

Reports of Cases

OPINION OF ADVOCATE GENERAL TANCHEV delivered on 21 December 2016¹

Case C-535/15

Freie und Hansestadt Hamburg V Jost Pinckernelle

(Request for a preliminary ruling from the Bundesverwaltungsgericht (Federal Administrative Court, Germany))

(Registration, evaluation, authorisation and restriction of chemicals (REACH) — Scope ratione materiae of obligation to register with the European Chemicals Agency ('ECHA') — Member State authority prohibiting export from the EU of nicotine sulphate not registered at import — Article 5 of Regulation (EC) No 1907/2006 — Article 126 of Regulation No 1907/2006 concerning penalties for non-compliance)

1. The question put to the Court in this case is concerned with the scope *ratione materiae* of the registration requirements imposed by Article 5 of Regulation (EC) No 1907/2006² ('the REACH Regulation'). More specifically, the Bundesverwaltungsgericht (Federal Administrative Court, Germany) queries whether a trader that has imported a chemical into the EU, and in this case nicotine sulphate, without complying with the requirement to register it with the Europe Chemicals Agency ('the ECHA'), can be refused permission by a Member State authority like the City of Hamburg to export the chemical out of the EU. The City of Hamburg is so doing on the basis that exportation of the nicotine sulphate in question amounts to a self-standing breach of Article 5 of the REACH Regulation.

I – Legal framework

A – EU Law

- 2. Recitals 2, 3, 7 and 122 of the REACH Regulation state:
- (2) The efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.

^{1 —} Original language: English.

^{2 —} Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning 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).

OPINION OF MR TANCHEV – CASE C-535/15 PINCKERNELLE

(3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally in accordance with the Community's international commitments.

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(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported.

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- (122) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for penalties with a view to imposing effective, proportionate and dissuasive penalties for non-compliance, as non-compliance can result in damage to human health and the environment.'
- 3. Article 1 of the REACH Regulation is entitled 'Aim and scope'. Article 1(1) 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.'

4. Article 3 of the REACH Regulation is entitled 'Definitions'. Article 3 provides:

'For the purposes of this Regulation:

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(7) registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

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- (9) manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;
- (10) import: means the physical introduction into the customs territory of the Community;
- (11) importer: means any natural or legal person established within the Community who is responsible for import;
- (12) placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

...'

5. Article 5 of the REACH Regulation is entitled 'No data, no market' and 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.'

6. Article 6(1) of the REACH Regulation is entitled 'General obligation to register substances on their own or in mixtures' and provides:

'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 the Agency.'

7. Article 126 of the REACH Regulation is entitled 'Penalties for non-compliance' and provides:

'Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. ...'

B – National law

8. The relevant provisions of national law are laid down in the Gesetz zum Schutz vor gefährlichen Stoffen (Law on protection from dangerous substances) ('the ChemG') as amended by the Official Notice of 28 August 2013 (BGBl. I, pp. 3498, 3991) and in the Hamburger Gesetz zum Schutz der öffentlichen Sicherheit und Ordnung (Hamburg Law on protection of public security and order (SOG)) (HmbGVBl., p. 77).

9. Paragraphs 21, 23 and 27b of the ChemG state as follows:

'Paragraph 21 Monitoring

- (1) The competent regional authorities shall monitor the enforcement of this law and regulations adopted under this law, in so far as this law does not provide otherwise.
- (2) Subparagraph 1 also applies to EC and EU Regulations that govern the subject matter of this law, in so far as the monitoring of their enforcement falls to the Member States. ...

Paragraph 23 Orders issued by authorities

(1) The competent Land authority may, in individual cases, issue orders which are necessary for the purposes of remedying action found to be in breach, or preventing future breaches, of this law or of the regulations adopted under this law or of an EC or EU Regulation as referred to in the first sentence of Paragraph 21(2) ...

Paragraph 27b Infringements of Regulation (EC) No 1907/2006

(1) A person is liable to punishment of up to two years' imprisonment or a fine if he infringes 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) ... in so far as he 1. breaches Article 5 by manufacturing or placing on the market a substance on its own, in a mixture, or in an article.

...'

10. Paragraph 3(1) of the SOG in the relevant version of 16 June 2005 (HmbGVBl p. 233) states:

'Paragraph 3 Tasks of the authorities

(1) The administrative authorities shall, in the course of their activities, after due consideration of the circumstances, adopt measures necessary for the protection of the general public or an individual in particular cases in order to avoid impending threats to public security or order or to remedy breaches thereof (Measures for the prevention of threats).

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II – The facts in the main proceedings and the question referred for a preliminary ruling

11. The applicant, Mr Pinckernelle, trades in chemical substances. He is seeking the annulment of a decision of the City of Hamburg of 29 June 2009 ('the decision') in which he was refused permission to export a consignment of 19.4 tonnes of nicotine sulphate ('the consignment') to a third country, in this case Russia, which he had imported into the European Union from China sometime after 1 December 2008. Nicotine sulphate is used in Russia as an industrial disinfectant and as a disinfectant in installations housing animals.³ It cannot, however, be used in the EU for this purpose, and is subject to severe restrictions.⁴

12. Prior to this, in the process of conducting a criminal investigation, the Hamburg river police and the economic and works department of the City of Hamburg seized the consignment. It was, and remains, in a warehouse in Hamburg. By orders dated 23 February and 18 May 2009 the City of Hamburg directed that the consignment was not to leave the warehouse.⁵ The order of 18 May 2009 added that it could only be removed from the warehouse with the prior authorisation of the City of Hamburg.⁶

13. Mr Pinckernelle had not, before importation, pre-registered the consignment pursuant to Article 28 of the REACH Regulation, and nor did any registration taken place pursuant to Article 6 of the REACH Regulation. The decision of the City of Hamburg stated that the nicotine sulphate was in Hamburg illegally: its export to a non-Member country cannot serve the purpose of rendering that situation lawful, but itself constituted a breach of public security and order.

