



Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

17 March 2016*

(Reference for a preliminary ruling — Registration, evaluation, authorisation and restriction of chemicals — Regulation (EC) No 1907/2006 (REACH Regulation) — Extent of harmonised field — Registration of chemical substances with the European Chemicals Agency before placing them on the market — Article 5 — National chemical product register — Notification requirement for registration purposes — Compatibility with the REACH Regulation — Articles 34 TFEU and 36 TFEU — Quantitative restriction on imports)

In Case C-472/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Högsta domstolen (Supreme Court, Sweden), made by decision of 8 October 2014, received at the Court on 20 October 2014, in the proceedings

Canadian Oil Company Sweden AB,

Anders Rantén

v

Riksåklagaren,

THE COURT (Second Chamber),

composed of R. Silva de Lapuerta, President of the First Chamber, acting as President of the Second Chamber, J.L. da Cruz Vilaça, A. Arabadjiev, C. Lycourgos and J.-C. Bonichot (Rapporteur), Judges,

Advocate General: E. Sharpston,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 10 September 2015,

after considering the observations submitted on behalf of:

- Canadian Oil Company Sweden AB, by B. Hansson and M. Lönnqvist, advokater,
- Mr Rantén, by M. Wårnsby and M. Edqvist, advokater,
- the Swedish Government, by A. Falk, C. Meyer-Seitz, U. Persson, N. Otte Widgren, E. Karlsson and L. Swedenborg, acting as Agents,

* Language of the case: Swedish.

- the Danish Government, by C. Thorning and N. Lyshøj, acting as Agents,
- the Finnish Government, by H. Leppo, acting as Agent,
- the Norwegian Government, by I. Thue and I.S. Jansen, acting as Agents,
- the European Commission, by D. Kukovec and E. Manhaeve, acting as Agents, and by M. Johansson, advokat,

after hearing the Opinion of the Advocate General at the sitting on 10 December 2015,

gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation 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), 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, and corrigendum OJ 2007 L 136, p. 3), as amended by Commission Regulation (EU) No 552/2009 of 22 June 2009 (OJ 2009 L 164, p. 7; ‘the REACH Regulation’), and the interpretation of Articles 34 TFEU and 36 TFEU.
- 2 The request has been made in proceedings between Mr Rantén and Canadian Oil Company Sweden AB (‘Canadian Oil’) and the Riksåklagaren (Swedish State Prosecutor General) concerning the penalties imposed on Mr Rantén and Canadian Oil for having imported 320 tonnes of chemical products into Sweden without notifying that import to the Chemical Inspectorate (Kemikalieinspektionen) for registration in the national product register.

Legal context

EU law

- 3 Recital 19 to the REACH Regulation states:

‘... 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 [(ECHA)]. Registered substances should be allowed to circulate on the internal market.’

- 4 Article 1(1) of the REACH Regulation provides:

‘The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.’

5 Title II of that regulation concerns substance registration. Chapter 1 of that title is entitled ‘General obligation to register and information requirements’.

6 In Chapter 1, Article 5 of that regulation, entitled ‘No data, no market’, contains the following provisions:

‘Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the [European Union] or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.’

7 Also in Chapter 1, Article 6 of the REACH Regulation, entitled ‘General obligation to register substances on their own or in mixtures’, provides in paragraph 1:

‘Save where this regulation provides otherwise, 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 shall submit a registration to [ECHA].’

8 Under Article 125, the Member States are required to maintain a system of official controls and other activities as appropriate to the circumstances.

9 Article 128 of Regulation No 1907/2006 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 provisions

The Environment Code

10 Under Chapter 29, Paragraph 5(5) of the Environmental Code (miljöbalken), a person who deliberately or through negligence, in connection with the manufacture or import of chemical products in the course of a business, infringes a rule laid down by the government on the basis of Chapter 14, Paragraph 12, of that code, on the obligation to make a notification for registration in a product register is guilty of obstruction of environmental controls.

11 Chapter 14, Paragraph 12 of the miljöbalken provides:

‘Chemical products which are manufactured in or imported into Sweden in the course of a business shall be registered in a product register in accordance with the rules laid down by the government or the authority appointed by the government. That register shall be held by the authority appointed by the government.’

Chemical Products and Biotechnical Organisms Ordinance (2008:245)

- 12 Paragraph 3 of the Chemical Products and Biotechnical Organisms Ordinance (2008:245) (förordningen (2008:245) om kemiska produkter och biotekniska organismer) provides that chemical products or biotechnical organisms which are manufactured in or imported into Sweden in the course of business must be notified to the Kemikalieinspektionen for registration in the product register which that body is required to hold if such products or organisms relate to a product listed in the annex to that ordinance.
- 13 Under Paragraph 4 of that ordinance, it is the person who, in the course of business, manufactures a chemical product or a biotechnical organism in or imports it into Sweden who must make that notification.
- 14 Paragraph 5 thereof provides for an exception from the notification requirement which covers persons who import less than 100 kilogrammes of a product per annum.

