REPORT FOR THE HEARING

in Case E-9/16

APPLICATION to the Court pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice in the case between

EFTA Surveillance Authority

and

The Kingdom of Norway

seeking a declaration that by maintaining in force a national provision, such as section 2, paragraph 32, of the Norwegian Product Regulation, which bans the manufacture, import, export and sale of consumer products containing 0.001% or more by weight of perfluorooctanoic acid, Norway has breached its obligation arising from the Act referred to at point 12zc of Chapter XV of Annex II of the Agreement on the European Economic Area (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 EEA Supplement 2012 No 35, p. 79)), as adapted by way of Protocol 1 thereto, and/or its obligations under the EEA Agreement.

I Introduction

1. The EFTA Surveillance Authority ("ESA") contends that, by maintaining in force a national regulation prohibiting the manufacture, import, export and sale of consumer products containing 0.001% or more by weight of perfluorooctanoic acid, Norway has breached its obligations under 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 EEA Supplement 2012 No 35, p. 79) (the "REACH

Regulation") and/or its obligations under the Agreement on the European Economic Area ("EEA").

2. Norway contests the action.

II Legal background

EEA law

3. Article 3 EEA reads:

> *The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.*
>
> *They shall abstain from any measure which could jeopardize the attainment of the objectives of this Agreement.*
>
> *Moreover, they shall facilitate cooperation within the framework of this Agreement.*

The REACH Regulation

4. The REACH Regulation was incorporated into the EEA Agreement at point 12zc of Chapter XV of Annex II to the Agreement by EEA Joint Committee Decision No 25/2008 of 14 March 2008.[1] Constitutional requirements were indicated and the decision entered into force on 5 June 2008.

5. Recital 1 in the preamble to the REACH Regulation reads:

> *This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.*

6. Recital 2 in the preamble to the REACH Regulation reads:

> *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] OJ 2008 L 182, p. 11, and EEA Supplement 2008 No 42, p. 6.

7. Recital 70 in the preamble to the REACH Regulation reads:

Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance. Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur. For any substance for which authorisation has been granted, and for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects. Measures to ensure adequate control should be identified in any Chemical Safety Report. These measures should be applied and, where appropriate, recommended to other actors down the supply chain.

8. Article 1(1) of the REACH Regulation reads:

(1) 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.

9. Point (31) of Article 3 of the REACH Regulation reads:

For the purposes of this Regulation:

…

(31) Restriction: means any condition for or prohibition of the manufacture, use or placing on the market;

10. Article 68(1) of the REACH Regulation reads:

(1) 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 in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture,

use or placing on the market of substances on their own, in mixtures[2] or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

11. Article 69 of the REACH Regulation reads in extract:

(1) If the Commission 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, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XV.

(2) After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.

(3) Within 12 months of the receipt of the request from the Commission in paragraph 1 and if this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

(4) 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 it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If the substance is not on the list maintained by the Agency referred to in paragraph 5 of this Article, the Member State shall prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XV, in order to initiate the restrictions process.

The Agency or Member States shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or Member State under this Regulation.

[2] In a previous version of the Regulation, the word "preparations" was used. In the consolidated version in force at the expiry of the period for replying to ESA's reasoned opinion, the word "preparations" had been replaced by "mixtures". This change is relevant for Articles 68(1), 69(1), 69(4), 128(1) and 129(1) of the REACH Regulation.

The Agency or Member States shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or Member State concerned on request.

The Committee for Risk Assessment and the Committee for Socioeconomic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XV. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a Member State to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance.

12. Article 128 of the REACH Regulation reads:

(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.

13. Article 129(1) of the REACH Regulation reads:

(1) Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a mixture or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.

III Factual background

14. Perfluorooctanoic acid ("PFOA") is a synthetic chemical used as a processing aid in the manufacture of fluoropolymers, as well as the photographic and imaging industry.

15. On 27 May 2013, Norway adopted Section 2-32 of Regulation No 922 of 1 June 2004 relating to restrictions on the use of chemicals and other products hazardous to health and the environment ('the Norwegian Product Regulation'), making it illegal, from 1 June 2014:

> (1) to manufacture, import, export and sell consumer products containing PFOA and certain salts and esters of PFOA as a pure substance or in a mixture when the mixture contains 0.001% or more of the chemical.
>
> (2) to manufacture, import, export and sell textiles, carpets and other coated consumer products where the content of PFOA, and certain salts and esters of PFOA, is present in amounts equal to or greater than 1$\mu g/m^2$ (one microgram per square meter).
>
> (3) to manufacture, import, export and sell consumer products containing PFOA, and certain salts and esters of PFOA, when the content of the substance in the product's individual components is greater than or equal to 0.1% of weight.