14. Mr Pinckernelle challenged the decision before the Verwaltungsgericht (Administrative Court) but his action was dismissed. On appeal by Mr Pinckernelle, the Oberverwaltungsgericht (Higher Administrative Court) overturned the judgment of the Verwaltungsgericht (Administrative Court) in a judgment of 25 February 2014. It annulled the decision, and ordered the City of Hamburg to authorise the export of the consignment. The Oberverwaltungsgericht (Higher Administrative Court) explained

³ — According to the written observations of the Commission.

^{4 —} Ibid. The Commission cites inter alia Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and the use of biocidal products (OJ 2012 L 167, p. 1).

⁵ $\,-\,$ According to the written observations of the Commission.

^{6 —} Ibid.

that the intended export of a substance imported in breach of Article 5 of the REACH Regulation was not a fresh breach of Article 5 read in conjunction with Article 3(12) of the REACH Regulation, if, as in the present case, the substance was not available to the European market on the basis of a prohibition on its commercialisation.

15. The City of Hamburg sought review on a point of law that was directed against that judgment by bringing an application before the national referring court.

16. However, separately from the administrative proceedings that form the subject of the order for reference, Mr Pinckernelle was sentenced, in criminal proceedings in Germany, to a period of imprisonment of 18 months, suspended for a probationary period of 3 years and subject to a fine of EUR 340 000 with respect to unlawful activities in the trading of chemicals ('the criminal proceedings').⁷ They were not brought by the City of Hamburg but rather by the authority responsible for criminal prosecutions.⁸

17. The Bundesverwaltungsgericht (Federal Administrative Court) referred the following question for a preliminary ruling:

'Is Article 5 of the REACH Regulation to be interpreted as meaning that, subject to Articles 6, 7, 21 and 23 of the REACH Regulation, substances may not be exported out of the European Union unless they have been registered in accordance with the relevant provisions of Title II of the REACH Regulation where this is required?'

18. Written observations were submitted to the Court by the City of Hamburg, the Governments of Germany and Italy, and the European Commission. All except Italy made oral submissions in the hearing which took place on 28 September 2016, as did the representative of Mr Pinckernelle.

III – Analysis

A – Introduction

19. Nicotine sulphate is a flammable product which can be toxic to humans either when inhaled, on contact with skin, or otherwise absorbed. It can also have long term adverse effects for the aquatic environment, given that it is toxic to marine life and can harm bio-diversity.⁹

20. The REACH Regulation aims at securing the safe management of risks associated with chemical substances throughout the supply chain,¹⁰ from the manufacturing and import of chemicals all the way down to consumers of products incorporating chemicals and to some degree the disposal of chemicals. As a consequence its scope is vast.¹¹ But does it extend *ratione materiae* to exports that were not manufactured in the European Union, but which were not registered with the ECHA at their import as they should have been? This is essentially the issue the Court is asked to consider in the case to hand.

21. Before I proceed to considering the question posed by the Bundesverwaltungsgericht (Federal Administrative Court), it is important to note that it has narrow parameters.

^{7 —} The representative of Mr Pinckernelle said at the hearing that the criminal proceedings came to an end in January of 2012.

⁸ — According to the oral submissions of the City of Hamburg.

^{9 —} See Annex III, of the REACH Regulation as well as https://echa.europa.eu/substance-information/-/substanceinfo/100.000.551.

^{10 —} Bergkamp, L., and Penman, M., 'Introduction' in Bergkamp, L. (ed), *The European Union Reach Regulation for Chemicals: Law and Practice*, Oxford University Press, 2013, p. 1, at p. 2.

^{11 —} Ibid.

22. As pointed out by the Commission at the hearing, the Court has been asked to address the discrete question of whether export to a third State from the EU of chemicals unregistered at import amounts to a breach of Article 5 of the REACH Regulation that is separate and distinct from the compliance failure with Article 5 of the REACH Regulation that occurred at import. That being so, the preponderance of my analysis will be confined to this question.

23. As can be seen from the written observations filed with the Court, a conventional exercise in statutory interpretation is central to resolving the contentions between the parties in this case, and more specifically determining the meaning of the term 'placed on the market' in Article 5 of the REACH Regulation.

24. Do the words 'placed on the market' in Article 5 mean that it is confined to chemical substances placed on the internal market of the EU,¹² thereby excluding chemical substances that were not registered at import into the EU but which a trader wishes to export, as argued by Mr Pinckernelle and the Commission, or does 'placed on the market' mean that Article 5 is triggered when chemicals are placed on any of the world's markets, thereby encompassing chemical substances unregistered at import that are to be exported to third States, as argued by the City of Hamburg, Germany, and Italy?

25. I have come to the conclusion that, on the basis of the Court's established methods of interpretation, the term 'placed on the market' in Article 5 of the REACH Regulation is to be interpreted as referring to the internal market of the EU. My reasons for so doing will be given in Part III B below.

26. That said, the extent to which an effective, proportionate and dissuasive sanction has ever been issued with respect to the (unlawful) importation of the consignment came into doubt at the hearing, notwithstanding the remedial obligations incumbent on Germany by virtue of Article 126 of the REACH Regulation. Mr Pinckernelle's representative asserted that failure to register the consignment was addressed in the criminal proceedings (which included punishment for breaching Article 5 of the REACH Regulation), whereas the representative of the City of Hamburg said the consignment was not part of them. According to the City of Hamburg, the criminal proceedings were rather concerned with false declarations made by Mr Pinckernelle with respect to other chemicals, and an attempt to sell, under false names, chemicals that are banned in Europe. If that were the case, the infraction of the REACH Regulation that occurred when Mr Pinckernelle imported the consignment into the EU may remain unaddressed to date, aside from the act of impounding them.

27. These considerations, along with arguments raised by Germany and the City of Hamburg on the need to interpret Article 5 of the REACH Regulation so as to prevent the emergence of loopholes to its enforcement, shows that it is impossible to interpret Article 5 of the REACH Regulation, and the extent to which it applies to exports unregistered at import, in a vacuum from Member State remedial obligations under Article 126 of the REACH Regulation.

