

*Extract from a report on a Government commission in 2009 carried out by the Swedish Chemicals Agency: The Swedish Products Register and the chemicals legislation of the European Union.*

## **The relationship of Swedish provisions to European Union law**

To summarise, it can be concluded that the rules of the Products Register in its present form are not in breach of the provisions of REACH or the new European Community regulation on classification, labelling and packaging of substances and mixtures. The requirements on the supply of data to the Products Register constitute an obstacle to trade under Article 28 of the EC Treaty, but can be justified by public interests that have been acknowledged under Article 30 of the Treaty and European Court of Justice case law. The requirements cannot be regarded as disproportionate, but it should be ensured that they do not deviate unjustifiably from similar requirements laid down in accordance with European Community rules in these regulations.

The commission includes conducting an analysis of the relationship of the Products Register to, and compatibility with, European Union law as a basis for continued development and simplification. The analysis is to encompass an assessment of the compatibility of the registration requirements with the EC Treaty, in particular Articles 28 and 30.

An account is given below of Kemi's assessment of the issue of the relationship with European Union law. In connection with this issue Kemi has consulted the Swedish National Board of Trade, which considers some particular questions in a statement attached to this report as [Annex 4](#). We comment on these questions at the end of this section.

### **The Products Register rules**

In summary and somewhat simplified, the Swedish rules on products registers comprise the following<sup>1</sup>. Those who professionally manufacture or import into Sweden chemical products or biotechnical organisms belonging to certain tariff headings must notify these to Kemi. The notification must include information concerning the company, what products are concerned and (to some extent) the composition of the products and how they are intended to be used. The information has to be updated annually with regard to the manufactured or imported quantity of the products. Anyone who contravenes these rules is guilty of the offence of obstruction of environmental control (Chapter 29 Section 5 of the Environmental Code). If information on quantities is not submitted, an environmental sanction charge is payable under the Ordinance 1998:950 on Environmental Sanction Charges. The rules on the Products Register are linked to the rules on chemical charges in Sections 2-5 of the Chemical Charges Ordinance Etc. (1998:942). A chemical charge is levied on the basis of information in the Products Register on the number of products and quantities handled by each operator.

These rules can be said to serve the purpose of making supervision possible, providing a basis for chemical charges and providing information and statistics on chemicals management in Sweden. The charges are used to pay for enforcement. Knowledge of national chemicals management is important

<sup>1</sup> Cf. Chapter 14 Sections 12-14 of the Environmental Code, Sections 3-6 and the Annex to Ordinance (2008:245) on Chemical Products and Biotechnical Organisms and Chapter 3 and Annex 1 to Swedish Chemicals Agency Regulations KIFS 2008:2.

in order to plan enforcement but is also important for the follow-up of measures taken for chemicals control, as a basis for research and for general interest. The rules are thus focused on the operator, are closely related to supervision and do not represent requirements relating to the properties of the chemical products as such. The Products Register is mentioned as an example in the recently conducted inventory (Ministry Publication Series (Ds) 2008:75) of national rules which can be regarded as permit procedures for the exercise of service in application of the European Community Services Directive.

## **The relationship of the Products Register to REACH**

An analysis of the relationship of the Products Register to European Union law should be initiated with an assessment of whether there are rules in secondary legislation (directives, regulations and decisions) that set limits for the contents of national rules. To the extent that a technical issue is governed by secondary legislation, it is the secondary legislation that is to be applied and there is no reason to examine the relationship with Articles 28 and 30<sup>2</sup>. If, on the other hand, it is a case of a regulation that lies outside the scope of the legislative instruments which constitute secondary legislation, an assessment must be made of whether the national rules fulfil the requirements of Articles 28 and 30 of the Treaty.

A European Community legislative instrument which is relevant in this context is REACH, in particular the requirements on registration contained in REACH. The issue of the relationship between the requirements on registration in REACH and the Products Register is addressed in the preparatory documents for the national legislation implementing REACH<sup>3</sup>. The conclusion drawn is that the Products Register has different functions (supervision, analyses and statistics) than the European Chemicals Agency (ECHA) register and partly relates to different data on chemical products than those submitted to ECHA in connection with registration. The conclusion is therefore that there is not, as a consequence of REACH, "cause to reduce the extent of the submission of information to the Swedish Chemicals Agency (Government Bill p. 85).

