioned in § 3(1) of *REACH-Durchführungsgesetz* incur higher fines. Within § 3 (1) of *REACH-Durchführungsgesetz*, the Austrian legislator deemed it unnecessary to mention each Article of REACH, the infringement of which incurs higher fines, since the Articles in themselves contain clear orders and prohibitions.

The Federal Ministry of Agriculture, Forestry, Environment and Water Management is primarily responsible for the enforcement and supervision of REACH. Its minister is authorised to issue instructions to the competent authorities of the nine federal states, each headed by the “*Landeshauptmann*”, who directs chemical inspectors to carry out supervision by means of on-site controls, sampling, review of books etc. If there is a concrete suspicion of an offence, the chemicals inspectors have to inform the competent authority, “*Bezirksverwaltungsbehörde*”, which initiates the appropriate legal procedure to sanction the infringement. On average every federal state uses three chemical inspectors. The enforcement measure most often applied to redress an offence is to ask the offender to restore lawful conditions in accordance with § 68 ChemG.

The current payroll expenses are covered and there is a legal obligation to finance the examination of samples. The external costs for supervision have to be reimbursed by the supervised offender, if a sanction has been definitely imposed upon him.

##### *Belgium*

The environmental legislation – and its enforcement - is a shared competence between the federal level and the regional level, depending on the obligations at stake. The distribution of the

competences among these authorities is dealt with in the Belgian Constitution and in a Special law on the State Reform.

A cooperation agreement is currently prepared in order to precise the cooperation of each entity. At the federal level eg., the law mentions that the Federal Public Service for Public Health, Security of the Food Chain and Environment is competent to monitor the enforcement of the REACH obligations.

The sanctions apply in case of infringement of the articles of the REACH Regulation that are regulated at the federal level, meaning that the level of sanctions is uniform throughout the country. However, all the environmental consequences in terms of use and production on air, water, soil and human health consequences of the infringement of REACH are dealt with at the regional level.

REACH provisions subject to sanctions are expressly designated in the federal law. This approach is meant to help the administration and the judiciary identifying infringements of the REACH regulation. The federal law makes a distinction between serious infringements and minor infringements. The degree of seriousness of the infringement is assessed taking into account the consequences on the environment and on human health of a breach of a specific provision of REACH. For example, minor infringements are mainly infringements of ‘an administrative obligation’ with a minor impact on human health and the environment.

The infringement procedure is not the same for ‘minor REACH infringements’ and ‘serious REACH infringements’. In case of less serious infringements, the civil servant designated to this aim by the King, issues an administrative fine to the offender, while for a serious infringement the competent authority sends a report in writing to the public prosecutor who decides whether or not to pursue the proceedings. A minor infringement can also trigger criminal proceedings in case the offender does not comply with the administrative sanction (e.g., does not pay a fine).

Prior to the imposition of a sanction, a warning or a letter of formal notice is addressed to the person who is acting in contradiction with the obligations of REACH in order to inform him that he acts against the law and to invite him to correct the situation. Such warning procedure does not apply in case of recidivism or when a specific deadline imposed by REACH or by an ECHA decision has not been respected.

### ***Bulgaria***

Bulgaria does not provide specific criminal sanctions when REACH obligations are infringed. However, false statements before competent authorities are incriminated (such as declarations, false information in applications, etc.) and thus subject to criminal liability.

Administrative sanctions are determined taking into account the level of dangerousness of the infringement, all the negative impacts, all the circumstances when the infringement took place, the duration and repetition of the infringement within the minimum and maximum amount set out in the law. If the same person infringes REACH obligations for a second time the sanctions are doubled.

The competent authorities in Bulgaria responsible for enforcing compliance with the REACH obligations are the Regional Inspectorates of Environment and Water, Regional Inspectorates of Public Health Protection and the General Labour Inspectorate. The inspectors are entitled to access to premises, check of documentation, files, taking samples, etc. The Minister of Environment and Water has approved Instructions for carrying out inspections for compliance with the requirements of REACH. The Inspectors are obliged to fill in a report with their findings and recommend measures for achieving compliance if possible.

The preparatory work for implementing the requirements of REACH started at the Ministry of Environment and Water (MoEW) more than 2 years ago. The Ministry has worked in close collaboration with the industrial chambers, mainly Bulgarian Chamber of Industry and the Chemical

industry chamber for awareness and training of target groups for their REACH obligations. All the guidance manuals and instructions for application of REACH are consulted with the industry prior to their adoption. Due to the preliminary registration carried out as a result of a wide campaign amount the industrial and commercial sector, the competent authorities have compiled a detailed database.

### ***Cyprus***

Breaches of REACH may result in legal proceedings, which may result upon conviction in the imposition of a fine of up to 80 000 EUR and/or two years imprisonment. In the case of multiple infringements the fines are cumulative. In the event of the repetition of infringements, the fine cannot exceed 80 000 EUR and the duration of imprisonment cannot exceed four years.

In parallel, a procedure for administrative sanctions has been adopted for the specific purpose of enforcing REACH. The national legislation provides for daily fines of up to 500 EUR per day of infringement and fines of up to 20 000 EUR. Administrative fines are calculated depending on the nature, the seriousness and the duration of infringement. If the infringement does not cease, the Minister may impose an administrative fine of between 100 EUR and 1 000 EUR per day, depending on the severity of the infringement.

These provisions can be seen as supplementing earlier chemicals legislation (the Dangerous substances laws and regulation of 1991 to 2004), which did not provide for any administrative fines. Administrative fines were thus introduced as a method of enforcement and provide a new tool for inspectors. Administrative fines apply to certain violations, but not all. The provisions for which administrative fines apply were carefully selected. This selection procedure did not review all possible violations but just identified the REACH provisions which could be covered with administrative fines. It is considered that administrative fines are a faster procedure for handling violations, because the procedure to impose criminal sanction is more complex and longer. The decision to apply either an administrative or a criminal sanction remains at the discretion of the Ministry's auditors.