16. These prohibitions apply from 1 January 2016 for a) adhesive, foil or tape in semiconductors, and b) photographic coatings for film, paper or screen. The prohibitions do not apply to food packaging, materials in direct contact with food and medical equipment, nor do they apply to spare parts for consumer products that were made available for sale before 1 June 2014.

17. On 27 May 2014, amendments were made to Section 2-32 of the Norwegian Product Regulation in order to allow products which were manufactured before the ban entered into force to remain on sale until 1 January 2018.

18. On 27 May 2014, Norway amended Section 2, paragraph 32, of the Norwegian Product Regulation in order to allow products which were manufactured before the ban entered into force to remain on sale until 1 January 2018.

19. On 19 February 2014, Norway, together with Germany, notified the European Chemicals Agency ("ECHA") of their intention to submit an Annex XV dossier, under Article 69(4) of the REACH Regulation, proposing an EEA-wide restriction of PFOA. The dossier was formally submitted on 17 October 2014.

20. Furthermore, following Norway's submission of a dossier prepared under Annex VI to Regulation (EC) no 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, and EEA Supplement 2016 No 54, p. 1) (the "CLP Regulation") with a view to having PFOA classified as toxic for reproduction, the Committee for Risk Assessment ("RAC") concluded, by decision of 2 December 2011, that PFOA should be classified as toxic for reproduction category 1B in accordance with the CLP Regulation. PFOA was introduced in Annex XVII to the REACH Regulation (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles) with effect from 1 January 2015, by Commission Regulation (EU) No 317/2014 of 27 March 2014, amending REACH as regards carcinogenic, mutagenic or reproductive toxicant substances ("CMR substances") (OJ 2014 L 93, p. 24). That regulation was inserted to point 12zc of Chapter XV of Annex II to the EEA Agreement by EEA Joint Committee Decision No 180/2015 of 10 July 2015, which entered into force on 11 July 2015.

21. On 25 September 2015, the first prohibition mentioned in paragraph 17 above was removed from Section 2-32 of the Norwegian Product Regulation in order to implement Regulation (EU) No 317/2014. The other prohibitions remained unchanged.

IV Pre-litigation procedure

22. On 27 August 2013, the Norwegian Government informed ESA that it had amended the Norwegian Product Regulation by the introduction of restrictions on the manufacture, import, export and sale of consumer products containing PFOA and certain salts and esters of PFOA on 27 May 2013.

23. Draft regulations to introduce a ban on PFOA in consumer products had previously been submitted to ESA in the context of the draft technical regulations procedure laid down under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1998 L 204, p. 37, and EEA Supplement 2001 No 3, p. 198) ("Directive 98/34/EC"), first in 2007 and then again in 2010. ESA issued comments on both of these draft regulations, questioning the compatibility of the proposed Norwegian regulations with existing harmonised EEA legislation applicable to products intended for use by consumers.

24. On 30 October 2013, ESA sent a "pre-Article 31 letter" to Norway setting out its concerns regarding the prohibition on PFOA. Norway replied by letter of 10 January 2014. The prohibition was further discussed during package meetings in Oslo in 2013 and 2014.

25. On 14 January 2015, ESA sent Norway a letter of formal notice, concluding that Norway had failed to fulfil its obligations under the REACH Regulation by maintaining in force Section 2-32 of the Norwegian Product Regulation, and/or its obligations under the EEA Agreement. On 15 April 2015, Norway submitted to ESA its formal observations on the letter of formal notice, rejecting the view adopted by ESA.

26. On 8 July 2015, ESA delivered its reasoned opinion, maintaining the conclusions set out in its letter of formal notice. Pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice ("SCA"), ESA required Norway to take the measures necessary to comply with the reasoned opinion within two months following the notification, that is, no later than 8 September 2015.

27. On 16 October 2015[3], Norway responded to the reasoned opinion, maintaining its position and providing some additional comments. In its response, Norway explained that it had repealed the part of Section 2-32 concerning PFOA as a substance or mixture, as a consequence of the implementation of Regulation (EU) No 317/2014. However, the remaining prohibitions against products containing certain concentrations of PFOA were upheld.

V Procedure and forms of order sought by the parties

28. On 5 August 2016, ESA brought an action under the second paragraph of Article 31 SCA requesting the Court to declare that:

1. *By maintaining in force a national provision such as section 2, paragraph 32, of the Norwegian Product Regulation which bans the manufacture, import, export and sale of consumer products containing certain concentrations of perfluorooctanoic acid (PFOA), Norway has failed to fulfil its obligations arising from the Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement (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), in particular Article 128(1) thereof, as adapted to the EEA Agreement by Protocol 1 thereto.*

2. *In the alternative, by maintaining in force a national provision such as the aforementioned one once the restriction process under Title VIII of the aforementioned Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement has been initiated, Norway has failed to fulfil its obligations arising from Article 3 of the EEA Agreement read together with Article 128(1) of that Act.*

[3] The parties agree that the date at which any infringement needs to be determined is 16 October 2015, the date on which the extended period for reply to the Reasoned Opinion granted to Norway expired.