28. Accordingly, I will make some observations in Part III C with respect to the context in which my answer to the question referred necessarily has to be read.¹³

^{12 —} This is without prejudice to the fact that the REACH Regulation applies to Iceland, Lichtenstein, and Norway. See Agreement on the European Economic Area, Annex II, Part II (OJ 1994 L 1, p. 3). Additionally, this Opinion will refer to the 'European Community' when the same occurs in the REACH Regulation.

^{13 —} Judgment of 27 October 2009, ČEZ (C-115/08, EU:C:2009:660, paragraph 81 and the case-law cited).

OPINION OF MR TANCHEV – CASE C-535/15 PINCKERNELLE

29. Finally, there was debate at the hearing as to whether an affirmative answer to the question as formulated by the national referring court would result in violation of the principle of *ne bis in idem*, protected under EU law by Article 50 of the Charter of Fundamental rights of the EU. Given the absence of reference to *ne bis in idem* in the order for reference,¹⁴ and the unresolved factual issue on the relationship between the criminal and administrative proceedings in this case, this is a matter for decision by the Bundesverwaltungsgericht (Federal Administrative Court), which is entitled to make a further reference under Article 267 TFEU.¹⁵

B – Interpretation of Article 5 of the REACH Regulation

1. Approach

30. As one commentator has observed,¹⁶ the REACH Regulation contains not one regulatory programme but is rather a collection of them that are gathered together in one instrument. Eight of its titles set out the bulk of its substantive law. Title I covers general issues. Title II addresses registration of chemical substances. Title III regulates data sharing and avoidance of unnecessary testing. Title IV is concerned with information in the supply chain. Title V sets out rules on downstream users, while Title VI encapsulates evaluation, Title VII authorisations, and Title VIII restrictions.

31. I observe at the outset that recourse to the words 'placed on the market' or temporal variations of 'placed' in combination with the words 'on the market' is not confined to Article 5 of the REACH Regulation in Title II. It occurs in Article 1(2) of Chapter 1 of Title I, the part of the regulation that lays out its aim and scope. It is repeated in Title IV on information in the supply chain (Article 31(5)), Title VII on authorisation (Articles 56(1) and 58(1)(c)) and Title VIII on restrictions (Articles 67(1) and (3), 68(1) and 69(1) and (4)).

32. Further, as pointed out in the written observations of Germany, the REACH Regulation is novel in that it creates a comprehensive system for the regulation of chemical substances within the EU, and managed by a pan-European authority, namely the ECHA, which is set up pursuant to Title X of the REACH Regulation.

33. Thus, in the interests of legal certainty and coherence,¹⁷ and in the light of the fact that the Court has noted the 'integrated' nature of the system established by the REACH Regulation,¹⁸ I would reject an approach pursuant to which the meaning of 'placed on the market' and its temporal variations could differ depending on the article or title of the REACH Regulation in which it appears. Such an approach would be inconsistent with Article 3(12) of the REACH Regulation, which furnishes a definition of 'placing on the market' that is applicable to all its Titles, and the well-established case-law of the Court to the effect that the architecture or general structure of the EU legislation in which a provision appears informs the meaning to be afforded it.¹⁹

^{14 —} The information provided in the order for reference serves not only to ensure that the Court can supply a useful answer, but equally to give the governments of the Member States and other interested parties the option of presenting their observations in conformity with Article 23 of the Statute of the Court. See Opinion of Advocate General Jääskinen in *Banif Plus Bank* (C-312/14, EU:C:2015:621, points 20 to 21).

^{15 —} The Court considered a mixture of criminal and administrative penalties for the enforcement of EU law, and *ne bis in idem* under Article 50 of the Charter in the judgment of 26 February 2013, Åkerberg Fransson (C-617/10, EU:C:2013:105).

^{16 —} Bergkamp, op.cit., p. 2.

^{17 —} These concerns are reflected in the Commission's white paper proposing REACH COM/2003/0644 final – COD 2003/0256 e.g. at pp. 2 to 5.

^{18 —} Judgments of 10 September 2015, FCD and FMB (C-106/14, EU:C:2015:576, paragraph 32), and of 17 March 2016, Canadian Oil Company Sweden and Rantén (C-472/14, EU:C:2016:171, paragraph 25).

^{19 –} E.g. judgment of 31 March 1998, France and Société commercial des potasses and de l'azote and Enterprise minière and chimique v Commission (C-68/94 and C-30/95, EU:C:1998:148, paragraph 168).

34. The REACH Regulation equally makes no reference to the law of the Member States to determine the meaning and scope of 'placed on the market'. Therefore, it is to be given an autonomous and uniform interpretation throughout the EU,²⁰ and one which is to be determined by the methods of construction recognised by EU law.²¹

2. Meaning

a) Language versions

35. The written observations of the City of Hamburg, Germany, Italy and the Commission all feature discussion of the various language versions of Article 5 of the REACH Regulation with respect to the meaning of 'placed on the market'. Its main features are as follows.

36. According to the written observations of Germany, there is in fact no ambiguity in Article 5, in the sense that, on its plain meaning there is no territorial limitation to the phrase 'placed on the market' in Article 5, or indeed in Article 3(12) of the REACH Regulation. Germany refers to the German, English and French language versions to support its interpretation of the phrase 'placed on the market' in Article 5 of the REACH Regulation.

37. Italy and the City of Hamburg argue that the absence of recourse to specific words in Article 5 of the REACH Regulation attaching 'placing on the market' to 'in the Community' in the same way as Article 5 circumscribes 'manufacture', means that a territorial limitation to the EU does not apply to substances 'placed on the market'. The City of Hamburg contends that simple recourse to the word 'internal' in front of 'market' would have limited Article 5 of the REACH Regulation in the manner advocated by Mr Pinckernelle and the Commission, had the EU legislature been minded to do so. Both the City of Hamburg and Italy contend that there is nothing in Article 3(12) of the REACH Regulation to call this thesis into question.