The Department of Labour Inspection is the only competent Cypriot authority capable of enforcing REACH and does so by means of an inspection system. This system was designed according to ILO principles and is also used for the enforcement of the Health and Safety legislation.

### ***Czech Republic***

In the Czech legislation, criminal liability of legal persons does not exist. Moreover, criminal liability of natural persons in the "environmental area" is very limited and thus rarely applied in practice. Consequently, administrative liability applies in the majority of cases and administrative sanctions are imposed. These are mostly financial penalties. Apart from financial penalties, corrective measures can be imposed, including closing down an operation, or suspending or cancelling an authorisation.

Pursuant to the Czech legislation, all breaches of the obligations under REACH are covered by a "catch-all provision". This provision imposes a financial penalty of up to 5 000 000 CZK (195 695 EUR) on legal persons and natural persons with a business licence. Furthermore, the enforcement authorities may order to withdraw the relevant substance or mixture from the market.

Generally, the maximum amounts of fines set out in the legal acts transposing or implementing REACH regulation seem sufficiently dissuasive. However, there is so far little data to verify whether the maximum amount has ever been used. The data available for comparable environmental legislation tends to indicate that enforcement authorities impose penalties that are more often close to the bottom end of the allowed range<sup>62</sup>.

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<sup>62</sup> For example, the Act on the integrated prevention states that a fine of maximum 7 000 000 CZK (273 972 EUR) can be imposed if an operator operates the installation without a valid IPPC permit or in breach of the conditions of the permit. According to the data published by the Czech Environmental Inspectorate<sup>62</sup>, the fines

## ***Denmark***

In Denmark, the penalties for infringements of REACH are covered in “the consolidated act No. 1755 on Chemical Substances and Products dated 22 December 2006”. This legislation applies to chemicals in general and does not refer expressly to REACH. Section 59 contains a so-called “catch-all provision” stating that violations of “the European Community regulations regarding chemical substances, products and articles”, shall be sentenced to a fine (proportional to the perpetrators daily income) according to the Chapter 6 of the Danish Penal Code. If the breach is done deliberately or by gross negligence, the penalty can increase to up to 2 years of imprisonment.

In accordance with Chapter 9 of the Danish Penal Code, any economic gain from violations of REACH can be confiscated. If confiscation is not possible this is taken into account when the amount for the fines is decided.

For the same infringements as those stated in Section 59, a legal person can be sentenced to a fine according to Ch. 5 and 6 of the Danish Penal Code.

The Environmental Ministry has the general responsibility for the implementation and enforcement of REACH. The Ministry is assisted by the Danish Environmental Protection Agency, the Danish Working Environment Authority, the Danish Maritime Authority and the Danish Energy Agency.

## ***Estonia***

Estonia provides some specific administrative sanctions for the infringement of REACH. Criminal sanctions can also be imposed when REACH obligations are infringed but only when they lead to the infringement of the Estonian Criminal Code provisions on the handling of dangerous chemicals or waste.

The main type of administrative penalties is the fine. According to the Chemicals Act, violation of the requirements of the REACH regulation is punishable with a fine of up to 300 fine units (21 000 EEK: 1 342.14 EUR); the same act, if committed by a legal person, is punishable by a fine of up to 350 000 Estonian crowns (22 369.02 EUR).

A case-by-case approach to determine the amount of financial penalties shall be used for each infringement. Administrative bodies have the right of discretion and should take into account the level of dangerousness, the duration, gravity and other circumstances of the infringement

The following extra-judicial bodies conduct supervision in matters of administrative offences as regards REACH:

- 1) the Technical Inspectorate;
- 2) the Rescue Board and local offices of the Rescue Board;
- 3) the Labour Inspectorate;
- 4) the Environmental Inspectorate;
- 5) the Consumer Protection Board;
- 6) the Health Protection Inspectorate.

A person exercising supervision has the right to issue precepts for termination of violations of the requirements of REACH, or the legislation established on the basis thereof, set terms for compliance with the precepts and monitor compliance with the precepts; upon failure to comply with a precept a

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imposed for this offence in 2009 do not exceed 300 000 CZK (11 742 EUR). Such fines do not seem sufficiently dissuasive.



person exercising supervision has the right to impose penalty payments or apply substitutive enforcement. The upper limit for a penalty payment is 10 000 kroons (639 115 EUR).

### ***Finland***

The Finnish Chemicals Act expressly provides for criminal sanctions for the breach of the REACH obligations. However, it should be noted that all infringements of REACH can lead to an administrative measure under section 45 and section 51 of the Chemical Act (respectively a coercive fine or the prohibition from continuing to carry out or repeating an infringing procedure). These two sections however, do not refer to REACH obligations as such, but have a much broader scope. It should be noted that the Chemicals Act will be renewed in the near future, and it may thus be subject to changes implying more precisions on the specific obligations to which these two sections apply.

Section 52 of the Chemical Act states precisely the violations of the REACH provisions that are subject to criminal sanctions. Some sanctions of the Criminal code could also apply indirectly to the infringement of REACH provisions; however these sanctions do not refer to REACH precisely but to broader categories of violations relating to chemicals and are more severe than the ones under section 52 of the Chemical Act. It is not yet entirely clear whether the REACH infringements only lead to a fine under section 52 of the Chemical Act or could be subject to more severe punishment under the Criminal Code.

The environmental authorities co-operate on the supervision of the use of chemicals and the enforcement of the REACH Regulation with various other organisations, including health authorities, occupational health and safety authorities, the agricultural authorities, officials responsible for safety standards. The Finnish Government has also nominated the Advisory Committee on Chemicals to oversee co-operation between the authorities and businesses.