3. *By maintaining in force a national provision such as aforementioned one, Norway has failed to fulfil its obligations arising from Article 11 of the EEA Agreement.*

4. *The Kingdom of Norway bears the costs of the proceedings.*

29. On 20 October 2016, Norway submitted a statement of defence, contesting the application and requesting the Court to dismiss the action as unfounded and order ESA to pay the costs.

30. On 21 November 2016, ESA submitted its reply. On 22 December 2016, Norway submitted its rejoinder.

31. The European Commission ("the Commission"), as well as the Government of the Federal Republic of Germany, submitted written observations on 20 December 2016. The Swedish Government submitted written observations on 21 December 2016.

32. By letter of 16 February 2017, reacting to the present Report for the Hearing, ESA has informed the Court of the withdrawal of its third plea. It nevertheless maintains that it should be awarded the costs in respect of the third plea, as the withdrawal is, in its view, essentially due to the conduct of Norway (with reference to Article 66(5) of the Rules of Procedure, by analogy). For the sake of completeness, the arguments relating to the third plea are kept in this Report.

VI Written procedure before the Court

33. Written arguments have been received from the parties:

- ESA, represented by Carsten Zatschler and Auður Ýr Steinarsdóttir and, subsequently, by Carsten Zatschler and Marlene Lie Hakkebo, Members of the Legal and Executive Affairs Department, acting as Agents;

- Norway, represented by Ketil Bøe Moen, Advocate, Office of the Attorney General (Civil Affairs), and Ingunn Skille Jansen, Senior Adviser, Department of Legal Affairs, Ministry of Foreign Affairs, acting as Agents.

34. Pursuant to Article 20 of the Statute of the Court and Article 97 of the Rules of Procedure, written observations have been received from:

- the Commission, represented by Ken Mifsud-Bonnici and Emmanuel Manhaeve, Members of the Legal Service, acting as Agents;

- the Swedish Government, represented by Anna Falk, Director, and Hanna Shev, Senior Legal Adviser, acting as Agents; and

- the German Government, represented by Thomas Henze and David Klebs, Federal Ministry for Economic Affairs and Energy, acting as Agents.

VII Summary of the pleas in law and arguments submitted to the Court

ESA

Introductory remarks

35. ESA seeks to obtain clarification that once a substance has been identified as posing an uncontrolled risk to the environment and human health, unilateral national regulation of substances covered by the REACH Regulation is permissible only in certain narrowly defined circumstances, provided for under that Regulation. The REACH Regulation harmonises the restriction process itself, depriving EEA States of the possibility of acting unilaterally. It is thus not open to EEA States to unilaterally bypass the harmonised restriction process provided for in Articles 68 and 69 of the REACH Regulation, which would jeopardise the uniform high level of protection of human health and the environment, as well as the free movement of substances which the REACH Regulation was adopted to ensure.

36. ESA in no way seeks to question the necessity of regulating PFOA as a substance. Rather, the present infringement action concerns a procedural matter. When an EEA State identifies a risk to health or the environment arising from a substance covered by the REACH Regulation, it is essential for the functioning of the system established by that Regulation that those concerns are acted upon within its framework and not by means of unilateral action. The latter results in a hindrance to the free movement of substances within the internal market, sought to be ensured by the Regulation as a whole, and in particular by the free movement clause in Article 128. It also undermines the achievement of the health and environmental protection objectives of the REACH Regulation, by removing any incentive on individual EEA States to share their dossiers through the REACH system so as to ensure equally high protection throughout the internal market.

Unilateral action is precluded where the REACH restriction procedure is available

37. In ESA's view, a unilateral prohibition of a chemical substance by an EEA State is precluded where the substance at issue is covered by the REACH Regulation and the restriction procedure provided for therein is available.

38. ESA submits that Article 128(1) of the REACH Regulation guarantees the free movement of products within the scope of and compliant with the Regulation, harmonising the treatment of those substances and thus preventing EEA States from prohibiting, restricting or impeding the manufacturing, import, placing on the market or use of such products. The procedure outlined in Articles 68 to 73 of the REACH Regulation must be

read in light of this provision. Consequently, a decision by any EEA State to impose restrictions on PFOA, which undisputedly falls within the scope of Article 128(1) of the REACH Regulation, requires the use of the restriction procedure laid down in that Regulation.

