Reports of Cases

OPINION OF ADVOCATE GENERAL
Sharpston
delivered on 10 December 2015 [1]

Case C-472/14

Canadian Oil Company Sweden AB
Anders Rantén
v
Riksåklagaren(Request for a preliminary ruling

from the Högsta domstolen (Supreme Court, Sweden))

(Registration, evaluation, authorisation and restriction of chemicals (REACH) — Scope of harmonisation — Registration of chemical substances with the European Chemicals Agency before placing them on the market — Parallel obligation to register chemical products which are manufactured in or imported into a Member State in the course of business — Articles 34 and 36 TFEU — Quantitative restriction on imports — Justification — Protection of human life and health and of the environment — Proportionality)

1. By its reference to the Court, the Högsta domstolen (Supreme Court, Sweden; 'the referring court') seeks guidance as to whether the requirement in the REACH Regulation [2] to notify chemical substances for registration, on the one hand, and Treaty provisions ensuring the free movement of goods, on the other hand, preclude Member States from introducing a similar notification and registration requirement relating to such substances at national level. How far does the REACH Regulation harmonise notification and registration of chemical substances; and how much scope is left for Member States to pursue their own policies on manufacture, placing on the market or use of chemical products?

Legislation

European Union law

2. In accordance with Article 34 TFEU, '[q]uantitative restrictions on imports and all measures having equivalent effect, shall be prohibited between Member States'. Article 36 TFEU provides that Member States may place proportionate restrictions on the movement of goods if justified on certain permissible grounds, including the protection of health and life of humans and animals.

1 — Original language: English.

2 — Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1). The version of the REACH Regulation relevant to the facts in the main proceedings is that last amended by Commission Regulation (EC) No 552/2009 of 22 June 2009 (OJ 2009 L 164, p. 7).

3. The preamble to the REACH Regulation contains the following relevant recitals:

‘…

(16) This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in mixtures and in articles. …

…

(19) … the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the [European Chemicals] Agency. [3] Registered substances should be allowed to circulate on the internal market.

(20) … If the Agency in cooperation with the Member States considers that there are grounds for considering that a substance constitutes a risk to human health or the environment, the Agency should, after having included the substance in the Community rolling action plan for substance evaluation, relying on the competent authorities of Member States, ensure that this substance is evaluated.

(21) Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation. Therefore it should be ensured that this information is available to the competent authorities and may be used by them for the purpose of such procedures.

…

(44) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. …

…

(103) Through a Member State Committee, the Agency should aim to reach agreement amongst Member States’ authorities on specific issues which require a harmonised approach.

…

(105) In the light of the increased responsibility of natural or legal persons for ensuring safe use of chemicals, enforcement needs to be strengthened. The Agency should therefore provide a Forum for Member States to exchange information on and to coordinate their activities related to the enforcement of chemicals legislation. …

…

(119) Apart from their participation in the implementation of Community legislation, Member State competent authorities should, because of their closeness to stakeholders in the Member States, play a role in the exchange of information on risks of substances and on the obligations of

3 — In what follows, I shall refer to ‘the Agency’.

natural or legal persons under chemicals legislation. At the same time, close cooperation between the Agency, the Commission and the competent authorities of the Member States is necessary to ensure the coherence and efficiency of the global communication process.

…'

4. Article 1(1) of the REACH Regulation indicates that the latter's purpose is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessing dangers posed by substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Article 1(2) states that the REACH Regulation lays down provisions on substances and mixtures, which apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures. Pursuant to Article 1(3), the REACH Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances in ways that do not adversely affect human health or the environment.

5. Article 3 contains the following definitions:

'(1) substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(2) mixture: means a mixture or solution composed of two or more substances;

(3) article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

…

(13) downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. …

…

(37) exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

…'

6. Article 5 ('No data, no market'), which is in Title II ('Registration of substances') provides: 'Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.'

7. According to Article 6(1), any 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, is required to submit a registration to the Agency, save where the REACH Regulation provides otherwise. Likewise, pursuant to Article 7(1), any producer or importer of articles must submit a registration to the Agency for any substance contained in those articles if the substance is present in those articles in quantities totalling over one tonne per producer or importer per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use.

8. Under Article 10(a), any such registration must be accompanied by a technical dossier including in particular the identity of the manufacturer(s) or importer(s), the identity of the substance, information on the manufacture and use(s) of the substance (representing all the registrant's identified use(s)), the classification and labelling of the substance, and guidance on safe use of the substance; detailed requirements on what information the technical dossier should contain are found in Annexes VI to XI to the REACH Regulation. Pursuant to Article 10(b), notification to the Agency must also be accompanied by a chemical safety report.