38. The Commission argues that there are eight language versions in which the words 'in the Community' in Article 5 of the REACH Regulation applies both to manufacture and to placing on the market, three language versions that are ambiguous, and ten that appear to attach the territorial limitation 'in the Community' only to manufacture.²² The Commission therefore contends that the only way to avoid an interpretation that is *contra legem* the eight language versions in which 'in the Community' straddles both placing on the market and manufacture is to adopt the interpretation of Article 5 of the REACH Regulation that it advocates.²³

20 — E.g. judgment of 9 November 2000, Yiadom (C-357/98, EU:C:2000:604, paragraph 26).

^{21 —} On the interpretive methods employed by the Court of Justice see e.g. Lenaerts, K., and Gutiérrez-Fons, J., 'To Say What the Law of the EU is: Methods of Interpretation and the European Court of Justice', (2014) 20, *Columbia Journal of European Law*, p. 3; Sebastian Martens, A.E., *Methodenlehre des Unionsrechts*, Max Planck Institut für ausländisches und internationals Privatrecht, 2013; Beck, G., *The Legal Reasoning of the Court of Justice*, Hart Publishing, 2012, particularly chapter 7.

^{22 —} The Commission states in its written observations that the Spanish, Lithuanian and German language versions can be interpreted in two ways. The Bulgarian, Estonian, Finnish, Greek, Italian, Dutch, Polish and Portuguese versions, like the French and English versions, give the impression that 'in the Community' relates only to manufacturing. The Danish, Latvian, Hungarian, Romanian, Slovakian, Swedish, Slovenian, and Czech versions are clear, and tie 'in the Community' to both manufacture and placing on the market.

^{23 —} All language versions have the same weight and this does not vary by reference to the size of the Member State using the language in question. Judgment of 2 April 1998, EMU Tabac and Others (C-296/95, EU:C:1998:152, paragraph 36).

39. Where there is divergence between the various language versions of a European Union legal text, the provision in question must be interpreted by reference to the general scheme and context of the rules of which it forms a part, and the provision's purpose.²⁴ Along with this, the origins of a provision of EU law may provide information relevant to its interpretation.²⁵ It is in the light of these principles that I will interpret the term 'placed on the market' in Article 5 of the REACH Regulation.

b) General scheme and context

40. Context in the interpretation of EU measures covers a number of different points of reference. It encompasses comparison with legislation that preceded the measure in issue but which that measure has repealed.²⁶ It encapsulates EU legislation that is related to or linked in some substantive way with the measure in question.²⁷ And it also appertains to the context of the provision concerned in relation to the other provisions of the EU instrument in which it is housed and the broad architecture of the latter.

41. With regard to the first of these, nothing significant can be read into the fact that two of the measures preceding the REACH Regulation, and which were repealed by it, contained clauses imposing an express territorial limitation to the EU internal market while the REACH Regulation itself does not.²⁸ As for the second, I do not view it as pivotal whether or not the REACH Regulation falls within the measures caught by the Commission's Notice 'the Blue Guide' of 2016 on the implementation of EU product rules,²⁹ and the assertion in this document that, for the purposes of EU harmonisation, a product is placed on the market when it is made available for the first time on the Union market.³⁰

42. This is so because I consider both of these as indicia of a rebuttable presumption that EU legislation which expressly regulates the placing of anything on 'the internal market' has the same meaning when reference is made in the same legislation to a placing 'on the market'. This presumption is rebuttable by application of the rules of interpretation of EU measures so that, for example, unambiguous reference to a particular geographic market other than the internal market would ordinarily be afforded its plain meaning.³¹

- 25 Judgment of 27 October 2016, Commission v Germany (C-220/15, EU:C:2016:815, paragraph 39).
- 26 E.g. Opinion of Advocate General Saugmandsgaard Øe in Carrefour Hypermarchés (C-562/15, EU:C:2016 781, paragraph 23) (pending).
- 27 For a detailed discussion see Beck, op. cit., note 21, at p. 193. See e.g. judgments of 16 July 1998, *Gut Springenheide and Tusky v* Oberkreisdirektor des Kreises Steinfurt (C-210/96, EU:C:1998:369, paragraphs 28 to 30), and of 27 September 2001, Bacardi (C-253/99, EU:C:2001:490, paragraph 50).
- 28 See Article 1(1) and Article 1(2)(b) of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201) and Article 1(1) of Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (OJ 1991 L 76, p. 35).
- 29 OJ 2016 C 272, p. 1 ('Blue Guide'). There is nothing in the ECHA Guidance concerning Article 5 of the REACH Regulation to suggest that Article 5 encompasses exports unregistered at import. I note that, in any event, ECHA guidance is not legally binding. See judgment of 10 September 2015, FCD and FMB (C-106/14, EU:C:2015:576, paragraphs 28 and 29), and the Opinion of Advocate General Mengozzi in Polynt v ECHA and Hitachi Chemical Europe and Polynt v ECHA (C-323/15 P and C-324/15 P, EU:C:2016:727).

^{24 —} Judgment of 18 September 2014, Vueling Airlines (C-487/12, EU:C:2014:2232, paragraph 31 and the case-law cited). See also judgments of 22 June 2016, Thomas Philipps (C-419/15, EU:C:2016:468, paragraph 18 and the case-law cited) and of 4 February 2016, Hassan (C-163/15, EU:C:2016:71, paragraph 19 and the case-law cited).

^{30 —} Blue Guide, ibid., p. 18.

^{31 —} On the relationship between literal meaning, purpose and context see judgment of 27 October 2016, Commission v Germany (C-220/15, EU:C:2016:815, paragraphs 37 to 39). Cf Opinion of Advocate General Bobek in Commission v Germany (C-220/15, EU:C:2016:534, particularly at point 38). If the literal meaning of a provision would lead to a nonsensical result it falls to be reappraised. See point of 37 the Opinion of Advocate General Bobek in European Federation for Cosmetic Ingredients (C-592/14, EU:C:2016:179) and case law cited.

43. However, words of this kind do not appear in Article 5 of the REACH Regulation, and the provisions of the REACH Regulation which suggest that it is intended to govern only chemical substances placed on the EU internal market outnumber to a considerable degree the indicia of an intent on the part of the EU legislator to regulate chemical substances placed on the markets of third States.