39. According to ESA, Article 69(4) of the REACH Regulation is equally clear. If an EEA State considers that a substance presents a risk to human health or the environment that is not adequately controlled, notification to ECHA and subsequent preparation of an Annex XV dossier are mandatory. This mechanism is compulsory, thereby depriving EEA States of the possibility of addressing uncontrolled risks through unilateral national restriction measures, unless the restriction procedure under Title VIII of the REACH Regulation has been triggered. Only after it has been decided, on the basis of a dossier of that kind, that EEA-wide action is not necessary, can national restrictions be introduced. If the restriction mechanism is not triggered by way of the notification, no restrictions can be imposed, with the exception of situations of urgency provided for in the safeguard clause of Article 129 of the REACH Regulation. The 12-month deadline for the preparation of a dossier after notification is reasonable since EEA States are expected to have solid evidence for any concerns before triggering the restriction mechanism.

40. Moreover, EEA States are obliged to initiate the restriction procedure under the first sentence of Article 69(4) of the REACH Regulation if they consider that a substance poses a risk that is not adequately controlled and needs to be addressed. Whether that risk needs to be assessed at EEA or national level is to be assessed under the REACH procedure and not unilaterally by the EEA State concerned. National action is only possible once it is clear that EEA-wide action is not necessary. This is essential for achieving harmonisation.

41. On the other hand, the fact that the restriction procedure in Articles 68 to 73 of the REACH Regulation has not yet led to any specific restrictions by no means implies that the substance at issue falls outside the scope of REACH system, leaving the field open to national regulation and restrictions. That would counteract the objective of the REACH Regulation to ensure free circulation of substances in the internal market. Its provisions should thus be read in light of its object and purpose, which is to provide a single, comprehensive and over-arching system for the regulation of chemical substances in the EEA.

42. While it is true that Norway, together with Germany, submitted an Annex XV dossier to ECHA on 17 October 2014, the unilateral national restrictions pre-date such action and the provisions of Section 2-32 of the Norwegian Product Regulation constitute restrictive measures in light of Article 128(1) of the REACH Regulation. For the REACH system to work efficiently, all the parties involved should respect the processes under the Regulation, refraining from engaging in unilateral action.

43. Unilateral national measures are only allowed under the REACH system in cases where an EEA State believes there is an urgent need for action, using the safeguard

provisions of Article 129 of the REACH Regulation. That clause was, however, never invoked by Norway. Instead, Norway has invoked Article 128(2) of the REACH Regulation to justify its conduct.

44. ESA contends that Article 128(2) of the REACH Regulation does not apply to the facts of the case. In its view, this paragraph is intended to address merely two specific situations. First, to address cases in which the REACH Regulation itself contained no harmonisation of the requirements of manufacture, placing on the market or use in the transitional period when it was introduced. Second, in order to regulate substances more strictly for reasons not covered by the REACH Regulation, subject to the general free movement provisions of the EEA Agreement.

45. Thus, according to ESA, Article 128(2) of the REACH Regulation is evidently required as a transitional measure to allow the maintenance of restrictions existing prior to the introduction of the REACH system. Although comprehensive, the REACH Regulation is not a measure of universal application. There are broad areas in which it does not provide for harmonisation, as follows from the list of exceptions contained in Article 2 (where PFOA is not mentioned). Moreover, insofar as Article 128(2) is an exception to the free movement of substances specified in Article 128(1), it is to be interpreted narrowly. Permitting its application in general terms would limit any harmonisation under the REACH Regulation to substances already subject to restriction under its regime.

46. Furthermore, from a systematic point of view, it would seem strange if Article 128(2) of the REACH Regulation could be relied upon generally by EEA States in order to introduce new regulations in non-urgent situations more easily and subject to fewer checks by the Commission or ESA than those provided for under the safeguard clause in Article 129 of the REACH Regulation. The latter requires EEA States wishing to take unilateral action to immediately inform the Commission (or ESA as appropriate), ECHA and the other EEA States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. The Commission or ESA is then bound to take a decision on the matter within 60 days and may require the State concerned to revoke the provisional measure. Moreover, Article 129(3) of the REACH Regulation expressly requires the submission of an Annex XV dossier if the Commission or ESA authorises a provisional measure. If Norway's reading of Article 128(2) of the REACH Regulation were correct, it would deprive Article 129 of the REACH Regulation of its field of application.

47. ESA disputes the Norwegian Government's contention that harmonisation can be achieved only by the establishment of a restriction by means of an Annex XVII entry and not simply through the availability of the restrictions procedure provided for in Title VIII. Likewise, it disagrees with the Norwegian Government's argument that were a State's discretion to introduce national legislation to exist only in the exceptional circumstances envisaged by Article 129 of the REACH Regulation, Article 128(2) of the REACH Regulation would be deprived of "its proper purpose".