9. The first subparagraph of Article 37(4) provides that a downstream user of a substance on its own or in a mixture must prepare a chemical safety report for any use outside the conditions described in an exposure scenario or, if appropriate, a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against. Pursuant to Article 38(1) and (2), the downstream user must in that case, before commencing or continuing with a particular use of a substance that has been registered by an upstream supplier in accordance with Article 6, report to the Agency information on, inter alia, his identity and contact details, the registration number of the substance(s) if available, the identity of the substance(s), the identity of the manufacturer(s) or the importer(s) or other supplier, and a brief general description of the use(s) and of the conditions of use(s).

10. In principle, Article 56(1) makes the placing on the market of substances listed in Annex XIV subject to authorisation from the Commission. Article 56(2) states in essence that a downstream user may use a substance subject to authorisation without seeking further authorisation provided that that use is in accordance with the conditions of an authorisation granted to an upstream supplier for that use. Article 57 lists the categories of substances that may be included in Annex XIV. Those categories include substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction.[4] Article 59 sets out the procedure for establishing a list of candidate substances for possible inclusion in the Annex XIV list. Pursuant to Article 59(3), any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency.[5]

11. Article 67(1) provides that a substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction, may not in principle be manufactured, placed on the market or used unless it complies with the conditions of that restriction. Article 68(1) provides: 'When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended … by adopting new restrictions, or amending current restrictions …'. Article 69(4) states that, if a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed on a Community-wide basis, it shall submit a dossier to the Agency which meets the requirements of Annex XV, in order to initiate the restrictions process.

4 — That classification appears in Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition, 1967, p. 234).

5 — Annex XV indicates that such a proposal must include in particular the identity of the substance(s) concerned, available use and exposure information and information on alternative substances and techniques.

12. Pursuant to Article 76(1)(e), the constituent parts of the Agency include a Member State Committee, which is responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or by the Member States and proposals for identification of substances of very high concern.

13. Article 125 requires the Member States to 'maintain a system of official controls and other activities as appropriate to the circumstances'. Article 117 read together with Article 127 requires the Member States, every five years, to submit to the Commission a report on the operation of the REACH Regulation in their respective territories, including sections on evaluation and enforcement covering the results of the official inspections carried out during the previous reporting period.

14. Article 128 reads as follows:

'1. Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a mixture or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

2. Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use.'

Swedish law

15. Pursuant to Chapter 14, Paragraph 12, of the Environmental Code (Miljöbalken), chemical products which are manufactured in or imported into Sweden in the course of business must be entered in a register ('the Swedish product register') held by the competent national authority. Chapter 14, Paragraph 2(1), of the Environmental Code defines a chemical product as a chemical substance or a preparation of chemical substances which is not a commodity.

16. A person who deliberately or negligently infringes the obligation to make a notification for registration under Chapter 14, Paragraph 12, is guilty of obstruction of environmental controls and thus subject to a fine or a maximum of two years' imprisonment pursuant to Chapter 29, Paragraph 5(5), of the Environmental Code.

17. The Government has implemented Chapter 14, Paragraph 12, of the Environmental Code in the Chemical Products and Biotechnical Organisms Ordinance (Förordningen om kemiska produkter och biotekniska organismer; 'the Ordinance'). In essence, the Ordinance requires a person who, in the course of business, manufactures 100 kilogrammes or more of a chemical product per annum in Sweden or imports such quantities of that product into that Member State, to notify that manufacturing or import to the Chemicals Inspectorate (Kemikalieinspektionen). [6]

18. Pursuant to Chapter 3, Paragraph 4 of the Chemicals Inspectorate's Chemical Products and Biotechnical Organisms Regulations (Föreskrifter om kemiska produkter och biotekniska organismer; 'the Chemicals Inspectorate's Regulations'), the information to be notified includes, in particular: (i) the name, address and telephone number of the person required to notify; (ii) the product's name and, where applicable, common designation; (iii) its statistical number; (iv) a statement as to whether the person required to notify is a manufacturer or importer of the product from the internal market or from a third country; (v) whether the product has been given a new trade name, a new product name or a new product designation; (vi) whether it is intended to be available to consumers for their private

6 — The order for reference mentions this rule only in relation to the import of chemical products into Sweden. However, it appears from Sweden's and the Commission's written submissions that it applies equally to the manufacture of chemical products.

use; (vii) the product's primary use or, where used as an ingredient in manufacture as a starting product, the estimated percentage distribution of use over up to three different business sectors; (viii) for products exported by the person required to notify, the approximate percentage of exports; (ix) the product's function; (x) the substance name and the concentration of all substances included which have been classified as, in particular, carcinogenic, mutagenic, toxic for reproduction or sensitising; (xi) in the case of certain paints, varnishes or vehicle refinishing products, the sub-category to which the substance belongs and the concentration of volatile organic compounds in grammes per litre in the form of the product when ready for use; and (xii) which substances in the product are preservatives, and the concentration of each such substance.