44. For example, recital 2 refers to 'the efficient functioning of the *internal market* for substances' (my emphasis) as a goal of the REACH Regulation,³² while Article 1, entitled 'Aim and scope', further provides that ensuring 'free circulation of substances on the internal market' is one of the REACH Regulation's purposes. Conspicuous in its absence in either the recitals or Title I entitled 'General issues' is an aim connected with regulation of chemical substances placed on the market of third States.

45. As noted above, there are other provisions of the REACH Regulation, aside from Article 5, which refer to substances being 'placed on the market' as opposed to the 'internal market', ³³ and I acknowledge that this drafting inconsistency is unfortunate. I also acknowledge that the definition of 'placing on the market' in Article 3(12) makes no express reference to the internal market. However, once a broad perspective is taken of the REACH Regulation, it can be seen that when recourse is made to 'placed on the market', or its temporal variations, it is usually narrowed by its context to the EU 'internal' market, thereby defining its scope *ratione materiae* to the exclusion of export of chemical substances that were not registered at import.

46. More specifically, throughout the text of the REACH Regulation the proximity of the phrase 'on the market' to another provision often confines the term to the parameters of the Union's internal market.³⁴ On other occasions, linkage of 'on the market' to an article of the REACH Regulation located in another Title leads to the same result.

47. Indeed, this occurs in Article 3(12), which states in its second sentence that import 'shall be deemed to be placing on the market'. This is so because 'import' is then defined in Article 3(10) as meaning 'the physical introduction into the customs territory of the Community'.

48. Article 56(1) in Title VII on authorisations states that a manufacturer, importer, or downstream user shall not place a substance 'on the market'. However, it is immediately preceded by Article 55, which refers to an aim of Title VII as being the good functioning of the internal market.

49. Article 56(1)(e), also in Title VII, allows a substance to be 'placed on the market' if authorisation has been granted to an immediate downstream user. However, the definition of downstream user in Article 3(13) is tied to natural or legal persons 'established within the Community'.

50. Article 68 in Title VIII on restrictions is entitled 'Introducing new and amending current restrictions'. It refers to unacceptable risks to human health and the environment arising from, inter alia, 'placing on the market', but then immediately refers to the need for a response to this 'on a Community-wide basis'.³⁵

^{32 —} Recitals in the preamble perform the dual role of both the construction of pertinent provisions and identifying the purpose of the measures in question. See Beck, op. cit., at p. 191.

^{33 —} See above, point 31.

^{34 —} For an example of recourse to schematic positioning in order to determine the meaning of a provision see the Opinion of Advocate General Stix-Hackl in *Transport Maatschappij Traffic* (C-247/04, EU:C:2005:277, points 20 to 25).

^{35 —} Thus, the references to 'placing on the market' in Article 69(1) and (4) of the REACH Regulation governing preparations for proposals by the Commission in the event of a risk to human health or the environment must equally be restricted to proposals that address a Community-wide response.

51. I also refer to Article 31(5) in Title IV on information in the supply chain. It carries an implication that 'placing on the market' means the internal market of the EU, given that the safety data sheet to which it refers is to be supplied in the relevant Member State language (unless the Member State/s concerned provide otherwise).

52. And finally, and most importantly, Article 5 itself falls to be interpreted as referring to the 'internal' market once due account is taken of Article 6. Article 5 must necessarily be read in the context of Article 6 because the first line of Article 5 says that it is subject to, inter alia, Article 6. Further, Article 5 goes on to say that registration is to take place in accordance with the relevant provisions of Title II where this is required. Article 6 of the REACH Regulation, which provides for registration of substances on their own or in mixtures, is the provision that appears to be relevant to the registration of the consignment in issue in this case.³⁶

53. Yet Article 6 addresses its registration obligations to 'any manufacturer or importer' and makes no reference to exporters. This is perhaps unsurprising, given that the definition of 'Registrant' in Article 3(7) is equally silent with respect to exporters, stating that registrant means 'the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance'.

54. Indeed, the REACH Regulation is overwhelmingly directed at the activities of importers and manufacturers, reference to whom is made over 40 times throughout the regulation.³⁷ In Article 1(3) on the REACH Regulation's aim and scope it is stated that: 'This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are under-pinned by the precautionary principle.' However, Article 1(3) imposes no obligations on exporters.

55. In relative terms, sparse reference is made throughout the REACH Regulation to the activities of exporters, and none of them support the thesis that export of chemicals to third States that were not registered at import into the EU amounts to a fresh and free-standing breach of Article 5.

56. Recital 7 is directed at the manufacturing of substances and refers to the goal of preserving the integrity of the internal market. Thus, the clause that ends recital 7 'even if those substances are exported' is designed to stop manufacturers based in the internal market from escaping the scope *ratione materiae* of the REACH Regulation by arguing that the chemical substances used in such processes are destined for export. I come to this conclusion because 'manufacturer' is defined in Article 3(9) of the REACH Regulation as 'any natural or legal person established within the Community who manufactures a substance within the Community'.

57. Moreover, there is a *lex specialis* in the REACH Regulation appertaining to chemicals that are registered in the EU, exported, and then re-imported. Article 2(7)(c) in Title I creates an exemption from Title II registration, Title V obligations on downstream users, and Title VI evaluation when the export is undertaken by an actor in the supply chain and re-imported into the EU by the same or another actor in the supply chain. This exemption is operative when such an actor shows that (i) the substance being re-imported is the same as the exported substance; and (ii) the actor has been provided with all relevant information in accordance with Articles 31 or 32 of the REACH Regulation relating to the exported substance.³⁸

^{36 —} There is nothing in the case file to suggest that the consignment amounts to a substance in an article as governed by Article 7. See generally judgment of 10 September 2015, *FCD and FMB* (C-106/14, EU:C:2015:576).

 $^{37\,-}$ Downstream users are also regulated extensively, but mostly in Title V.