48. According to ESA, Articles 68(1) and 69(4) of the REACH Regulation set out the exhaustive character of the harmonising effect of both the restriction process and its outcome (entry into Annex XVII to the REACH Regulation). Consequently, in its view, the fact that PFOA was not added to Annex XVII following a procedure under Title VIII has no bearing on the applicability of the exception provided for in Article 128(2) of the REACH Regulation due to the harmonising effect of the restriction procedure itself.

49. ESA notes that Norway relies on the judgment of the Court of Justice of the European Union ("ECJ") in Case C-473/98 *Kemikalieinspektionen and Toolex Alpha AB ("Toolex")*.[4] That case arose from a challenge to the Swedish decision to ban trichloroethylene, which had been classified as a category 3 carcinogen under 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 1967 196, p. 234). In its judgment, the ECJ upheld the ban on the basis that it was necessary to protect human life, despite uncertainties surrounding the substance in question. According to ESA, however, the scope of the legislation at issue in the present case is clearly distinct from that of the REACH Regulation, since the former laid down only minimum requirements and did not harmonise the conditions under which substances could be marketed.

50. Specifically, ESA argues that Norway's reliance on paragraphs 31 and 32 of *Toolex*, which deal with Council Regulation (EC) No 793/93 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1) ("Regulation (EC) No 793/93"), an instrument introducing a system for evaluating the risks related to chemical substances, is misplaced. Unlike the REACH Regulation, Regulation No 793/93 did not harmonise rules on the use of substances in general. As is apparent, REACH is fundamentally different to the previous EU legislation in this field, as can be seen from the fact that it contains an express free movement clause as it also applies to substances considered benign. The fundamental differences in the scope of these instruments thus dictate that *Toolex* cannot be used to support Norway's claims, nor is it in any way helpful to address the issues in the present case.

51. Consequently, Norway has not produced any convincing legal arguments as to why unilateral measures were necessary in the case of PFOA. In those circumstances, ESA contends that the restrictions procedure under Title VIII of the REACH Regulation deprives EEA States of the possibility, following the identification of a substance posing an uncontrolled risk to the environment and human health, to address such uncontrolled risks through unilateral national measures. By keeping in force a national legal provision such as section 2, paragraph 32, of the Norwegian Product Regulation, Norway has breached its obligations under Article 128(1) of the REACH Regulation.

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[4] Judgment in C-473/98, *Toolex*, EU:C:2000:379.

Unilateral action is precluded when the REACH restriction procedure is triggered

52. Alternatively, in the event that the Court concludes that the restriction procedure itself under Title VIII of the REACH Regulation does not have a harmonising effect, ESA submits that Norway is in breach of Article 3 EEA, read in conjunction with Article 128(1) of the REACH Regulation. The initiation of the restriction procedure represents a point of departure for EEA action, which implies that Norway is under a duty of close cooperation with the EEA States and institutions in order to ensure that the aims of the REACH Regulation, in particular the effective functioning of the internal market, can be upheld. This happened, however, only on 19 February 2014, when Norway notified ECHA of its intention to submit an Annex XV dossier.

53. Article 3 EEA imposes upon the Contracting Parties the general obligation to take all appropriate measures, whether general or particular, to ensure fulfilment of their obligations arising out of the EEA Agreement.[5] Read in conjunction with Article 128(1) of the REACH Regulation, Article 3 EEA thus required Norway to refrain from introducing any unilateral national legislation on PFOA until the restriction process triggered had been finalised.

54. Norway's decision to restrict PFOA by unilateral national measures demonstrates that it had identified this substance as presenting an uncontrolled risk to the environment and human health. Hence, in ESA's view, Norway had the obligation to follow the restriction process set out in the REACH Regulation, in particular the requirements of Article 69(4).

55. In response to Norway's allegation of procedural deficiencies as a reason for taking unilateral measures, ESA stresses that the effectiveness of the system depends on the effective cooperation of the EEA States. While it is true that Article 69(4) of the REACH Regulation does not specify a deadline for EEA States to notify the intention to prepare an Annex XV dossier, it is clear that such notification must be made promptly, so as to guarantee the effective functioning of the system. Only early notification will prevent a duplication of work.

56. In this case, Norway and Germany notified ECHA of their intention to initiate the restriction process on 19 February 2014, that is, nine months after the national legislation was adopted, and following ESA's pre-Article 31 letter, sent on 30 October 2013, reminding Norway of its obligations under the REACH Regulation. The dossier was finally submitted on 17 October 2014.