19. The Chemicals Inspectorate's Regulations require the name, address and telephone number of the person subject to the obligation to notify to be notified as soon as possible and at the latest when the activity is commenced. The remaining information must be notified to the Chemicals Inspectorate by 28 February in the calendar year after the obligation to notify arose in respect of the product.

Factual background, procedure and questions referred

20. On 24 April 2013, the Hovrätten över Skåne och Blekinge (Court of Appeal of Scania and Blekinge; 'the Hovrätten') found Mr Anders Rantén guilty of obstruction of environmental controls under Chapter 29, Paragraph 5(5), of the Environmental Code. Mr Rantén had failed to notify the Chemicals Inspectorate, by 28 February 2010, that Canadian Oil Company Sweden AB ('Canadian Oil') had imported 392 tonnes of chemical products into Sweden in 2009.[7] As Mr Rantén was responsible for that importation, the Hovrätten fined him SEK 100 per day for 60 days.[8] In addition, the Hovrätten imposed a corporate fine of SEK 200 000 on Canadian Oil.[9]

21. It is common ground in the main proceedings that Canadian Oil imported those chemicals into Sweden in compliance with the registration requirements under the REACH Regulation.

22. Mr Rantén and Canadian Oil appealed against the decision of the Hovrätten to the referring court, which stayed the proceedings and requested a preliminary ruling on the following questions:

'(1) Does it run counter to [the REACH Regulation] that a person who, in the course of a business, imports a chemical product into Sweden — in respect of which there is an obligation to notify under REACH — must notify it in accordance with the Swedish legislation to the Chemicals Inspectorate for registration in the Swedish product register?

(2) If the answer to Question 1 is negative, does the Swedish obligation to notify run counter to Article 34 TFEU, having regard to the exceptions in Article 36 TFEU?'

23. The applicants in the main proceedings submitted very brief written observations, in which they indicated in essence that they maintained all the submissions they made before the referring court. Written observations were also submitted by the Danish, Finnish, Norwegian and Swedish Governments and the European Commission. The applicants in the main proceedings, the Norwegian and Swedish Governments and the Commission made oral submissions at the hearing on 10 September 2015.

7 — It appears from the national file deposited with the Court that Canadian Oil imports chemical products from other EU Member States.

8 — That is a total of approximately EUR 640 at the exchange rate applicable at the time of writing.

9 — That is, approximately, EUR 21 300 at the exchange rate applicable at the time of writing.

Assessment

Preliminary remarks

24. It is apparent from the main proceedings that there is a degree of overlap between the national notification and registration requirement in issue in those proceedings and the notification and registration requirement under the REACH Regulation.[10] The referring court's first question asks whether that latter requirement leaves scope for the Member States to require additional notification and registration of chemical products.

25. That question focuses on the *importation* of chemical products into Sweden. It arises however in identical terms for the *manufacture* of chemical products in that Member State. Both importation and manufacture are subject to the additional notification and registration requirement in issue in the main proceedings.[11] Accordingly, my reasoning on Question 1 would be transposable to the manufacture of chemical products. By contrast, Question 2 touches specifically on the obstacle which the requirement to notify chemical products for registration in the Swedish product register may constitute to the free movement of goods in so far as it applies to chemical products imported into Sweden from other Member States.

26. Next, it is common ground that the fines imposed on Mr Rantén and Canadian Oil can be upheld in the main proceedings only if the notification and registration requirement in issue is consistent with the REACH Regulation and with Articles 34 TFEU and 36 TFEU.

27. At the hearing, the applicants in the main proceedings devoted some time to the fees which Sweden seems to require for manufacturing or importing chemical products. They maintained in essence that those fees, which are calculated on the basis of quantities registered in the Swedish product register, are unrelated to the actual costs borne by the competent authorities for monitoring chemical products and impede free movement in the internal market in so far as they are charged on the importation of chemical products into Sweden. Canadian Oil added that those fees constitute a heavy burden for small and medium-sized undertakings and that they are thus inconsistent with the objective reflected at recital 8 in the preamble to the REACH Regulation.[12]

28. However, the present reference is exclusively concerned with whether EU law precludes a Member State from requiring persons who, in the course of business, import a chemical product into that Member State to notify it to a national authority for registration in a chemical products register. The referring court does not seek guidance on whether any fees charged on chemical products imported into Sweden are consistent with EU law.[13]

29. Finally, the Court's answer to the questions referred will be of special relevance in Denmark, Finland and Norway,[14] where comparable chemical products registers exist to the Swedish product register and which share that information in the SPIN Database (Substances in Preparations in the Nordic Countries).[15]

10 — For a more detailed comparison of the scope of the two requirements, see points 41 to 44 below.