Rules on Chemical Products and Biotechnical Organisms (KIFS 2008:2)

- 15 Chapter 3 of the Kemikalieinspektionen's Regulations (KIFS 2008:2) on Chemical Products and Biotechnical Organisms (Kemikalieinspektionens föreskrifter (KIFS 2008:2) om kemiska produkter och biotekniska organismer) sets out the procedure for notification to the product register. The name of the person obliged to notify or the company name, his address and telephone number and the national registration or organisation number, which the notification document must include, must be sent as soon as possible and at the latest when the activity is commenced. The remaining information must be notified by 28 February in the calendar year after the obligation to notify arose in respect of the product.

The dispute in the main proceedings and the questions referred for a preliminary ruling

- 16 During 2009, Canadian Oil imported 392 tonnes of chemical products into Sweden.
- 17 In breach of Swedish law, that import was not notified to the Kemikalieinspektionen before the time limit of 28 February 2010.
- 18 Canadian Oil and Mr Rantén, as managing director of that company, were prosecuted, on the basis of the miljöbalken.
- 19 By a judgment of 24 April 2013, the Hovrätten över Skåne och Blekinge (Court of Appeal for Skåne and Blekinge) fined Mr Rantén SEK 100 (approximately EUR 11) per day for 60 days and Canadian Oil SEK 200 000 (approximately EUR 22 113).
- 20 In their appeals before the Högsta domstolen (Supreme Court), Mr Rantén and Canadian Oil argued, in essence, that the requirement to notify the Kemikalieinspektionen in order to register the products restricts the free movement of the substances which are subject to the REACH Regulation. That register pursues basically the same objectives as those of that regulation and it is therefore incompatible with the provisions of Article 128 thereof, the rules of which in the relevant areas, in particular as regards notification and registration of chemical substances, must be regarded as having been fully harmonised. In any event, that notification requirement constitutes a restriction on imports prohibited under Article 34 TFEU and none of the exceptions provided for in Article 36 TFEU is applicable to the main proceedings.

- 21 It is not clear to the referring court that the harmonised scope of that regulation goes so far as to include the registration of chemical products or substances for the purposes, as in the Swedish register, of obtaining information regarding the use of those products or substances, of the authorities' monitoring and inspection of the undertakings handling them, or of creating statistics. It also asks whether the notification requirement constitutes a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU and, whether, in that case, one of the exceptions provided for in Article 36 TFEU would, proportionately, apply.
- 22 In those circumstances, the Högsta domstolen (Supreme Court) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:
- '(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 Kemikalieinspektionen 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?'

Consideration of the questions referred

The first question

- 23 By its first question, the referring court asks, in essence, whether the REACH Regulation must be interpreted as precluding national legislation which requires an importer of chemical products to register those products with the competent national authority when that importer is already under an obligation under that regulation to register those same products with ECHA.
- 24 In that regard, it must be borne in mind that the purpose of the regulation, in accordance with Article 1(1) thereof, is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
- 25 To that end, the REACH Regulation introduces an integrated system for monitoring chemical substances, including registration, evaluation and authorisation, together with possible restrictions on their use. The cardinal principles governing those factors were presented by the European Commission in the introduction to its Proposal for a Regulation COM(2003) 644 final of 29 October 2003. That proposal describes 'the REACH system' as comprising, first of all, registration, which requires 'industry to obtain relevant information on their substances and to use that data to manage them safely', next, '[e]valuation[, which] provides confidence that industry is meeting its obligations' and authorisation for substances of very high concern whose '[r]isks associated with uses are adequately controlled, if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies'. Lastly, '[t]he restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system' (judgment in *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 32).
- 26 Free movement in the internal market is ensured by the fact that, pursuant to Article 128(1) of the REACH Regulation, the Member States are under an obligation not to 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 which complies with the regulation and, where appropriate, with Community acts adopted in implementation thereof. Nonetheless, under Article 128(2) of the REACH Regulation, nothing therein is to prevent Member States from maintaining or laying down national rules to protect workers,

human health and the environment applying in cases where that regulation does not harmonise the requirements on manufacture, placing on the market or use (judgment in *Lapin luonnonsuojelupiiri*, C-358/11, EU:C:2013:142, paragraph 32).