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[5] Reference is made to Case E-6/13 *Metacom AG* v *Rechtsanwälte Zipper & Collegen* [2013] EFTA Ct. Rep. 856, paragraph 69; Case E-25/13 *Engilbertsson* v *Íslandsbanki* [2014] EFTA Ct. Rep. 524, paragraph 159; and Case E-15/12 *Jan Anfinn Wahl* v *the Icelandic State* [2013] EFTA Ct. Rep. 534, paragraph 54, and case-law cited.

57. ESA draws a parallel with Case C-246/07 *Commission* v *Sweden*.[6] That case was brought by the Commission to challenge Sweden's unilateral decision to propose the addition of the substance perfluoroctane sulfonate ("PFOS") to the Stockholm Convention on Persistent Organic Pollutants. At the time of Sweden's proposal, no formal proposal had been forthcoming from the European Union regarding PFOS, but there was a common strategy regarding this substance. The ECJ upheld the Commission's challenge, finding that Member States are "subject to special duties of action and abstention"[7] where proposals, although not yet adopted, represent a point of departure for concerted Community action.

58. While the substance of *Commission* v *Sweden* does not concern the EEA Agreement, according to ESA, the initiation of the restriction process under Title VIII of the REACH Regulation represents, by analogy, a point of departure for concerted EEA action which precludes unilateral action by EEA States.

Unjustified restriction on the free movement of goods (this title relates to the third plea, which has been withdrawn by ESA by letter of 16 February 2017)

59. In any event, ESA submits that the restrictions on PFOA introduced by Norwegian Product Regulation are unlawful under the general rules of the EEA Agreement on free movement of goods.

60. First, the measure constitutes a restriction within the meaning of Article 11 EEA, since it prevents the placing on the market of products containing PFOA which have been lawfully manufactured and marketed in other EEA States. Article 13 EEA provides for certain exceptions, and the protection of public health is expressly recognised as a justification.[8] In the absence of harmonised rules, where there is uncertainty as to the state of scientific research, it is for the EEA States to decide on the degree of protection and the way to achieve it, within the limits of the EEA Agreement.[9] It is, however, settled case-law that exceptions under Article 13 EEA must be interpreted strictly.[10] Any national rule likely to have a restrictive effect on imports can only be accepted if it is proportionate.[11]

61. While ESA does not dispute, in principle, that PFOA is a serious hazardous substance, Norway has failed to provide sufficient evidence to demonstrate that the

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6 Judgment in C-246/07, *European Commission* v *Kingdom of Sweden*, EU:C:2010:203.

7 Ibid., paragraph 74.

8 Reference is made to Case E-16/10 *Philip Morris Norway* v *Norway* [2011] EFTA Ct. Rep. 330, paragraph 77 and case-law cited.

9 Reference is made to Case E-4/04 *Pedicel AS* v *Sosial- og helsedirektoratet* [2005] EFTA Ct. Rep. 1, paragraph 55, and the judgment in C-322/01, *Deutscher Apothekerverband*, EU:C:2003:664, paragraph 103.

10 Reference is made to Case E-1/94 *Ravintoloitsjain Liiton Kustannus Oy Restamark* [1994-1995] EFTA Ct. Rep. 15, paragraph 56, and Case E-5/96 *Ullensaker Kommune* v *Nille AS* [1997] EFTA Ct. Rep. 30, paragraph 33.

11 Reference is made to the judgment in *Deutscher Apothekerverband*, cited above, paragraph 104.

measures taken are proportionate. Assessment of proportionality in the field of public health must take into account the fact that an EEA State has the power to determine the degree of protection that it wishes to afford to public health and the way in which protection is to be achieved.[12] Nevertheless, national rules or practices which restrict, or are capable of restricting, a fundamental freedom under the EEA Agreement can only be justified if they are appropriate for securing the attainment of the objective in question and do not go beyond what is necessary in order to attain it.[13]

62. In order to rely on Article 13 EEA, Norway must thus show that the risk to public health appears sufficiently established based on the latest scientific data available at the date of adoption of the measures.[14] This entails the obligation of providing a risk assessment based on scientific and technical evidence, demonstrating that the measures are proportional to the risks identified,[15] and that the ban proposed is the least restrictive measure. ESA notes that Norway, in its reply to the reasoned opinion, referred to "the risk assessments provided for in the proposal under REACH Title VIII". However, the only document submitted to ESA was the impact assessment for the regulation of PFOA in consumer products in the notification of proposed measures in the 2010 draft technical regulations procedure, under Directive 98/34/EC. The impact assessment does not address the issues of substantiated justification, necessity and proportionality originally raised by ESA in its comments on the 2007 notification. The Commission too, in its comments on the 2010 notification, called upon Norway to "provide the scientific evidence that it has collected to establish the limits proposed in the notified drafts". Consequently, ESA contends that in all the circumstances Norway has failed to provide sufficient evidence to demonstrate the proportionality of the measures taken.