11 — Chapter 14, Paragraph 12, of the Environmental Code.

12 — Under that recital, '[s]pecial account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them'.

13 — Understandably, therefore, the referring court provides no information on the legal basis of those fees, their amount or how they are calculated. It merely refers to the finding of the Hovrätten that the product register in issue in the main proceedings is used inter alia as the basis for invoicing chemical fees which finance monitoring activities (paragraph 25 of the order for reference).

14 — The REACH Regulation applies in Norway as a result of Decision of the EEA Joint Committee No 25/2008 of 14 March 2008 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (OJ 2008 L 182, p. 11).

15 — The database may be consulted online at the following address: http://195.215.202.233/DotNetNuke/default.aspx.

Does the REACH Regulation preclude a Member State from requiring chemical products imported into its territory to be notified for registration in a chemical products register, even though those products are already subject to a notification and registration requirement under that regulation (Question 1)?

30. Question 1 essentially concerns the interpretation of Article 128 of the REACH Regulation. Article 128(1) in principle precludes Member States from prohibiting, restricting or impeding the circulation of substances which fall within the scope of the Regulation and which comply with it. That means in particular that substances that are subject to the notification and registration requirement under the REACH Regulation (such as the 392 tons of chemical substances imported into Sweden in the main proceedings) are in principle allowed to circulate on the internal market after registration in the EU register. [16]

31. However, according to the introductory sentence of Article 128(1), that rule applies '[s]ubject to paragraph 2'. Under that latter provision, Member States are free to maintain or lay down national rules protecting workers, human health and the environment, in cases where that regulation does not harmonise the requirements on manufacture, placing on the market or use of chemical substances.

32. Article 128(2) did not figure in the Commission's original proposal. [17] However, debates within the Council 'reiterated the importance of retaining national capability to respond to challenges and of retaining capability to evaluate substances likely to constitute a risk to health and/or the environment'. [18] A majority within the Council therefore supported including that additional provision, [19] which confirms that the REACH Regulation harmonises the requirements on manufacture, placing on the market or use in certain cases only. [20]

33. Article 128(2) in fact contains two conditions. First, the flexibility which it confers on the Member States is limited to situations where the REACH Regulation does *not* harmonise the requirements on manufacture, placing on the market or use of chemical substances. [21] Second, national measures adopted on that basis must aim to protect workers, human health or the environment.

34. The national notification and registration requirement in issue in the main proceedings ultimately aims to protect human health and the environment. [22] The decisive issue here thus becomes whether the provisions of the REACH Regulation requiring notification and registration of chemical substances entail a degree of harmonisation that precludes a national requirement of that type.

16 — Recital 19. Additional conditions may have to be fulfilled before a substance can circulate on the internal market (see in particular Article 56(1) and Article 67(1) of the REACH Regulation).

17 — Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants, COM(2003) 644 final. Article 125 of the proposal contained only the substance of what became Article 128(1) of the REACH Regulation.

18 — Press Release on the 2665th Council meeting Competitiveness (Internal Market, Industry and Research) held in Luxembourg on 6 and 7 June 2005, C/05/133, p. 9.

19 — Common guidelines of the Council's General Secretariat on a Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants, and on a Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals, Council document 15472/05, 8 December 2005, p. 6.

20 — See, to that effect, the judgment in *Lapin ELY-keskus, liikenne ja infrastruktuuri*, C-358/11, EU:C:2013:142, paragraph 33.

21 — By contrast, Member States are entitled to adopt safeguard measures derogating from the harmonised rules only under the strict procedural and substantive conditions set out in Article 129 of the REACH Regulation.

22 — See further on those objectives point 40 below.