Article 128(1) in REACH states that Member States must not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance falling within the scope of this Regulation and complying with it. At the same time it is stated in Article 128(2) that nothing in REACH is to prevent Member States from maintaining or laying down national rules to protect workers, human health or the environment applying to cases where REACH does not harmonise requirements. The Products Register in its present-day form in the Government's own assessment thus cannot be said to regulate issues which fall under Article 128(1) and are therefore not affected by REACH.

Of course in theory, one could envisage a products register that contains requirements not permitted in accordance with REACH, for example if the register laid down requirements for data and risk assessments for substances which duplicate or extend the requirements already laid down by REACH for registration. Such a products register could at least to some extent be said to fall within the scope of REACH and additionally prohibit, limit or impede the manufacturing, import, placing on the market or use of the substance, and would consequently be entirely or partially non-permitted according to REACH.

## **The Products Register and rules on classification and labelling**

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has recently been adopted. The Regulation lays down criteria for classification with respect to hazardous properties and requirements on manufacturers and importers to classify and label their chemical products. The Regulation contains rules which entail requirements for the submission of information in two respects. Firstly it is stated that manufacturers and importers have to report how they classify their substance to a central

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<sup>2</sup> See for example point 14 in the *Roby Profumi* judgment commented on below.

<sup>3</sup> Government Bill 2007/08:80 p. 78 ff.

classification and labelling inventory at ECHA (Title V Chapter 2 of the Regulation). Secondly, under Article 45 of the Regulation the Member States have to appoint bodies responsible for receiving information relating to emergency health response (i.e. in cases of poisoning) and relating to the composition of mixtures (preparations) with hazardous properties. This information may only be used to deal with emergency situations and for statistical analysis relating to risk management measures. The Poisons Information Centre fulfils such tasks in Sweden.

In addition, under the Regulation the Member States have to establish systems for enforcement (Article 46). Under Article 51, Member States must not prohibit, limit or impede the placing on the market of substances or mixtures which comply with the joint requirements on grounds relating to classification, labelling or packaging within the meaning of the Regulation.

With regard to the relationship between the classification and labelling inventory in the Regulation and the Products Register there is no reason to make a different assessment than that described above with respect to the relationship with REACH. The Products Register fulfils a different function than the EU inventory and mainly relates to different data. The Regulation is concerned with substances, while the Swedish Products Register principally contains classifications of composite chemical products. This part of the Regulation does not impede a Swedish Products Register in the present-day form.

The rules on information regarding poisons in the EU Regulation are harmonised, but do not regulate in detail what information the Member States shall request from importers and downstream users. Under the Regulation the Commission may, however, review whether the requirements on submission of information are to be harmonised further (Article 45(4)). Similar rules are contained in the EU Cosmetics Directives<sup>4</sup>.

The Regulation's rules on information on poisons relate to national information systems which bear clear similarities to the products register with regard to which particulars have to be submitted. The rules additionally state that the information gathered may only be used for medical purposes and "may not be used for other purposes" (Article 45(2)). The latter limitation cannot, however, apply to information to which the authorities gain access or which they demand in their general enforcement activity. The Poisons Information Centre exists to deal with acute cases of poisoning, while the Regulation in its entirety has a far broader scope (classification, labelling requirements, long-term health effects, environmental effects etc.). The bodies which are responsible for information on poisons are often linked to the health service and do not have authority status, which may motivate a specific regulation. The harmonising effect of Article 45 is therefore limited to the particular functions regulated by the article. In Sweden this information is voluntarily submitted directly by companies to the Poisons Information Centre, which undertakes not to divulge confidential information.

The rules applying to the Products Register could be viewed as an element in the implementation of the requirement for a national enforcement organisation, a requirement which is contained both in REACH (Article 125) and the Regulation on Classification and Labelling (Article 46). A principal task for the Products Register is to be used as a basis for national enforcement. Although enforcement is concerned in both regulations, it cannot be said that enforcement is regulated in a harmonised manner in these Regulations. Enforcement at least in the environmental area is to a large degree a national matter which is not governed by common rules.