^{38 —} Article 31 pertains to requirements concerning safety data sheets and Article 32 to the duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required.

58. Therefore, Article 2(7)(c) of the REACH Regulation is indicative of a scope *ratione materiae* with respect to export of chemical substances that is confined to those that are being re-imported. The same is suggested by Article 2(1)(b) of the REACH Regulation, which exempts substances under customs supervision from the regulation, provided they are, inter alia, intended for re-exportation or in transit, ³⁹ and by the fact that a separate EU regulation, namely Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals,⁴⁰ lays down specific rules and procedures for export of chemical substances which are banned or severely restricted within the EU.⁴¹

59. One commentary contends that given that 'REACH does not apply to chemical use outside the European Union, it makes sense to interpret this term to cover solely users located in the European Union. In a similar vein, the requirements triggered by placing on the market should be interpreted as applying only to placing on the EU market, not including non-EU markets.'⁴² I have come to the conclusion that a contextual analysis of Article 5 of the REACH Regulation supports this thesis.

c) Origins

60. The Court was referred to very little *travaux préparatoires* to the REACH Regulation that was indicative of an intention on the part of the EU legislature for the registration requirements of Article 5 of the REACH Regulation to cover exports unregistered at import.⁴³ Granted, Germany suggested a modification to draft Article 64(1) on banning and the restriction of substances so that it would refer to 'any supplying or making available' on the market. However, this proposal seemed to relate only to the Commission's proposal on bans and restrictions. Moreover, it also seemed to be aimed primarily at ensuring that banning and restriction rules apply on every occasion a chemical substance is put on the market, and not just the first time, rather than being concerned with exports. I acknowledge that the same document also attributes to Germany the view that the definition of placing on the market encompasses 'supplying a substance to a third party in another country (*"export"*)' (emphasis in original). However, it then adds that if 'there is no consensus on this point, it may also have to be clarified'.⁴⁴

61. When the clarification came, it occurred at the post-legislative stage, with the Commission explaining why it was of the view that 'placing on the market' in Article 3(12) of the REACH Regulation refers to the placing of chemical substances on the EU market.⁴⁵ Germany rejected this view.⁴⁶

62. Thus, on its own, this material is insufficient to establish an intention on the part of the EU legislature for third State markets to be included in the term 'placed on the market' in Article 5 of the REACH Regulation,⁴⁷ and nor, I would add, can the same be inferred from the text of the Commission's proposal.

- 39 See also recital 10. I take the view that Annex XVII of REACH, as amended by Regulation No 552/2009, in so far as it precludes the application to exports under REACH of restrictions imposed by Directive 76/769 supports this interpretation.
- 40 OJ 2012 L 201, p. 60.
- 41 See Commission Document CA/20/2012 of 9 March 2012 on the 10th Meeting of the Competent Authorities for REACH and CLP (CARACAL), p. 2.
- 42 Bergkamp, L., and Herbatschek, K., 'Key concepts and Scope', in Bergkamp, L. (ed), op. cit., p. 40 at p. 73.
- 43 The importance of the origins of a provision to its interpretation were mentioned recently by the Court in judgment of 27 October 2016, Commission v Germany (C-220/15, EU:C:2016:815, paragraph 39).
- 44 Council Working Document 168/05, Ad-hoc Working Party on Chemicals, 30 May 2005, p. 3.
- 45 On the Commission's position see Doc CA/20/2012, 9 March 2012, 10th Meeting of the Competent Authorities for REACH and CLP (CARACAL) 21-22-23 March 2012.
- 46 10th CARACAL meeting follow up. German comment on document CA/20/2012, 'Clarification on the concept of placing on the market'.
- 47 It is further contended in the written observations of the Commission that the term 'placed on the market' was inserted into Article 5 of the REACH Regulation after a proposal for amendment put forward by the Dutch Government, and which was not concerned with bringing exports unregistered at import within the rubric of the REACH Regulation. The Commission refers to the following; Council of the European Union DG C I, Working Document 214/05 (Ad hoc Working Party on Chemicals), Brussels, 11 July 2005.

d) Purpose

63. Indeed, the Court stated recently in *Canadian Oil Company Sweden and Rantén* (C-472/14, EU:C:2016:171) that the 'cardinal principles' governing the REACH Regulation's integrated system for monitoring chemical substances were presented by the European Commission in the introduction to its Proposal for a Regulation COM(2003) 644 final of 29 October 2003. The Court stated as follows:

'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".'⁴⁸

64. The inclusion of chemical substances that are destined to leave the customs area of the EU after initial importation without registration is not logically consistent with the achievement of any of the REACH Regulation's post registration objectives of evaluation, authorisation and restriction. This is so not least because of the practical difficulties the ECHA would have, or indeed any other EU or Member State body, in monitoring and managing the substances once they have left the customs area of the EU, and because the Court has held that 'the principal objective' of the REACH Regulation is to monitor chemical substances, whether present by themselves or in a mixture.⁴⁹

65. As was pointed out by the City of Hamburg at the hearing, once the consignment is in Russia, the City of Hamburg will not be in a position to put its hands on it. There is an absence, in other words, of provisions in the REACH Regulation empowering and enabling either EU or Member State authorities to manage and monitor chemicals that have been placed on third State markets. An interpretation of Article 5 of the REACH Regulation to support the *effet utile* of such an end would therefore appear unwarranted.⁵⁰

66. I note, therefore, that the case to hand differs from the problem recently considered by the Court in the judgment of 21 September 2016, *European Confederation for Cosmetic Ingredients* (C-592/14, EU:C:2016:703) where testing on animals of cosmetic ingredients that took place outside of the EU was held to fall within the purview of Article 18(1)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.⁵¹ This ruling was made in the context of an application by a trade association representing the manufacturers within the European Union of ingredients for use in cosmetic products to determine the possible exposure of its members to criminal penalties if they were to place on the UK market cosmetic products containing ingredients that have been the subject of animal testing outside the EU. Thus, there was no question of the EU lacking the practical means to regulate the testing on animals of the ingredients, given that regulation was only to commence at import.