35. As the Court has recently held, the REACH Regulation introduces an integrated system for monitoring chemical substances, including registration, evaluation and authorisation, together with possible restrictions on their use.[23] The cardinal principles governing those aspects were presented by the Commission in the introduction to its proposal, which describes the REACH system as comprising: first, registration (which requires industry to obtain relevant information on substances and to use that data to manage them safely); next, evaluation (which provides a check on whether industry is meeting its obligations), and authorisation for substances of very high concern (provided that the risks associated with uses are adequately controlled, or that the socio-economic benefits outweigh the risks where there are no suitable alternative substitute substances or technologies); and, lastly, a restrictions procedure (which provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system).[24]

36. In accordance with those principles, the REACH Regulation places the responsibility for analysing chemical substances with industry. For that purpose, it institutes a number of information-related mechanisms aimed, all along the supply chain, at identifying any dangerous properties and at managing risk in order to ensure that human health and the environment are not adversely affected.[25] Manufacturers and importers are thus required, in particular, to produce data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures.[26] It is not until manufacturers or importers have submitted that information to the Agency for registration that the substances concerned may be manufactured or placed on the market in the European Union ('No data, no market' principle).

37. It is against that background that I shall now examine whether the REACH Regulation precludes a national notification and registration requirement such as that in issue in the main proceedings, taking into account the objectives of that regulation and the ensuing degree of harmonisation that it achieves.

38. In *Lapin ELY-keskus, liikenne ja infrastruktuuri*,[27] the Court clarified the extent to which the REACH Regulation harmonises *restrictions* on the use of substances. The Court held that 'the manufacture, placing on the market or use of a substance referred to in Article 67(1) of the REACH Regulation cannot be subject to conditions other than those laid down by that regulation and which, as is clear from the provisions of Articles 68(1) and 69 thereof, meet the need for "action on a Community-wide basis"'.[28] In principle, therefore, the adoption of conditions other than those set out in the REACH Regulation was found to be incompatible with the objectives of that regulation and, more particularly, with its Articles 67 and 128.[29] As I see it, the same reasoning logically must apply to the authorisation of substances. Subjecting substances duly authorised by the Commission to additional authorisation at national level would clearly undermine the integrated system of authorisation set up by the REACH Regulation and, by extension, the principle in Article 128(1) that substances which comply with that regulation may circulate freely within the internal market.[30]

39. However, in my opinion the Court's reasoning concerning the degree of harmonisation achieved by the REACH Regulation with respect to *restrictions* (and indeed *authorisations*) cannot be transposed to the present case, which concerns the degree of harmonisation regarding *registration* of substances. The notification and registration requirement in issue in the main proceedings is not a pre-condition for placing a chemical product on the Swedish market. It appears in particular from Paragraph 4 of the Chemicals Inspectorate's Regulations that that requirement is rather a formality that follows from

23 — Judgment in *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 32.
24 — Judgment in *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 32.
25 — Judgment in *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 33.
26 — Recital 19 in the preamble to the REACH Regulation.
27 — C-358/11, EU:C:2013:142.
28 — Judgment in *Lapin ELY-keskus, liikenne ja infrastruktuuri*, C-358/11, EU:C:2013:142, paragraph 35.
29 — Judgment in *Lapin ELY-keskus, liikenne ja infrastruktuuri*, C-358/11, EU:C:2013:142, paragraphs 37 and 38 and the case-law cited.
30 — Such additional authorisation could only be upheld under the safeguard clause in Article 129 of the REACH Regulation.

either the manufacture or the importation of chemical products. In addition, the material before the Court indicates that non-compliance with that requirement does not render the marketing of those products illegal. Rather, it results in a fine or imprisonment for those who disregard their obligation to notify. [31]

40. Next, the Swedish product register aims to provide an overview of chemical products (that is to say, chemical substances and preparations of chemical substances that are not commodities) [32] manufactured in or imported into Sweden in the course of business and of the uses to which they are put. That overview has various functions. [33] First, it is used as a database by the Chemicals Inspectorate and other authorities to monitor chemical products. That database provides those authorities with useful information, before any inspection, on economic operators and the products they manufacture or import. It thus helps the authorities to select which installations require inspection on the basis of a risk assessment. At the hearing, the Swedish Government cited, among the authorities other than the Chemicals Inspectorate which use the database, poison centres, fire brigades (which may, for example, need information on which chemicals are present where an accident has occurred), bodies responsible for inspecting classified installations and local authorities. Second, information in the Swedish product register serves as the basis for calculating chemical fees intended to finance the monitoring of chemical products. Third, the Swedish product register helps to provide statistics, including official statistics on the use and sale of chemicals, and enables trends to be analysed. Finally, the competent national authorities use the Swedish product register when preparing environmental policy — including policy at EU level — and for research purposes.

41. These objectives and the consequent need to have an overview of chemical products manufactured in or imported into Sweden in the course of business, including their precise location in that Member State, explain why the Swedish product register and the EU register differ from each other to a significant extent in their scope and detailed information that they contain.