The conclusion drawn is thus that neither can the Regulation on Classification and Labelling be regarded as impeding the rules on the Products Register in its present-day form.

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<sup>4</sup> Case C-257/06 *Roby Profumi* concerned the application of a corresponding provision in the Cosmetics Directive 76/768/EEC. The Directive stated that the Member States had to require such "appropriate and adequate information" on substances in cosmetics required for medical treatment in the event of difficulties. Italy had introduced provisions which meant that particulars must be submitted to the authorities by importers and others who handled cosmetic products. These particulars would include information on the company, manufacturing and the composition of the cosmetic product. The Italian provisions were not considered to be in breach of the Directive.

## Articles 28 and 20 of the Treaty Establishing the European Community

Under Article 28 of the Treaty Establishing the European Community, quantitative restrictions on imports and measures having equivalent effect are prohibited between Member States. The term “measures with equivalent effect” has been given a very broad interpretation by the European Court of Justice in the “Dassonville” case<sup>5</sup> and later case-law. This case-law means in practice that all national rules which in any way are oriented towards or affect trade in goods within the EU are deemed to fall under Article 28, even if the extent of the effect is small<sup>6</sup>. There are few exceptions to this principle. The most important is the *Keck* case<sup>7</sup>, where the Court expressly modified its previous case-law and stated that national rules which only pertained to selling arrangements would fall outside Article 28.

National measures which fall under Article 28 are thus prohibited in principle, but under Article 30 of the Treaty are nevertheless to be permitted if they entail prohibitions or restrictions on “import, export or transit” based on the interest of protecting human or animal health or life or preserving plants. The national rules may not constitute a means of arbitrary discrimination or a disguised restriction on trade. This provision has been broadened in case-law by the famous *Cassis de Dijon* case<sup>8</sup> and later case-law. As a result of this development the environment has been recognised as a public interest the protection of which the Member States may cite as a reason for applying national rules which constitute “measures with equivalent effect” under Article 28.

A trade-impeding national measure which in principle is possible under Article 30 or the Court’s case-law must, however, be proportionate. This means that the measures have to be appropriate (i.e. actually to lead to their purpose) and necessary (i.e. the purpose cannot be attained with a measure which is less far-reaching in relation to the internal market).

To summarise it is thus the case that a trade-impeding measure (import restriction or measure with equivalent effect) may be introduced if it relates to an interest to be protected which has been recognised by the EU and if the measure is proportionate. The possibility of applying discriminatory measures (which treat operators from Sweden and from other EU Member States differently) is very limited. If the issue is regulated in secondary legislation, it is the secondary legislation that applies. It can also be pointed out that EU rules in general always take precedence over national law. Directive 98/34/EC and Ordinance (1994:2029) on technical rules are closely linked to these provisions. Under these provisions, proposals for a technical rule have to be notified within the EU and to the WTO before it is introduced. Technical rules are typical measures falling under Article 28. Other countries or the Commission may submit views on the rule in order to limit its trade-impeding effect. If the duty of notification is not fulfilled, the rule cannot be asserted in relation to individuals. The term “technical rule” is more limited than “measure with equivalent effect” and is directly focused on the properties of articles. The term is defined in Section 2 of the Ordinance.

## The Products Register and Articles 28 and 30

It is clear that the provisions on the Products Register to some extent affect the possibility of undertaking a particular activity which consists in handling chemical products. The provisions do not, however, govern the chemical products as such and cannot be viewed as technical rules under the Ordinance (1994:2029) on technical rules. The right to trade in chemicals is not affected by the obligation to submit information to the Products Register not being fulfilled. This does not, however, prevent the regulation being “capable of hindering, directly or indirectly, actually or potentially, intra-Community trade” according to the European Court of Justice’s wording in *Dassonville* and therefore falling under Article 28.

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<sup>5</sup> Case 8/74 *Dassonville* (1974) ECR 837.

<sup>6</sup> The term “articles” in this context includes chemical products, which does not apply in application of Chapter 14 of the Environmental Code (see Chapter 14 Section 2).

<sup>7</sup> Joined cases C-267/91 and C-268/91.

<sup>8</sup> Case 120/78 *Rewe-Zentral AG* (1979) ECR 649.