### ***France***

In France, infringements to environmental laws are mainly addressed at this administrative level. This procedure is considered more flexible and faster than the criminal procedure. Furthermore, specialised administrative authorities are deemed to be more competent to deal with technical matters such as chemical regulations than criminal jurisdictions.

Unlike REACH administrative infringements, REACH criminal infringements are clearly defined in the law (for example, the failure to respect the restrictions measures enacted in Title VIII of EC Regulation 1907/2006). Therefore, it is easier for criminal jurisdictions to determine whether a criminal infringement of the REACH Regulation has occurred than in cases where there is no specific infringements mentioned in the law.

In France, inspectors from different competent authorities shall control and assess in their area of competence whether any REACH obligations have been infringed:

- Inspectors of the veterinary services,
- Inspectors of labour law,
- Inspectors of General Directorate for Fair Trading, Consumer Affairs and Fraud Control,
- Customs agents,
- Inspectors of sanitary security and health products,
- Inspectors of classified installations<sup>63</sup>

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<sup>63</sup> For example, inspectors of classified installations shall do their inspection based on specific guidelines and shall fill tables with the different REACH requirements to be respected. 350 inspections of producers and importers of chemical substances shall be done in 2009. The formation of inspectors of classified installations on the REACH regulation has only started early this year.

Following this, inspectors send their report to the competent authority. The competent authority, while identifying an infringement to the REACH obligation, shall inform the person concerned. This person has the right to submit comments. The competent authority, if not satisfied with these comments, can give notice to the person concerned.

### Germany

The competent authorities of the Federal States, determined by the law of the Federal States, control and enforce REACH. Depending on each Federal State, the control and enforcement of REACH is carried out on different administrative levels. Within these administrative levels, the departments (*Amt*) for chemical safety for occupational safety and for consumer protection are primarily responsible for these controls and enforcements. Technical inspectors carry out on-site inspections and are supported by specialized authorities providing scientific support.

Criminal offences are prosecuted by the prosecutor and offenders are convicted by the criminal court, while “*Ordnungswidrigkeiten*” (offences belonging to the administrative criminal law) are handled by the competent surveillance authority of the Federal State. If the alleged offender appeals against the fine, the administrative procedure ends and competence is transferred to the court.

The Federation/Federal State working group on Chemical Safety (*Bund/Länder Arbeitsgemeinschaft Chemiesicherheit*, BLAC) serves to coordinate the supervision and the enforcement of REACH in the Federal State and constitutes a platform for the exchange of information. BLAC has developed non-public guidelines for monitoring the chemical market (*Leitfaden für die Marktüberwachung von Chemikalien*) for the Federal States. The Committee of the Federal States on occupational safety and safety engineering has also published guidelines for the supervision and enforcement of REACH in the area of occupational protection (*Handlungsanleitung für die Umsetzung der REACH-Verordnung im Arbeitsschutz*).

Some competent authorities of the Federal States have reported that they regard the issuing of enforceable administrative acts and their enforcement as preferable to the imposition of sanctions following the carrying out of “*Ordnungswidrigkeiten*”, as long as the offender appears to be willing to comply with REACH and has not committed repeated violations of REACH, without prejudice to considerations on a case-by-case basis. This approach aims at maintaining an open dialogue between the authorities and the companies.

### Greece

The transposition of REACH in the Greek legislation was carried out by the Ministerial Decision 87/2007, which modified the Decision 378/1994 of the Supreme Chemical Council of the State. Ministerial Decision 3013966/2726/2007 then defined the Competent National Authority for monitoring of REACH implementation. The Ministerial Decision 450/2008 defines the control measures set for the REACH Regulation. Finally, Ministerial Decision 82/2009 defined the sanctions associated with infringements of articles of REACH.

The Greek legislative system does not provide criminal sanctions for infringement of REACH provisions. The General Chemical State Laboratory which is the Competent National Authority for the implementation of REACH does not have the jurisdiction to issue criminal sanctions. The only sanctions provided are administrative. Administrative fines are determined, taking into consideration a number of parameters such as the quantity of the substance concerned, the associated hazard as well as the type of undertaking concerned (very small, SME, etc.). In case of multiple infringements, the fines are added up. In case of repetition of infringements, the fine is increased by 50%.

Administrative sanctions such as fines, prohibition of production, circulation and use are imposed by the Head of the Division of Environment of the General Chemical State Laboratory. The General

Chemical State Laboratory undertakes inspections, controls and samplings with regard to REACH implementation, currently employing a staff of 30 Chemists and Chemical Engineers. The Regional Chemical Services of the General Chemical State Laboratory, under the co-ordination of the Division of Environment, can also undertake routine or ad-hoc inspections.

### ***Hungary***

Hungary does not provide criminal sanctions when REACH obligations are infringed. Thus, no imprisonment sanctions for the infringement of REACH in Hungary can be imposed.

Administrative sanctions are determined taking into account the level of dangerousness and quantity of dangerous substance or dangerous mixture, the duration, gravity, and repetition of the infringement, the time and costs involved to eliminate the danger, the size of the undertaking.

The penalty may be imposed again if the person that infringes REACH obligations does not execute or does not properly execute the administrative decision.

The Minister responsible for health shall issue a normative order which will explain how REACH infringement penalties shall be specifically determined. This normative order shall be first prepared in consultation with the professional unions of the chemical industry.

### ***Iceland***

Penalties for infringements of REACH are laid down in the Icelandic Act no. 45/2008 on chemicals. Indeed with this Act, the REACH Regulation was adopted as a whole into Icelandic law and the sanctions under article 12 of this Act apply to all infringements of REACH. Iceland has taken a so-called 'catch all provision' approach. Article 12 of the Icelandic Act no. 45/2008 on chemicals provides that violations of the Act and regulations issued accordingly shall be punished with a fine and if the breach is severe or repeated to up to two years imprisonment.