63. Norway argued, during the pre-litigation procedure, that the 0.001 weight percent concentration for PFOA was based on the concentration limit for PFOS in Regulation (EC) No 850/2004 2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending directive 79/117/EEC (OJ 2004 L 158, p. 7, and EEA Supplement 2011 No 35, p. 235), since both substances have similar chemical properties and hazards. In ESA's view, this does not qualify as a concrete risk assessment as required by Article 13 EEA. Norway has equally claimed that the prohibition was necessary to guarantee public health, with the measures ensuring the phasing out of PFOA in production and consumer products. ESA considers that a reference to broad policy objectives is not sufficient to demonstrate the adequacy of the measures – a mere reference to the inherent properties of the substance does not take into account factors such as

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[12] Reference is made to *Philip Morris*, cited above, paragraph 80.

[13] Ibid., paragraph 81 and case-law cited.

[14] Reference is made to the judgments in C-41/02, *Commission* v *the Netherlands*, EU:C:2004:762, paragraphs 47 to 49, and C-333/08, *Commission* v *France*, EU:C:2010:44, paragraph 87 and case-law cited.

[15] Reference is made to the judgments in *Commission* v *the Netherlands*, cited above, and C-192/01, *Commission* v *Denmark*, EU:C:2003:492.

likelihood of exposure or concentrations, and hence does not provide sufficient scientific evidence or a valid risk assessment to justify the restrictions.

64. A decision to prohibit the import of products containing certain substances is the most restrictive obstacle to trade in products lawfully manufactured in other EEA States. A national rule banning a product cannot benefit from the derogation provided for in Article 13 EEA if human health can be protected just as effectively by measures which are less restrictive of intra-EEA trade.

65. Moreover, in spite of identifying PFOA as a hazard, Norway has not attempted to explain the exemptions which apply under the Norwegian Product Regulation, in particular the amendment which allows products that were manufactured before the ban entered into force to remain on sale until 1 January 2018. The national measures hence do not appear to pursue the objective identified in a coherent and systematic manner, and thus cannot be considered appropriate for attaining that objective.[16]

66. ESA submits that the absence of any risk assessment, as well as the failure to demonstrate the proportionality of the restriction on PFOA, means that Norway has failed to justify recourse to the public health exemption set down in Article 13 EEA. As a result, ESA considers the Norwegian restriction on PFOA to infringe Article 11 EEA. In its Reply, ESA notes that Norway provided additional scientific data for the first time in the Defence. ESA regrets this late submission of the data, not commensurate with the level of cooperation expected within the framework of the EEA Agreement, which has prevented it from considering in detail the matters raised within the time frame for the reply. ESA thus reserves the right to challenge the new scientific data at the oral hearing, and requests the Court, in the event that it finds against ESA on the third plea on the basis of any of the new evidence, to award ESA its costs, as it could not have been expected to take that evidence into account when deciding to bring proceedings before the Court.

Norway

Introductory remarks

67. In the view of the Norwegian Government, this case concerns the possibility for Norway to regulate PFOA in consumer products. The situation on the expiry of the period prescribed in ESA's reasoned opinion can be characterised as follows: (i) PFOA is a substance of very high concern to human life and health, as well as to the environment (ii) no EEA-wide regulation of PFOA in consumer products existed; and (iii) there was an ongoing process within ECHA for possible future regulation of PFOA.

68. Moreover, Norway wishes to ensure that the Court is informed in detail about the risks related to this substance. PFOA is widely recognised as a substance harmful to health

[16] Reference is made to the judgment in C-169/07, *Hartlauer*, EU:C:2009:141, paragraph 55.

and the environment. PFOA is listed on the Candidate List for substances of very high concern both for reprotoxic and persistent, bioaccumulative and toxic ("PBT") properties. Since PFOA is a PBT-like substance or a substance of equal concern, it is impossible to establish an acceptable level for substances with such properties in the environment, and emissions and exposure should be limited to the greatest extent possible. Impact assessment documents have shown PFOA's wide-spread occurrence in the environment, the presence in biota in the Arctic and in particular the time trend data in the Arctic. PFOA is positively associated with diagnosed high cholesterol (hypercholesterolemia); there is a positive trend of increased risk for inflammatory bowel disease (combining ulcerative and Crohn's Disease); recent publications have demonstrated an overall reduction in birth weight associated with PFOA exposure in humans, and recent data points to the transferral of PFOA via the placenta to the foetus in the uterus and to babies via breast milk.[17]

69. Norway further notes that, in addition to the ongoing restriction procedure under the REACH Regulation, the EU submitted, in 2015, a proposal for the listing of PFOA, its salts and PFOA-related compounds to the Stockholm Convention on Persistent Organic Pollutants. This implies that an extensive, ongoing procedure, initiated by the EU, is currently underway to consider not only an EEA wide restriction on PFOA, but a global restriction. This illustrates the very high concern related to PFOA and products containing PFOA.