A conclusion could be that the requirements for the submission of information to the Products Register might be viewed as a restriction on the freedom to provide services (Article 49 of the Treaty) rather than as a restriction of trade in articles under Article 28. The requirements in the Products Register are, however, linked to an individual article, i.e. the chemical product, and are additionally associated with a chemical charge which may amount to relatively significant sums (the annual charge may be as high as SEK 75,000 if large volumes are concerned)<sup>9</sup>. The rules are linked to those who trade in chemical products (manufacturers and importers). The requirements of the Products Register must therefore be regarded as a trade-impeding measure which falls under Article 28. This conclusion is also supported by the Court's case-law<sup>10</sup>.

As mentioned above, the requirements on the submission of information in the rules on the Products Register serve the purpose of making enforcement possible, providing a basis for chemical charges and providing information and statistics on chemicals management. The latter is important in order to limit risks in the management of hazardous chemicals in Sweden. There ought not to be any doubt that the requirements on the submission of information, which apply equally to domestic articles and articles from other EU Member States, can be justified by the purposes (health and the environment) which are acceptable under Article 30 and the Court's case-law. It therefore remains to be assessed whether the rules are proportionate to their purpose.

Cases can theoretically be imagined in which requirements on the submission of information to a products register might contravene the requirement of proportionality. Examples of such cases might be:

- if the products register demanded information which is not needed for the (acceptable) purposes of the register,
- if omission to supply information to the register led to trade in the product being prohibited,
- if the information required differs in an unjustified manner from similar requirements made by European Community rules, for example with regard to forms of reporting, test methods, reporting periods etc.

If the information in the register was not needed for the purpose of the register, the requirements for submission of information are thus not proportionate. It is, however, difficult to assert that the information in the register would not be needed for the purposes of the register. Requirements quite similar to the requirements in the Products Register were made in the *Roby Profumi* case, and these requirements were not regarded as disproportionate. The greatest difference between the Italian requirements in *Roby Profumi* and the requirements in the Products Register is that the register requests annual information on quantities handled. This information on quantities may, however, be said to be needed for the Products Register to fulfil its function as a basis for enforcement. The requirements for information to the register are quite extensive (Chapter 3 of KIFS 2008:2) but ought to be possible to justify in each individual case with respect to the purpose of the register. There are no other, less far-reaching ways of obtaining equivalent knowledge.

Prohibiting the handling of a chemical which has not been notified to the register might be viewed as an unnecessary radical sanction measure. The sanctions now applied in the Environmental Code in the event of breaches of the rules (fines or an environmental sanction charge, where appropriate also a penalty charge) do not, however, have this effect and ought not to be open to questioning.

Coordinating the requirements on submission of information in the Products Register with similar requirements in European Community rules is the purpose of the Government commission which is the subject of this report. The Swedish National Board of Trade points out in its statement (Annex 4)

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<sup>9</sup> The chemicals charge is regulated separately and need not necessarily be linked to the Products Register. The chemicals charge is not a measure which in itself falls under Articles 28 and 30 (cf. statement of the Swedish National Board of Trade).

<sup>10</sup> The Court's judgment in case C-114/96 *Kieffer*. The case concerned whether an obligation in a regulation to make detailed declarations of imports and exports of particular articles was permitted under the Treaty. The Court took as its point of departure that the obligation to provide information was a trade-impeding measure, as the parties were already in agreement on this. The Court found that the obligation was proportionate with respect to its purpose and therefore permitted.

that it must be possible for all deviations from an adjustment to the requirements in the ECHA inventory, for example with regard to structure, terminology and definitions, to be justified. The Swedish National Board of Trade also raises the question of the weight limit for notification to the Products Register. We return to this question in section 7.2.2.

### **Summary**

To summarise, it can be concluded that the rules of the Products Register in its present form are not in breach of the provisions of REACH or the new European Community regulation on the classification, labelling and packaging of substances and mixtures. The requirements on the supply of data to the Products Register constitute an obstacle to trade under Article 28 of the Treaty Establishing the Community, but can be justified by the interests to be protected which have to be accepted under Article 30 of the Treaty and Court case-law. The requirements cannot be regarded as disproportionate, but it should be ensured that they do not deviate unjustifiably from similar requirements laid down in accordance with European Community rules in these regulations.