- 27 It is therefore apparent from those provisions that the EU legislature intended to harmonise those requirements only in certain cases (see, to that effect, judgment in *Lapin luonnonsuojelupiiri*, C-358/11, EU:C:2013:142, paragraph 33).
- 28 In consequence, in order to answer the first question referred by the referring court, it is necessary to know whether the provisions of the REACH Regulation requiring notification and registration of chemical substances harmonise such requirements in such a way that they preclude national legislation requiring an importer of chemical products to register those products with the competent national authority.
- 29 In that regard, it is appropriate to recall that the EU legislature, as is apparent from recital 19 to that regulation, sought to require manufacturers and importers to produce, to ECHA, 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.
- 30 In accordance with those objectives, that regulation lays the burden of analysis of chemical substances on the 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. (judgment in *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 33).
- 31 However, as the Advocate General noted in point 42 of her Opinion, the registration of chemical substances with ECHA does not provide any overview of the manufacture or placing on the market of substances in each individual Member State. In particular, the EU register does not provide systematic information to national authorities on precisely where in the territory of the Member States a registered substance is located.
- 32 Accordingly, whilst the registration of chemical substances with ECHA constitutes a pre-condition for their free movement in the internal market, provided that those substances, in particular as regards their properties, also comply with the REACH Regulation, the harmonisation which that regulation operates in respect of such registration of those substances does not extend to another form of registration with the national authorities, such as that at issue in the main proceedings, which does not constitute such a pre-condition, which concerns information different from that required by that regulation and which pursues the same objectives as those pursued by that regulation or objectives complementary thereto, namely, in particular, to ensure a high level of protection of human health and the environment as well as the free circulation of such substances on the internal market.
- 33 In that regard, it is appropriate to note, firstly, that the registration required by the national legislation at issue in the main proceedings is not a pre-condition for importing chemical products into the territory of the Member State concerned, since the notification to the national authorities of the relevant information can be made after import, for some information at the latest when the activity is commenced and, for other information, until 28 February of the calendar year following that import.
- 34 Secondly, it is apparent from the observations submitted to the Court that the registration required by the national legislation at issue in the main proceedings seeks, in essence, to enable the national authorities to hold a database necessary for the monitoring of chemical products in the territory of the Member State concerned, which State is required, under Article 125 of the REACH Regulation, to ensure such a control system, by facilitating in particular the conditions for inspection of the establishments holding those products. Whilst that database also enables accounting or statistical

information, vital to the determination of the fees laid down to finance that control system, to be held, it also serves to define environmental policy, in order also to propose, at EU level, any useful improvements thereto.

- 35 The information to which the national authorities can have access at ECHA and which follow from the registration of those products with ECHA pursuant to the REACH Regulation do not comprise all of those data which enable the objectives set out in the preceding paragraph of the present judgment to be achieved.
- 36 That registration concerns only the manufacturers or importers of chemical substances, on their own, in mixtures or in articles, and when they are in quantities greater than one tonne per annum. With regard to preparations, that registration does not enable it to be known, in particular, the percentage of each chemical substance which a preparation contains. Registration with ECHA of chemical substances on their own, manufactured or placed on the market in the European Union does not make it possible to know on the market of which Member State those substances are supplied.
- 37 However, the information required for registration of the import of chemical products with the competent authority under the national legislation at issue in the main proceedings relates mainly to the quantities of the substances and preparations present on the territory of the Member State concerned, their location on that territory, their specific areas of use and the operators concerned.
- 38 In those circumstances, the harmonisation carried out by the provisions of the REACH Regulation in respect of the notification and registration requirement for chemical substances, however far-reaching it may be in order to establish an integrated system of control of those substances on EU territory enabling their safe management, is not such as to exclude another registration having the characteristics set out in paragraph 34 of this judgment which contributes, in particular, to the implementation of a system of controls of that management in the Member State concerned and the evaluation of that management in order, particularly, to propose any useful improvements thereto at EU level.
- 39 Accordingly, it does not appear that the harmonisation referred to in the preceding paragraph precludes a national rule requiring importers of chemical products to register those products with the competent national authority, provided only that the information required contributes mainly to those purposes. Whether that appears to be the case of those referred to in paragraph 37 of the present judgment remains, however, for the national court to ascertain.
- 40 In that context, the mere fact that certain basic information concerning in particular the identification of the importer and the products, the provision of which causes no difficulty, is already required for registration with ECHA is not sufficient to deprive that information as a whole, as required by a competent national authority, of its complementarity.
- 41 In those circumstances, the answer to the first question is that the REACH Regulation must be interpreted as not precluding national legislation which requires an importer of chemical products to register those products with the competent national authority when that importer is already under an obligation under that regulation to register those same products with ECHA, provided that that registration with the competent national authority does not constitute a pre-condition to the placing of those products on the market, it concerns information different from that required by that regulation and contributes to the achievement of the objectives pursued by that regulation, in particular those of ensuring a high level of protection of human health and the environment and the free movement of such substances in the internal market, in particular, by the implementation of a system of controls of the safe management of such products in the Member State concerned and the evaluation of that management, which it is for the referring court to ascertain.