^{48 —} Paragraph 25, citing the judgment of 10 September 2015, FCD and FMB (C-106/14, EU:C:2015:576, paragraph 32).

^{49 —} Judgment of 10 September 2015, FCD and FMB (C-106/14, EU:C:2015:576 paragraph 49). In the judgment of 13 May 2014 in, Google Spain and Google (C-131/12, EC:C:2014:317, paragraph 54) the Court held 'the European Union legislature sought to prevent individuals from being deprived of the protection guaranteed by the directive [in issue in that case] and that protection from being circumvented, by prescribing a particularly broad territorial scope.' Application of the rules of interpretation of EU legislation shows that the same cannot be concluded with respect to the REACH Regulation.

^{50 —} On the role of *effet utile* in the interpretation of EU measures see the Opinion of Advocate General Bobek in *Commission* v *Germany* (C-220/15, EU:C:2016:534, point 33 and the case-law cited).

^{51 —} OJ 2009 L 342, p. 59

67. It is true that Article 106 of the REACH Regulation provides for participation of third countries in the work of the ECHA, that Article 107 of the REACH Regulation furnishes a facility for representatives of international organisations to participate as observers in the work of the ECHA, that Article 120 of the REACH Regulation addresses cooperation with third countries and international organisations, and that Article 77(2) (a) of the REACH Regulation obliges the ECHA Secretariat to facilitate registration of imported substances under Title II in a way that is consistent with the EU's international obligations toward third countries.

68. I also acknowledge both the international environmental instruments mentioned in the REACH Regulation, namely the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development (recital 4) and the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai (recital 6).

69. However, none of the abovementioned provisions of the REACH Regulation, or any instrument concerned with international environmental protection relied on in this case,⁵² establishes a commitment on the part of the European Union to assume authority over chemical substances exported beyond its customs area.⁵³ Once that boundary had been breached, the EU is necessarily restricted, at minimum in practical terms, in what it is able to do to ensure a high level of protection of human health and the environment, as provided in Article 1(1) and recitals 1 and 3 of the REACH Regulation.⁵⁴

70. This leads to the conclusion that if Article 5 of the REACH Regulation as currently drafted is 'less than coherent and is inappropriate for the purposes' it seeks to achieve, then it is for the EU legislature 'to take steps in that regard and adopt suitable measures',⁵⁵ particularly given the complex repercussions that would follow if the REACH Regulation were to extend, *ratione materiae*, to exports unregistered at import.⁵⁶

^{52 —} Germany also made reference to 'Agenda 21', a non-binding, voluntarily implemented action plan of the United Nations with regard to sustainable development that was a product of the Earth Summit (UN Conference on Environment and Development) held in Rio de Janeiro, Brazil, in 1992 (http://www.unep.org/Documents.Multilingual/Default.asp?documentid=52).

^{53 —} On resort to international instruments concluded by the EU as an aid to interpretation see e.g. judgment of 11 April 2013, *HK Danmark* (C-335/11 and C-337/11, EU:C:2013:222, paragraphs 37 and 39).

^{54 —} The vexed question of extra-territorial jurisdiction under EU law is presently before the Court. See, in the context of competition law, the Opinion of Advocate General Wahl in *Intel Corporation* v *Commission* (C-413/14 P, EU:C:2016:788). See also the Opinion of Advocate General Wathelet in *InnoLux* v *Commission* (C-231/14 P, EU:C:2015:292).

^{55 —} See judgment of 23 March 2000, *Met-Trans and Sagpol* (C-310/98 and C-406/98, EU:C:2000:154, paragraph 47). This applies also to the national referring court's concerns with respect to Articles 21 and 23 of the REACH Regulation.

^{56 —} Germany and the City of Hamburg expressed concerns that EU law provides insufficient safeguards to prevent the import into the EU of foodstuffs contaminated outside the EU by dangerous chemicals. This is contested by the Commission, which refers in its written observation to Regulation 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs OJ 2004 L 139, p. 1, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ 2004 L 139, p. 55), and Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ 2005 L 70, p. 1). This is the type of multi-faceted problem which is best left for resolution by the EU legislature, as is the complex question of striking the balance between the EU's commitment to a high level of human health and environmental protection and its oblations to the World Trade Organisation, given the delicacy of concerns about REACH registration requirements that have been raised by the EU's international trading partners in the WTO's Technical Barriers to Trade Committee. For a recent discussion see Korkea-aho, E., 'Effects of the EU Chemicals Regulation REACH in a globalized internal market', 53 (2016), *Common Market Law Review* 764.

C – Article 126 of the REACH Regulation

71. It is not in dispute that the City of Hamburg has not sought a court order requiring registration of the consignment under Articles 5 and 6 of the REACH Regulation. According to the order for reference, it is possible to compel such registration under German administrative law, and as long ago as 2009, in the first order for reference concerning the REACH Regulation, one of the Court's Advocates General observed that 'the registration of substances serves precisely to improve knowledge of the risks associated with them.'⁵⁷

72. This situation is rendered troubling by the fact that, as noted above, if the criminal proceedings did not concern the consignment in issue in this case, then the infraction of Article 5 of the REACH Regulation that occurred at import may yet have to be corrected with an effective, proportionate and dissuasive remedy, as required by Article 126 of the REACH Regulation. Moreover, as pointed out in the written observations of the Commission, Mr Pinckernelle may have violated the REACH Regulation on several separate counts.⁵⁸

73. In the light of the high level of health and environmental protection required by Article 1 (1) of the REACH Regulation and recitals 1 and 3, and the high level of environmental protection and improvement of the quality of the environment that is integrated into EU policies by virtue of Article 37 of the Charter of Fundamental Rights of the European Union, ⁵⁹ Article 126 of the REACH Regulation obliges Member States to ensure that the sanctions deployed to enforce the REACH Regulation reflect the seriousness of the failure to adhere to it, ⁶⁰ the discretion afforded to Member States with respect to remedies in the absence of their harmonisation notwithstanding. ⁶¹ Further, infraction of the REACH Regulation must be penalised under conditions, both procedural and substantive, which are analogous to those applicable to national laws of a similar nature. ⁶² Taken as a whole, the system of remedies must be dissuasive. ⁶³

^{57 —} Opinion of Advocate General Kokott in S.P.C.M. and Others (C-558/07, EU:C:2009:142, point 82). See also judgment of 7 July 2009, S.P.C.M. and Others (C-558/07, EU:C:2009:430, paragraph 52).