Administrative sanctions for infringements of REACH are laid down in article 10 of Act no. 45/2008 on chemicals. The Environment Agency of Iceland (or local health inspectorates) can, according to paragraph 2 art. 19, stop the marketing of a product which does not fulfil the requirements of the Act or any regulations that are issued accordingly. Products can also be confiscated for the duration of the investigation. It can also be required to dispose of the product, withdraw it or store it until any mishandling has been corrected.

According to paragraph 3, art. 10 the Environment Agency (or local health inspectorates) can issue a formal notice. If the formal notice is not heeded coercive fines can be issued.

According to paragraph 3, art. 12 of the Act, chemicals, preparations or articles which are produced, imported or placed on the market in a way that violates REACH can be confiscated by a Court order. The profits from these operations can also be confiscated.

### ***Ireland***

The Chemicals Act No. 13 of 2008 encompasses the enforcement measures of REACH and also of two other EU regulations relating to chemicals (EC Regulation on export and import of dangerous chemicals, EC Regulation on detergents). Administrative sanctions as defined in the continental law system do not exist in Ireland; however alternatives to penal sanctions exist in the form of Enforcement Notices, such as a Prohibition Notice. Persons that infringe REACH obligations can be convicted on summary conviction (petty offences) or on conviction of indictment (serious offences) depending on the level of the infringement. It is worth mentioning that under the Chemicals Act, the REACH provisions that shall not be infringed are not expressly designated; however, an offence may be identified where duty holder who has an obligation under the REACH Regulation, fails to comply with that obligation. It is in general, up to the inspectors, and ultimately the courts, to identify when

there is an infringement to the REACH Regulation, as is the case for the workplace Health & Safety and other legislation which implemented by the Authority. H.S.A. inspectors are trained to enforce legislation in this manner for a wide range of legislative measures and therefore are experienced in this approach. Guidance material exists in the form of Inspectors enforcement Manual, and the HSA enforcement policy.

This catch-all approach was adopted because the Chemicals Act deals not only with REACH infringement but also infringements of the Rotterdam Convention and of the Regulation on Detergent, and also because it is coherent with the general enforcement approach and legislative framework in Ireland, thereby ensuring that inspectors can use the same system of enforcement for a range of legislative instruments.

The Chemicals Act No. 13 of 2008 designates the Health and Safety Authority (HSA) as the main authority responsible for the enforcement of REACH. The Environmental Protection Agency is responsible for the prevention of environmental pollution related to REACH, and the Department of Agriculture, Fisheries & Food (DAFF) has responsibility for pesticides in relation to REACH. HSA and the Environmental Protection Agency have already established a Memorandum of Understanding on how they will coordinate for the enforcement of REACH, and one is in progress with DAFF.

REACH inspections will be carried out mainly by the Chemical Enforcement Division of the HSA inspectorate. In 2009, this Division has mainly focused on the following areas:

- Registration and pre-registration of substances under REACH (with a check of 10% of the actors having a role under REACH<sup>64</sup>);
- Hazard communications;

In the Chemicals Act No. 13 of 2008, the custom authorities do not have specific competences related to the enforcement of REACH. However, Section 22 of the Chemical Act No. 13 of 2008 allows any national authority established under the Act to request customs officials to detain any chemical being exported or imported for up to 72 hours, in order to allow an inspector to examine it.

### ***Italy***

The *Decreto Legislativo n. 133/2009* encompasses the sanctions related to REACH in Italy. This *Decreto Legislativo* establishes a system of administrative sanctions.

Most of the REACH sanctions are administrative fines that can amount to up to 90 000 EUR. The *Decreto Legislativo* also provides for criminal sanctions for the infringement of Article 67 and Article 56(1)-2) of REACH relating to the authorisation requirements which can result in a fine of up to 150 000 EUR or/and imprisonment of up to 3 months.

The approach adopted in the *Decreto* results in the fact that the administrative sanctions do not apply if the infringement leads to the violation of criminal legislation. In the latter case, the criminal sanctions applicable to the specific criminal behaviour identified under the criminal legislation will apply instead.

The competent authority identified in the *Decreto* is the Ministry of Labour, Health and Welfare.

### ***Latvia***

In Latvia, there are no criminal sanctions for the infringement of REACH obligations. Latvia provides for administrative sanctions as this procedure is considered faster and more effective than the criminal procedure.

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<sup>64</sup> In the framework of the participation of Ireland in the REACH EN-FORCE-1 project

The Ministry of Health and the supervisory and control institutions which are subordinate thereto, as specified in regulatory enactments, shall control activities relating to the trade of chemical substances, chemical preparations and biocidal preparations and shall supervise the compliance of such activities with laws and other regulatory enactments in the field of protection of human life and health.

The Ministry of Welfare and the supervisory and control authorities which are subordinate thereto shall control activities relating to chemical substances, chemical preparations and biocidal preparations in the working environment and shall supervise the compliance of such activities with laws and other regulatory enactments in the field of protection of life and health of the employees.

The Ministry of Environment and the supervisory and control authorities which are subordinate thereto shall control activities relating to chemical substances, chemical preparations and biocidal preparations and their impact on the environment and shall supervise the compliance of such activities with environmental laws and other regulatory enactments. The State Environmental Service shall issue administrative acts related to the registration, temporary registration of chemical substances or chemical preparations, including biocidal preparations or issue of permits.

### ***Liechtenstein***

Liechtenstein provides for both administrative and criminal sanctions. In both systems, the main sanction applicable is a fine (of up to 20 000 CHF (13 186 EUR) for administrative sanctions, and ten times this amount for criminal offences).