42. Registration under the REACH Regulation concerns the manufacture or placing on the market of substances in the European Union as a whole, in accordance with the objective of setting up an integrated system at EU level. [34] That registration requires industry to obtain relevant information on their substances and to use that data to manage them safely. However, it provides no overview of the manufacture or placing on the market of substances in each individual Member State.

43. Thus, it is common ground that the REACH Regulation does not in principle require registration of substances by downstream users. [35] A downstream user must inform the Agency of its identity, contact details and the substance(s) which it uses only where, in essence, it intends to make a particular use of a registered substance that is not already covered by a registration or that the supplier advises against. [36] Consequently, as the Swedish Government and the Commission correctly point out, the EU register does not provide systematic information to national authorities on where in the European Union a registered substance is being used by downstream users and in what quantities. In contrast, a downstream user that imports at least 100 kilogrammes of a given chemical product into Sweden per annum is required to notify it to the Chemicals Inspectorate.

31 — See point 16 above.

32 — Chapter 14, Paragraph 2(1), of the Environmental Code.

33 — The submissions of the Swedish Government and of the Commission correspond on that point to the summary of the findings of the Hovrätten set out in the order for reference, which the referring court does not call into question.

34 — See point 35 above.

35 — Except where the downstream user is also a producer of articles in which a substance is present and subject to registration under Article 7 of the REACH Regulation.

36 — Article 37(4) read together with Article 38 of the REACH Regulation.

44. The Swedish product register's specific purposes also explain why the two registers have different coverage as regards the categories of chemical products subject to registration and the information available for each product. Thus, the notification and registration requirement under the Environmental Code applies to manufacturers and importers of chemical products in Sweden in so far as they manufacture or import at least 100 kilogrammes of a chemical product per annum. By contrast, registration in the EU register applies only to 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.[37] Furthermore, the national notification and registration requirement in issue in the main proceedings covers all chemical products, thus including *preparations* of chemical substances, whilst only *substances* themselves are subject to registration under the REACH Regulation (even where they are contained in a mixture or an article).[38] Moreover, some of the categories of information required under the Chemicals Inspectorate's Regulations exclusively or essentially concern preparations[39] or (more generally) go beyond information required under the REACH Regulation.[40]

45. In my view, neither the wording nor the objectives of the REACH Regulation suggest that a Member State is precluded from requiring manufacturers and importers of chemical products to provide a national authority with information such as that contained in the Swedish product register in order to pursue objectives like those set out in point 40 above. Thus, recital 44 in the preamble to the REACH Regulation, which states that 'all registrations should be submitted to the Agency', applies only within the scope of harmonisation achieved by the REACH Regulation.

46. It seems to me that, on the contrary, a chemical products register such as that in issue in the main proceedings is likely to promote the objective of the REACH Regulation to ensure a high level of protection of human health and of the environment besides the free circulation of substances on the internal market.

47. First, as the Finnish, Norwegian and Swedish Governments and the Commission submit in essence, a chemical products register such as that in issue in the main proceedings may help the competent national authorities to verify whether economic operators are complying with their obligations under the REACH Regulation. It can be used, for example, to verify whether a manufacturer or importer of a substance, either on its own or in a mixture, or a producer or importer of articles in which a substance is present, has reached the quantity thresholds that trigger an obligation to register under Article 6 or 7 of the REACH Regulation. It may also be useful in order to verify that a downstream user is using a substance subject to authorisation in accordance with the conditions of an authorisation granted to an upstream supplier.[41] A chemical products register such as that at issue in the main proceedings may thus form part of the system of official controls which a Member State puts in place in accordance with Article 125 of the REACH Regulation and, ultimately, assist that Member State in fulfilling its reporting obligations under Articles 117 and 127.

48. Second, such a register may serve as a basis for a Member State to propose amendments to the lists of substances that are subject to authorisation or to restriction(s) under the REACH Regulation.

37 — Article 6(1) of the REACH Regulation. Likewise, an importer or producer of articles must submit a registration to the Agency for any substance contained in those articles only if, inter alia, the substance is present in those articles in quantities totalling over one tonne per producer or importer per year (Article 7(1)).

38 — At the hearing, the Swedish Government confirmed that approximately 90% of all registrations in the Swedish product register concern preparations of chemical substances.

39 — For example, the indents of Paragraph 4 of the Chemicals Inspectorate's Regulations which concern paints, varnishes and vehicle refinishing products, and preservatives contained in products.

40 — For example, the indents of Paragraph 4 of the Chemicals Inspectorate's Regulations which concern the product's function or products that are used in manufacture as a starting product.

41 — Article 56(2) of the REACH Regulation.