The second question

- 42 Having regard to the answer given to the first question, it is appropriate to examine the second question, by which the referring court asks, in essence, whether the combined provisions of Articles 34 TFEU and 36 TFEU must be interpreted as precluding the notification and registration requirement for chemical products, as provided for by the national legislation at issue in the main proceedings.
- 43 In that regard, it must be borne in mind that, in accordance with settled case-law, all measures of a Member State which are capable of hindering, directly or indirectly, actually or potentially, trade within the European Union are to be considered as measures having an effect equivalent to quantitative restrictions within the meaning of Article 34 TFEU (see, inter alia, judgments in *Dassonville*, 8/74, EU:C:1974:82, paragraph 5, and *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 31).
- 44 As the Advocate General noted in point 53 of her Opinion, the mandatory nature of the registration of the import of chemical products with the competent national authority constitutes a measure having an effect equivalent to a quantitative restriction within the meaning of Article 34 TFEU, since the fact of imposing formalities for import is capable of hindering trade within the European Union and impeding access to the market for goods which are lawfully produced and marketed in other Member States (see, to that effect, judgment in *Ahokainen and Leppik*, C-434/04, EU:C:2006:609, paragraph 21), which is, moreover, disputed neither by the referring court nor by any of the parties interested in accordance with Article 23 of the Statute of the Court of Justice of the European Union who have submitted observations in the present case.
- 45 In accordance with settled case-law, a measure having equivalent effect to a quantitative restriction on imports can be justified, for example, on grounds of the protection of the health and life of humans, under Article 36 TFEU, only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it (judgment in *Scotch Whisky Association and Others*, C-333/14, EU:C:2015:845, paragraph 33). Furthermore, national measures that are capable of hindering intra-Community trade may be justified by overriding requirements relating to protection of the environment (see, to that effect, judgment in *Ålands Vindkraft*, C-573/12, EU:C:2014:2037, paragraph 77).
- 46 In the present case, it must be recalled that the registration required by national legislation such as that at issue in the main proceedings seeks to obtain data which, on the one hand, are essentially complementary to those falling within the relevant scope of the REACH Regulation and which, on the other, contribute, in the Member State concerned, particularly to the implementation of a control system for safe management of the chemical products covered by that regulation and to the evaluation of that management in order, in particular, to propose any useful improvements to it at EU level. Such an objective linked to that of the regulation, which seeks to ensure a high level of protection of human health and the environment, is capable of justifying any hindrance to the free movement of goods.
- 47 Furthermore, it does not appear that the information required from importers by the national legislation at issue, as set out in paragraph 37 of the present judgment, in addition to that laid down by that regulation in order to comply with the requirement to register chemical products imported is inappropriate to the objective pursued or goes beyond what is strictly necessary to achieve that objective. The registration required under that national legislation in order to obtain precise information enabling the competent national authorities to have an overview of the chemical products present on the territory of the Member State concerned, which the registration with ECHA does not provide, contributes to the achievement of the objective referred to in the preceding paragraph of the

present judgment, while having a limited effect on the free movement of those products in the internal market since the registration at issue in the main proceedings is not a condition for the placing on the market of such products coming from other Member States.

- 48 Having regard to the foregoing considerations, the answer to the second question is that the combined provisions of Articles 34 TFEU and 36 TFEU must be interpreted as not precluding the notification and registration requirement for chemical products, as provided for in the national legislation at issue in the main proceedings.

Costs

- 49 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

- 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended by Commission Regulation (EC) No 552/2009 of 22 June 2009, must be interpreted as not precluding national legislation which requires an importer of chemical products to register those products with the competent national authority when that importer is already under an obligation under that regulation to register those same products with the European Chemicals Agency, provided that that registration with the competent national authority does not constitute a pre-condition to the placing of those products on the market, it concerns information different from that required by that regulation and contributes to the achievement of the objectives pursued by that regulation, in particular those of ensuring a high level of protection of human health and the environment and the free movement of such substances in the internal market, in particular, by the implementation of a system of controls of the safe management of such products in the Member State concerned and the evaluation of that management, which it is for the referring court to ascertain.**
- 2. The combined provisions of Articles 34 TFEU and 36 TFEU must be interpreted as not precluding the notification and registration requirement for chemical products, as provided for in the national legislation at issue in the main proceedings.**

[Signatures]