The Office of Environmental Protection is responsible for the supervision and enforcement of REACH as far as the supervision and sanctioning of administrative offences is concerned. The Regional Court deals with criminal offences. The Office of Environmental Protection initiates general on-site inspections and takes into account the information of third parties for the detection of infringements.

In total three officials are in charge of the supervision and enforcement of REACH in the chemical area and the Office of Environmental Protection. If required, additional financial resources can be provided.

So far, no administrative measures to enforce REACH have had to be taken and no sanctions have had to be imposed.

### ***Lithuania***

There are no criminal sanctions provided for violation of REACH. Several articles laid down in the Criminal Code deal with criminal offences against environment, human health and disposal of hazardous chemicals in general. The Criminal Code also provides criminal sanctions for unlawful possession of poisonous substances<sup>65</sup>. These provisions may apply in certain cases for violation of REACH. However, they have been developed before REACH was adopted and do not specifically cover REACH violations.

The main changes in Lithuanian regulation related to sanctions for the violation of REACH have appeared in the Code of Administrative Offences. Lithuania established an approach consisting in a list of specific REACH obligations and their related sanctions. The infringement of the REACH provisions listed in the legislation is subject to fines with minimum and maximum limits. The subject of those fines may be natural persons or officers. The latter shall mean state representative or member of administrative staff of either public or private organization/company. There are no fines foreseen for legal persons. However, in case of damage resulting from the violation of REACH, they may be found liable under civil proceedings.

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<sup>65</sup> Poisonous substances - the certain group of the most dangerous substances (very toxic, toxic, carcinogenic, mutagenic, toxic to reproduction) regulated by the national legislation (Law on control of poisonous substances).

The Draft Law on the Amendment of Article 84<sup>1</sup> of the Code of Administrative Offences has been prepared, endorsed and already submitted to the Parliament for the final adoption. The amendment has been made seeking to implement 2 new Regulations (EC) of the European Parliament and Council (No. 1102/2008 (CLP) and 1272/2008 (on mercury)) and to improve the sanctions system for REACH violations currently in force. Therefore some changes will be introduced. First of all the changes in the Administrative Code aimed to mutually consistent the Administrative Code and the Criminal Code as regards the offences of the rules on poisonous substances. Secondly, the changes would clearly set the liability of the natural persons as well as of the managers or authorised representatives of the legal persons. Thirdly, seeking for more consistency, some provisions have been added to the Administrative Code, some editorial changes have been made for more precise and clear formulation of the violations.

### ***Luxembourg***

In April 2009, a new Grand Duchy law was enacted in order to provide the rules for the application, and the sanctions of REACH in Luxembourg. This law provides a precise list of the REACH provisions that shall not be infringed. The infringement of these provisions can lead to administrative and criminal sanctions. In other words, in the Luxembourg system, there is no hierarchy of sanction in the infringement of the REACH provisions listed (for example, this law does not mention the infringement of REACH provisions that could only lead to administrative sanctions).

The law provides a list of competent persons in charge of the monitoring and enforcement of the listed REACH provisions. It is worth noting that this enforcement is monitored by competent persons specialised in different fields (labour law inspectors, customs officers, doctors, engineers and technicians from the environmental administration, engineers and technicians from the management water administration, chemists from the Health care direction). The law provides that these persons, while exercising their function, become law enforcement officers that have to declare infringements to the REACH provisions. The procedure they shall respect when monitoring the application of the REACH provisions is very detailed in the law (for example, when they can access the premises to inspect, what kind of documents they can have access to, what kind of sampling they can do).

Finally it is worth mentioning that this law provides that certified associations have locus standi when there is an infringement of the listed REACH provisions and that this infringement causes a direct or indirect damage to the collective interests they are aiming to protect.

### ***Malta***

The Maltese Criminal Code (Chapter 9 of the Laws of Malta) distinguishes between crimes and contraventions, the former being of a more serious nature and attracting higher penalties. The penalties for infringements of REACH are either a fine (*multa*) ranging from a minimum of circa 466 euros to a maximum of circa 23,294 euros and/or imprisonment, the maximum term of which is four years. These are the typical penalties found in the Maltese legal system with respect to crimes.

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Implementation) Regulations, 2008 (Legal Notice 61 of 2008) were enacted by the Minister for Competitiveness and Communications under the Product Safety Act (Chapter 427 of the Laws of Malta). These regulations implement the provisions of Articles 121, 125 and 126 of REACH. Regulation 3 establishes the Malta Standards Authority (MSA) as the competent authority within the meaning of Article 121 of REACH and the authority responsible for enforcement. Regulation 5 provides that the penalties applicable following an infringement of the provisions of REACH shall be those provided for in Part IV (Articles 30 to 34) of the Product Safety Act. Infringements of REACH are criminal offences prosecuted before a court of criminal jurisdiction. The Director of the Market Surveillance Directorate of the MSA is the person responsible for instituting proceedings and conducting the prosecution.

The Registration, Evaluation, Authorisation and Restriction of Chemicals Enforcement (E-REACH) Committee Regulations, 2008 (Legal Notice 27 of 2008) were enacted to set up a committee to assist the MSA, with the aim of achieving a holistic multi-partite approach for the implementation and management of the enforcement of REACH. The E-REACH Committee consists of the Director responsible for chemicals within the MSA, the Director for environmental protection, the Director of the Market Surveillance Directorate within the MSA and the Controller of Customs (or their delegates). The Occupational Health and Safety Authority and the Public Health Department are consulted by the Committee in matters affecting their respective area of competence.

The responsibilities of the E-REACH Committee include the monitoring and coordination of enforcement of REACH and other relevant legislation, standards and practices and advising upon the proper legal and administrative framework to implement REACH.

### ***The Netherlands***

In the Dutch legal system, criminal and administrative enforcement can be imposed for a violation of a provision of REACH because these enforcement systems display different aims (compliance and punitive).