^{58 —} The Commission refers to importation without registration in breach of Article 5; failure to complete a chemical safety report in breach of Article 14; selling nicotine sulphate to clients in Germany, the Netherlands and Poland without filling out the safety data sheet as required by Article 31; and usage through storage of nicotine sulphate under Article 3(24) of the REACH Regulation, which should not have occurred until after registration. See also the requirements imposed by Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

^{59 —} See also Article 191(2) TFEU and Article 3(3) TEU. For a recent analysis of the meaning of a 'high level of environmental protection' in EU policy see Opinion of Advocate General Kokott in *Associazione Italia Nostra Onlus* (C-444/15, EU:C:2016:665; points 24 to 35).

^{60 —} Judgments of 9 November 2016, Home Credit Slovakia (C-42/15, EU:C:2016:842, paragraph 63), and of 9 June 2016, Nutrivet (C-69/15, EU:C:2016:425, paragraphs 48 to 56).

^{61 —} Judgment of 26 November 2015, Total Waste Recycling (C-487/14, EU:C:2015:780, paragraph 52).

^{62 —} E.g. judgments of 27 March 2014, LCL Le Crédit Lyonnais (C-565/12, EU:C:2014:190, paragraph 44), and of 13 November 2014, Reindl (C-443/13, EU:C:2014:2370, paragraph 38).

^{63 —} Judgment of 27 March 2014, LCL Le Crédit Lyonnais (C-565/12, EU:C:2014:190). For a recent commentary on penalty clauses see Ensig Sorensen, K., 'Member States' Implementation of Penalties to Enforce EU Law: Balancing the Avoidance of Enforcement Deficits and the Protection of Individuals', 40 (2015), <u>ELRev</u> 811.

74. Therefore, the competent authorities of the Member States may deploy any or all of the following to correct non-registration under the REACH Regulation.⁶⁴ The means resorted to will inevitably vary depending on all the circumstances to hand. Such means include (i) orders compelling registration; (ii) any necessary interim orders,⁶⁵ such as, for example, orders impounding the chemicals pending the termination of remedial processes so that, in practical terms, they cannot be exported; (iii) the levying of fines, and (iv) in severe cases the imposition of criminal sanctions.⁶⁶

75. The application of Member State remedial regimes to the end of enforcing the REACH Regulation is, of course, subject to compliance with the fundamental rights protected under the EU Charter,⁶⁷ and general principles of law such as the principal of proportionality. This means that the sanction or sanctions chosen must be appropriately adapted to achieve the aims of the REACH Regulation, and must not go beyond what is necessary to secure them.⁶⁸ It is at this juncture that a trader can argue, for example, that registration imposes disproportionate costs or that the sanction chosen by the Member State authority is otherwise excessive.

76. Finally, I underscore that the principles I have here mapped out apply equally to imports that will be traded on the EU internal market as they do to imports into the EU that are intended for export to third States, as required by the commitment to non-discrimination set out in the second sentence of recital 3 of the REACH Regulation.

77. Thus, while I acknowledge the concerns of Germany and the City of Hamburg to the effect that interpreting 'placed on the market' in Article 5 of the REACH Regulation to the exclusion of export of chemical substances unregistered at import might open a door to rogue importers wilfully breaching EU chemical registration requirements in the knowledge they can simply export, this eventuality would seem to be avoided by rigorous application of Articles 5, 6, 7 and 126 of the REACH Regulation combined.

IV – Conclusion

78. In the light of all the foregoing considerations, I am of the opinion that the Court should answer the question raised by the Bundesverwaltungsgericht (Federal Administrative Court, Germany) to the following effect:

Article 5 of Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning 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 Di rective 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC

64 — Details of the means employed by Member States enforce REACH available the web to are on site of Directorate General XI of the European Commission. See http://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf.

See http://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf. See also Milieu Ltd 'Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States'

See also Milieu Ltd Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm#top-page.

65 — Judgment of 10 September 2014, Kušionová (C-34/13, EU:C:2014:2189, paragraph 67).

66 — On the co-existence of national chemical registration requirements and EU chemical registration requirements see judgment of 17 March 2016, *Canadian Oil Company Sweden and Rantén* (C-472/14, EU:C:2016:171) and the Opinion of Advocate General Sharpston (EU:C:2015:809, particularly paragraph 41). There The Advocate General observes that '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'.

67 — See e.g. judgment of 30 June 2016, Toma and Biroul Executorului Judecătoresc Horațiu-Vasile Cruduleci (C-205/15, EU: 2016 499, paragraph 46); judgment of 30 June 2016, C-200/14 Câmpean (EU:C:2016, paragraph 70); judgment of 10 September 2014, C-34/13 Kušionová EU:C:2014:2189, paragraphs 45 to 47).

68 — For a recent example of the application of the principle of proportionality to a remedy aimed at sanctioning a wrong harming the environment see paragraph 44 of judgment of 29 April 2015, *Nordzucker* (C-148/14, EU:C:2015:287) : 'It is for the competent national authorities to have regard to all the considerations of fact or law specific to each case in order to determine whether a penalty must be imposed on an operator and, where appropriate, which penalty. That assessment requires, in particular, that the behavior of the operator be taken into account, as well as its good faith or its fraudulent intentions.'

and 2000/21/EC (OJ 2006 L 396, p. 1), as amended by Commission Regulation (EC) No 552/2009 of 22 June 2009, is to be interpreted as meaning that, subject to all the requirements of Articles 6, 7, 21, 23, and 126 of the REACH Regulation, substances may be exported out of the European Union that have not been registered in accordance with the relevant provisions of Title II of the REACH Regulation.