49. The broad coverage of the Swedish product register gives the competent authorities greater scope to carry out inspections on the manufacturing or use of chemical products in Sweden, above certain quantities and in the course of business. That is due in particular to the fact that the notification and registration requirement in issue covers the manufacture or import of *preparations* of chemical substances, as well as chemical substances themselves, and applies to a person who manufactures or imports at least 100 kilogrammes of a chemical product per annum (one tenth of the threshold under Articles 6 and 7 of the REACH Regulation). Such inspections may reveal, for example, what the competent authorities regard as an unacceptable risk to human health or the environment, which needs to be addressed on a Community-wide basis, arising from the manufacture, use or placing on the market of a substance. [42] In such a case, Sweden may propose either to add a new restriction to, or to amend an existing restriction in, the list in Annex XVII by submitting to the Agency a dossier in accordance with Article 69(4) of and Annex XV to the REACH Regulation. [43] Indeed, this illustrates the central role which the EU legislature has conferred on the Member States not only to enforce the REACH Regulation individually but also to exchange information through the Agency (in particular, through the Member State Committee established under Article 76(1)(e) of the REACH Regulation) in order to assess existing rules and suggest further harmonisation where necessary. [44]

50. I therefore conclude that Article 128 of the REACH Regulation does not preclude a Member State from adopting provisions — such as those of the Environmental Code, the Ordinance and the Chemicals Inspectorate's Regulations in issue in the main proceedings — which require a person who, in the course of business, imports a certain quantity of chemical products per annum into its territory to notify that importation to a public authority for registration in a chemical products register, with a view to protecting the environment and human health.

Do Articles 34 TFEU and 36 TFEU preclude a notification and registration requirement such as that in issue in the main proceedings (Question 2)?

51. Since the national provisions in issue in the main proceedings fall outside the scope of the harmonisation achieved by the REACH Regulation, it is necessary to address Question 2 concerning free movement of goods. [45] Is the notification and registration requirement laid down in Chapter 14, Paragraph 12, of the Environmental Code and implemented in the Ordinance and the Chemicals Inspectorate's Regulations a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU in so far as it applies to chemical products originating from other Member States? If so, is it justified by the objective of protecting the environment and human health?

52. All measures of a Member State which are capable of hindering, directly or indirectly, actually or potentially, trade within the European Union must be considered to have an effect equivalent to quantitative restrictions within the meaning of Article 34 TFEU. [46] In particular, formalities for import may hinder trade within the internal market and impede access to the market for goods which are lawfully produced and marketed in other Member States. [47]

42 — Article 68(1) of the REACH Regulation.

43 — That dossier should include the identity of the substance and the restriction(s) proposed, a summary justification, information on hazard and risk, information on alternative substances and techniques, information on why action on a Community-wide basis is required and information on the socio-economic impact of the proposed restriction.

44 — See in particular recitals 20, 21, 103, 105 and 119.

45 — See for example, by analogy, the judgments in *ATRAL*, C-14/02, EU:C:2003:265, paragraphs 49 and 61 and the case-law cited, and *Radlberger Getränkegesellschaft and S. Spitz*, C-309/02, EU:C:2004:799, paragraphs 56 and 57.

46 — The well-known 'Dassonville formula' (judgment in *Dassonville*, 8/74, EU:C:1974:82, paragraph 5). See, most recently, the judgment in *Capoda Import-Export*, C-354/14, EU:C:2015:658, paragraph 39 and the case-law cited.

47 — See, inter alia, the judgment in *Ahokainen and Leppik*, C-434/04, EU:C:2006:609, paragraph 21 and the case-law cited.

53. Whilst the notification and registration requirement in issue in the main proceedings is not a pre-condition for placing a chemical product on the Swedish market, [48] its obligatory character, the detailed nature of the information which the registrant has to submit to the Chemicals Inspectorate and the imposition of penalties for non-compliance are all liable to have restrictive effects on the free movement of chemical products imported into Sweden from other Member States. [49]

54. The Swedish Government submits that such a restriction is justified in the light of the objective, pursued by the national provisions in issue in the main proceedings, of protecting the environment and human health. [50]

55. According to Article 36 TFEU, Article 34 TFEU does not preclude prohibitions or restrictions on imports justified on grounds of, inter alia, the protection of health and life of humans and which are proportionate to these objectives. It is settled case-law moreover that national measures capable of hindering trade within the internal market and not falling within the exception in Article 36 TFEU may be justified by certain 'mandatory requirements', such as protecting the environment, provided that the measures in question are indistinctly applicable to domestic goods and to goods originating from other Member States [51] and are proportionate to the aim pursued. [52] That means that the national measures must be appropriate for securing the attainment of that objective and not go beyond what is necessary in order to attain it. [53]

56. In the present case, the national requirement in issue is aimed inter alia at environmental protection and applies to both importation and manufacture of chemical products. It thus does not discriminate between domestic and imported products.