Administrative penalties and enforcement are based on the *Environmental Management Act (Wet Milieubeheer: WM)*; the penalties can consist of incremental penalty payments (according to Article 5:32 Awb, the order defines the remedial action that needs to be taken); administrative coercion (the penalty depends on the violated interest and the expected effect of the penalty. This means it takes account of the seriousness of the offence and the financial benefit that the offender obtained by committing the offence) or a withdrawal of the permit. The WM also includes the possibility of an administrative fine. This does however not apply to chapter 9 WM which regulates REACH. There is ongoing discussion about the option to have this administrative fine applied to REACH, which requires changes in the WM. One specific question of application which is currently under discussion is whether Annex XVII to REACH should fall under the Commodity Act (on the basis of Article 9.3.3(5) of the WM).

Criminal penalties and enforcement are based on the WM, with reference to the Economic Offences Act (WED). The methodology for the penalties has been the subject of discussions with other Member States. Category 1 and 2 apply: Category 1 crimes are punished with six years in prison or a fine of the fifth category for individuals which can be up to 74 000 Euros. Under the Criminal Code, legal persons can be punished by a fine of the next higher category. For example, a sixth category fine is 740 000 Euros. Offences are punished with one year in prison or a fine of the fourth category (up to 18 500 Euros). Category 2 crimes are punished with two years in prison or a fine of the fourth category. Offences are punished with six months in prison or a fine of the fourth category (up to 18 500 Euros).

The inspectors that monitor REACH compliance are the Labour Inspection (AI), the Food and Consumer Product Safety Authority (VWA) and the VROM-Inspectorate (VI). Each individual service is responsible for monitoring specific groups:

- the Labour Inspection (AI) for the monitoring of compliance with the rules for the protection, safety and health of employees;
- the Food and Consumer Product Safety Authority (VWA) for the enforcement of rules to protect the safety and health of consumers in using consumer products;
- the VROM Inspectorate to monitor the enforcement of protection rules for humans and the environment through the industrial application of substances and products.

With the monitoring and enforcement of REACH having only recently started (2007), it cannot yet be said how the use of these penalties will evolve. Until now, obligations have included the registration of new substances and the establishment of safety data sheets. According to the 2008 year report of the steering group on the enforcement of REACH, the inspected companies were aware of the REACH

obligations and about 83% of the companies (subject to inspection) could provide the safety data sheets.

### ***Norway***

In Norway, REACH was incorporated in the corpus of law through the Norwegian Regulation 2008-05-30 nr 516 on REACH. This Norwegian regulation does not contain any substantial provisions referring to REACH, nor does it define which provisions of the REACH Regulation shall be enforceable. It however provides that violations to it shall be subject to administrative or criminal sanctions under the Pollution Control Act, the Product Control Act, the Fire and Explosion Prevention Act and the Working Environment Act. The provisions of these Acts are considered to cover REACH infringements. In other words, there are no specific REACH administrative or criminal sanctions in the Norwegian legislation but the infringement of REACH will lead to administrative and criminal sanctions under several legislations that are related to REACH.

The administrative sanctions are coercive fines imposed on a daily or weekly or monthly basis until the requirements of the related legislations are complied with. These coercive fines are not considered as a penalty or as a punishment in the Norwegian legal system. The criminal sanctions consist of fines and imprisonments.

The Norwegian Pollution Control Authority, The Norwegian Labour Inspection Authority, Petroleum Safety Authority Norway, and the Directorate for Civil Protection and Emergency Planning will be responsible for the enforcement of REACH within their specific field of competence.

### ***Poland***

In Poland, as a rule, the law concerning products is enforced by administrative sanctions rather than criminal ones. In the case of REACH, however, criminal sanctions are far more extensive. The regulations concerning both types of these sanctions entered into force at a relatively late date, i.e. only on 24 February 2009. As a result of this, to date there has been practically no experience related to their application.

As regards administrative sanctions, a number of authorities have been designated to supervise the application of the regulations concerning chemical substances and preparations:

- the State Sanitary Inspectorate,
- the Inspectorate for Environmental Protection,
- the State Labour Inspectorate,
- the Trade Inspectorate,
- the State Fire Service,
- Customs authorities.

The State Sanitary Inspectorate plays a major role in the enforcement of the REACH Regulation, as it has been granted special decision-making powers. However, all the other supervision authorities mentioned above have the right, within their field of competence, to issue a post-inspection order when they find that REACH provisions are not complied with. It is however worth mentioning that to date Polish authorities have had little experience with respect to the enforcement of environmental Community legislation. Furthermore, criminal sanctions relating to environmental law have been of secondary significance in Poland until now.

### ***Portugal***

The General Administrative Offences Regime (approved by Decree-Law 433/82 and last amended by Law 109/2001) sets out a simplified procedure, based on “an illegal fact that results in the application of a fine” which is within the competence of administrative bodies with the aim of preserving public



objectives and interests. It gives rise to the application of fines or accessory sanctions, which are administrative enforcement measures applied by administrative authorities.

A special regime of Administrative Offences has been established for violations of environmental laws and regulations which was approved by Law 50/2006 of 29 August and amended by Law 89/2009 of 31 August.

Decree-Law 293/2007, which defines the national CA and the sanctions scheme under Regulation (EC) n° 1907/2006, establishes a set of infringements to REACH classified as very serious or serious and refers to the Administrative Environmental Offences regime the amount of the fines and accessory sanctions to be determined on a case by case basis by the national CA.

The imposition of administrative enforcement measures is not automatic. It is assessed by the General Inspectorate of the Environment and the General Directorate of Customs and Special Taxes over Consumption on a case-by-case basis and shall be proportional to the objective and subjective seriousness of each violation.

The amount of the fine is determined in accordance with the following factors: the seriousness of the offence; the fault of the agent; the economic situation of the agent and the benefit he/she obtained from the offence.

Together with the fine, the CA may impose accessory sanctions, the application of which depends exclusively on the seriousness of the offence and the fault of the agent. These sanctions do not have a pecuniary nature but, rather, result in the deprivation of rights, including confiscation of assets or closure of establishment.

### ***Romania***

By the time Romania notified the Commission about the legislation in force to deal with infringements of REACH, the specific piece of legislation intended to tackle REACH infringements (The Governmental Decision (**H.G. 477/2009**)) was already approved by the Parliament but not yet in force. The Decision only came into effect at the end of May 2009.

This law provides only for administrative sanctions when REACH obligations are infringed. The amount of the fines is the same for legal and natural persons. The law itself does not provide any guidelines for how the fines are supposed to be calculated on a case-by-case basis; only a range with a minimum and a maximum amount is given.

The enforcement of this law is mainly attributed to inspectors of the National Guard for Environment. They are entitled to carry out controls on any premises. Some of those controls are known well in advance, because they are registered in an annual plan, but the inspectors also have the possibility to make unannounced visits.

### ***Slovakia***

Infringements of the obligations stipulated by the REACH Regulation are in the Slovak Republic punished by administrative sanctions, namely by fines.

The law stipulates four range categories of penalties, where the lowest penalty is 9 958,176 EUR and the highest penalty can reach the amount ten times higher, i.e. 99 581, 757 EUR. The actual amount of penalty is decided by the Inspection Authority with regard to the seriousness of administrative offence, the way of conducting the offence, its harmful consequences on human health and/or environment, and with regard to other circumstances of the offence.

The administrative penalty may be imposed only if the proceedings on the offence begin within two years after the Inspection Authority get acquainted with wrongdoing, but no later than five years of actual committing of the offence.

The legislation also stipulates provisions on enabling inspectors to provide inspection; the law stipulates procedural fines for obstructions during inspection. The amount of fine may be up to 3 319, 391 EUR, while the total amount may not be higher than quintuple of the fine.

Besides administrative fines the relevant Inspection Authority may decide that the substances, preparations or articles shall be removed from the market if a person responsible does not fulfil duties imposed by the Authority within given time. These duties refer to rectifying consequences of illegal conduct of a responsible subject such as:

- failure to fulfil the obligations concerning classification, packing or labelling,
- failure to provide data safety card,
- failure to follow prohibitions or restrictions concerning placing on the market or using of dangerous substance or preparation.

The decision of the Inspection Authority is issued in administrative proceedings. An appeal filed against the decision has no suspensive effect.

There is also a general criminal provision stating that natural persons are criminally liable for manufacturing, import, export, transfer, purchase, sale, exchange, modification, use, or procuring highly risky chemical substances without permission. Such a person may be punished by imprisonment from one to five years, or up to life imprisonment, depending on circumstances, motif and consequences.

A natural person is also criminally liable for manufacturing, gaining for him/herself or for another person, or keeping article which is designated for illegal manufacturing of highly dangerous chemical substance. The punishment is from one to five years, or even up to 15 years of imprisonment, depending on consequences, motif and other circumstances.

Legal entities are not criminally liable in the Slovak Republic.

### ***Slovenia***

All penalties for the breach of REACH obligations are administrative (the so-called "minor offences"). No criminal offences are prescribed specifically for the infringement of REACH Regulation. This does not mean that a violation of REACH Regulation cannot at the same time constitute a criminal offence; for example, the infringement of REACH may constitute a criminal offence called "Unlawful acquirement or use of radioactive or other dangerous substances" (Article 335 of the Criminal Code). However, this is a general criminal offence that criminalises any unlawful production, possession, or use of radioactive or other substances which are dangerous for health or to the life of humans or harmful to environment – it was not prescribed specifically for the violation of REACH Regulation.

In Slovenia, specific REACH penalties are contained in the "Decree on the implementation of the EU Regulation concerning the registration, evaluation and authorisation and limitation of chemicals (REACH)", which was adopted by the Slovenian Government in 2008. The legislator specifically enumerated the provisions of the REACH Regulation for which breaches shall constitute an offence. The fines are prescribed in a range of fines with a minimum and maximum fine. The maximum is set at 60 000 EUR, which is about two times less than the maximum penalty which can be prescribed for a minor offence in Slovenian legislation in accordance with the statute that governs the minor offence procedure (the maximum is 125 000 EUR).

Apart from the fine, one other type of penalty may be imposed in the case of a violation of REACH: if the fine is imposed upon the perpetrator, the substances and materials with which the offence has been

committed or which result from the offence may be confiscated from the perpetrator. Fines and confiscation are the only two administrative penalties which may be imposed in the case of REACH violation.

Other measures may be ordered by the inspector in the case of a violation of REACH:

- a prohibition to engage in the unlawful activity;
- a prohibition to produce chemicals or to put them on the market;
- a prohibition to use the chemicals which have been unlawfully produced or put on the market;
- and an improvement order.

The aim of these measures is not to fine or to punish the perpetrator but solely to put a stop to unlawful activity and to prevent its harmful effects. Because of this, these measures are not, technically speaking, penalties.

In Slovenia, the Chemicals Office of the Republic of Slovenia (Urad Republike Slovenije za kemikalije), which is an authority within the Ministry of Health, is responsible for the implementation of the REACH Regulation. Within the Chemicals Office, the Chemicals Inspectorate is responsible for the inspection of compliance with REACH and for the imposition of penalties prescribed in the above Decree.

### *Sweden*

In Sweden, the Environmental Code (SFS 1998:808) establishes the sanctions for most environmental laws (including the law implementing REACH). Chapter 29 lays out the criminal penalties and Chapter 30 the environmental sanction fees. The environmental sanction fees are also regulated by the Regulation on Environmental sanction fees (SFS 1998:950).