57. Since protection of the environment, on the one hand, and of human life and health, on the other hand, are closely related objectives, it is appropriate to examine them together. [54]

58. As regards the first part of the proportionality test, it is clear that the Swedish product register is appropriate for securing the attainment of most of the objectives set out in point 40 above. First, that register provides the competent authorities with useful information to identify where to carry out inspections on the basis of a risk assessment. It is therefore likely to facilitate the monitoring of manufacture or use of chemical products in the course of business in Sweden. That monitoring includes ensuring that economic operators act in compliance with their obligations under the REACH Regulation. [55] Moreover, the database contained in the Swedish product register generates statistics on the use and sale of chemicals and enables trends to be analysed — for example, concerning the categories and quantities of dangerous substances used by the Swedish industry, or the proportion of such products imported into Sweden compared to those manufactured there. Finally, it is common ground that the Swedish product register (and arguably also the statistics and trend analyses which it makes possible) may provide useful information to the competent national authorities when formulating environmental policies.

48 — Point 39 above.

49 — See, by analogy, judgment in *Kieffer and Thill*, C-114/96, EU:C:1997:316, paragraph 28.

50 — See point 34 above.

51 — See, for example, judgment in *Aragonesa de Publicidad Exterior and Publivia*, C-1/90 and C-176/90, EU:C:1991:327, paragraph 13.

52 — See, for example, judgments in *Commission* v *Denmark*, 302/86, EU:C:1988:421, paragraphs 9 and 12; *Commission* v *Austria*, C-320/03, EU:C:2005:684, paragraph 70; and *Mickelsson and Roos*, C-142/05, EU:C:2009:336, paragraph 32.

53 — See, inter alia, judgment in *ATRAL*, C-14/02, EU:C:2003:265, paragraph 64 and the case-law cited.

54 — See, by analogy, judgment in *Mickelsson and Roos*, C-142/05, EU:C:2009:336, paragraph 33.

55 — See point 47 above.

59. By contrast, I am not convinced that the Swedish product register is an appropriate instrument to facilitate rapid and proper response to accidents such as poisoning or fire at installations where chemical products are stored or processed. Most of the information concerning the chemical products does not have to be communicated to the Chemicals Inspectorate immediately after importation. That information is due only by 28 February in the calendar year after the obligation to notify arose. Consequently, it is entirely possible that the competent Swedish authorities will *not* have the necessary information to react appropriately to an accident involving chemical products. The information may (entirely legitimately) not yet have been notified. [56]

60. As regards the second part of the proportionality test, the notification and registration requirement in issue in the main proceedings does not seem to me to go beyond what is necessary to achieve the objectives set out in point 58 above.

61. First, the effects of that requirement on trade within the internal market appear to be limited. [57] It does not preclude chemical products originating from other Member States being placed on the Swedish market. [58]

62. Second, I agree with the Danish and Swedish Governments that only the global overview of chemical products in Sweden which the Swedish product register offers is capable of fulfilling the various functions described in point 40 above (within the limits set out in point 58) and consequently of achieving the level of protection of the environment and human life and health that Sweden seeks to ensure. The EU register compiled under the REACH Regulation does not provide that overview. [59]

Conclusion

63. For all the above reasons, I suggest that the Court should rule as follows in answer to the questions referred by the Högsta domstolen (Supreme Court, Sweden):

On a proper construction, neither Article 128 of 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), nor Articles 34 or 36 TFEU, preclude a Member State from adopting provisions — such as those contained in the national legislation in issue in the main proceedings — which require a person who, in the course of business, imports a certain quantity of chemical products per annum into its territory to notify that importation to a public authority for registration in a chemical products register, with a view to protecting the environment and human health.

56 — Of course, relevant information may be available to the competent authorities for other reasons. At the hearing, the Swedish Government explained that separate national or local legislation may well govern, for example, the transport of dangerous substances. Relevant information may also be available as a result of the notification requirement in Article 6 of Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJ 1997 L 10, p. 13) (the 'Seveso II Directive'). That provision has been replaced, with effect from 1 June 2015, by Article 7 of Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ 2012 L 197, p. 1) (the 'Seveso III Directive').

57 — I emphasise again that the reasoning here concerns the obligation to notify as such, not any fees which Sweden apparently charges on chemical products imported into its territory.

58 — See point 39 above.

59 — See points 42 and 43 above.