According to the Regulation on Environmental sanction fees, a violation of Article 31.5 of the REACH-Regulation leads to an environmental sanction fee of 5000 SEK (488 858 EUR). Apart from this provision, all sanctions on breaches of the REACH-Regulation are criminal sanctions. This means that an infringement of the REACH-Regulation needs to be intentional or a result of negligence from the perpetrator.

Criminal sanctions involve fines or imprisonment. The fines are proportional to the perpetrators' daily income. In most cases, the legislation also provides for the possibility to impose a sentence of imprisonment of up to two years (six years for failure to register or provide false information in the registration). When the seriousness of the offence is considered, special attention shall be paid to whether it concerned large quantities, or caused or might have caused damage on a large scale or of a dangerous nature or has continued for a long period of time.

In addition, for a crime committed in the exercise of business activities, a legal person may, at the instance of a public prosecutor, be ordered to pay a corporate fine if the crime has entailed a gross disregard for the special obligations associated with the business activities or is otherwise of a serious kind, and the legal person has not done what could reasonably be required of him to prevent the crime.

In Swedish legislation, only natural persons can be punished for breaches of REACH obligations.

The supervision of REACH compliance in Sweden is regulated in Ch 26 of the Environmental Code. The responsible authorities for REACH are the Swedish Chemicals Agency (Kemikalieinspektionen) and the municipalities.

### ***United Kingdom***

Administrative sanctions as defined in the continental law system do not exist in United Kingdom. Persons that infringe REACH obligations can be convicted on summary conviction (petty offences) or on conviction of indictment (serious offences) depending on the level of the infringement. The UK legislation has stated very precisely all the REACH obligations that might be subject to a penalty if not respected. (Schedule 1 of the REACH enforcement Regulation). This approach might have been taken in order to help judges to easily determine which infringements of the REACH obligations are subject to a penalty.

Regulation 3 of the Enforcement Regulations sets out which enforcing authorities are responsible for enforcing which provision of REACH and the limitations on that duty. The UK legislation aims at clearly defining the area of competence of each enforcement authorities. For example HSE (Health and Safety Executive) will enforce the *registration related duties* of REACH across the UK. The Enforcement Regulations also provide that, for a number of use-related duties in REACH, more than one enforcing authority has an enforcement duty. For instance, where the use of a substance presents risks to workers' health, safety and welfare and also to the environment, both the relevant health and safety regulator and the environmental regulator have enforcement responsibilities. However, the HSE in those circumstances shall always be the lead enforcing authority.

Inspectors, in order to enforce the REACH Regulation, shall do some visits to any premises where substances, mixtures or articles are manufactured, imported, supplied or used.

## **5. Conclusions**

This study gathers, compiles and analyses the legislation setting penalties for infringements of REACH adopted across all EU Member States and EEA countries. The report covers twenty-nine countries (all EU Member States and EEA countries, except Spain), and provides an overview of the level of sanctions set by the countries under study. It also provides a comparative analysis of the types of offences and level of penalties between countries, the costs of compliance against penalties, and comparable offences related to the implementation of other EC acts in the national legislation.

The information gathered and the analysis carried out lead to a few observations concerning the level of harmonisation of enforcement of REACH across the European Union and EEA countries.

First, it can be noticed that all countries (except Denmark) have adopted specific legislation or have amended their legislation to deal with REACH. Most provisions of the Regulation that can be enforced at the national level are subject to penalties, and the breach of REACH main obligations is punished under national law in almost all cases.

However, the level of penalties and the methods of enforcement vary quite a lot from one country to another. The enforcement regime adopted depends on the legal cultural background of each country when enforcing legal obligations. The common law countries have based enforcement mostly on criminal law. The Nordic Countries have based their enforcement policy on coercive measures. The other countries of the continental system enforce their legislation through administrative and criminal law or through administrative law only. The type of penalty also varies among the countries under study. Despite the whole range of instruments adopted in the different countries to enforce REACH, the most commonly used sanction is the fine. Most countries provide for fines between 50 000 and 1 000 000 Euros maximum for the first infringement (including for legal persons). A few countries have adopted lower fines, while a few others have adopted much higher fines (55 000 000 Euros for Belgium and unlimited fines for the UK). These variations illustrate a substantial lack of consistency as to the level of penalty from one country to another.

At the country level, the analysis compares the approach taken to enforce REACH obligations and comparable obligations under other pieces of legislation (authorisation to place on the market, supply of false information, etc.). The conclusion is that the penalties imposed for breach of REACH obligations and that imposed under other legislation are quite comparable in terms of type. In this regard at least, it seems that the sanctions imposed under REACH are quite proportionate with what is usually provided by national law.

The costs of compliance are also compared to the level of penalties, and in particular to the level of fine. The comparison demonstrates that in most countries, the penalties are higher than the costs of compliance until a production or import of 1000 tonnes or less. When the tonnage is higher, in most countries, the level of fine incurred is not high enough to match the high costs of compliance. The principle of dissuasiveness does not seem to be respected in such instances, as the amount of the fine is not adapted to the peculiarities of the REACH system of tonnage.

The question of effectiveness of the enforcement measures still remains to be assessed. The short description of the enforcement system in each country has shown that the enforcement powers have been well allocated under national law, and that the enforcement authorities are well prepared to ensure a maximum effectiveness of the measures at their disposal to encourage the addressees of the Regulation to respect the REACH obligations. However, actual enforcement of REACH is still in the early stages. Monitoring of REACH enforcement over the coming few years will enable the national authorities to have a better overview of enforcement requirements and to adapt their means and methods of sanctions as needed to ensure effective implementation of REACH.