EEA states may legitimately adopt national measures until EEA-wide harmonisation is established

70. The Norwegian Government fully acknowledges the harmonising effect of final, EEA-wide regulations, by means of Annex XVII entries. However, it does not accept ESA's assessment of the harmonising effect of a procedure which may or may not lead to such regulations. The Norwegian Government contends that it is entitled to maintain or introduce restrictions on a substance, or on products containing that substance, until an EEA-wide regulation on the same subject matter is in place. This must be the conclusion also when the procedure under Title VIII of the REACH Regulation has been initiated. Thus, the mere initiation of this procedure does not imply that all EEA States are prohibited from regulating the substance at national level.

71. The possible harmonising effect of the availability of the procedure set out in Title VIII must be assessed in the light of Article 128 of the REACH Regulation. Article 128(2) clarifies that the harmonising effect of the REACH Regulation is not absolute. A substance is not harmonised under the REACH Regulation only because it falls within the wide scope of the Regulation. National rules to protect workers, human health and the environment are only prohibited if the Regulation does indeed "harmonise the requirements on manufacture, placing on the market or use" of a substance. These concepts all concern the "use" of the substance in the wider sense and are premised on the existence of regulation of the

[17] Further data can be found in the annexes to the Defence.

substance itself. If no regulation exists, EEA States are not precluded from adopting national legislation, since no reference is made in Article 128 of the REACH Regulation to the harmonising effect of the restriction procedure that may eventually lead to a situation where, to use the words of Article 128(2) of the REACH Regulation, the Regulation does in fact "harmonise the requirements on manufacture, placing on the market or use".

72. Article 128(2) of the REACH Regulation refers to both maintaining existing rules and laying down new national rules, both of which may be legitimate provided that the manufacturing, placing on the market and the use of the substance has not been harmonised. The room for such national rules regarding hazardous substances would be very limited were ESA's understanding to be correct. Moreover, Article 128(2) was not part of the Commission's original proposal, having been introduced during the legislative process by the Council as a means to ensure national capability to respond to challenges related to substances falling within the scope of the REACH Regulation.

73. The Norwegian Government relies on two cases concerning the scope of harmonisation provided for under the REACH Regulation. In *Lapin*, the ECJ held that it followed from Article 128(2) of the REACH Regulation that the EU legislative bodies intended to harmonise the requirements in "certain cases".[18] That included the situation referred to in Article 67(1) of the REACH Regulation, i.e. the situation in which Annex XVII already contained a restriction on the same substance.[19] Since parallel EU-wide regulations existed, further national restrictions were prohibited, and Article 128(2) of the REACH Regulation was inapplicable.[20] The wording of the relevant paragraphs reflects the fact that EU-wide regulations were in place. There is no mention of a possible harmonising effect irrespective of EU-wide action, for instance because the chemical at issue in the case, arsenic, is, as such, a substance falling within the scope of the REACH Regulation. On the contrary, according to Norway, the natural reading of the judgment and the way it is phrased indicates that the manufacturing, placing on the market or use of a substance is not harmonised without EU-wide regulations, meaning that EEA States are permitted, under Article 128(2) of the REACH Regulation, to adopt national measures provided that they are compatible with EU/EEA law.

74. Second, in *Canadian Oil Company*, the ECJ concluded that the harmonisation carried out by the REACH Regulation did not preclude a national registration system such as the Swedish, in addition to the registration requirements under the REACH system, since the requirements were harmonised only "in certain cases".[21] The wording of Advocate General Sharpston's Opinion indicates that the harmonising effect under the REACH

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[18] Reference is made to the judgment in C-358/11, *Lapin*, EU:C:2013:142, paragraphs 20 to 21.

[19] Ibid., paragraph 33.

[20] Ibid., paragraphs 34, 35 and 37.

[21] Reference is made to the judgment in C-472/14, *Canadian Oil Company Sweden AB*, EU:C:2016:171, paragraphs 27 and 38.

procedures is the consequence of final measures taken at EU level, and not of the mere existence of a procedure for adopting such measures.[22] Inspiration can equally be drawn from *Philip Morris Brands*, where the ECJ's Grand Chamber concluded that Member States were allowed to regulate aspects related to packaging of tobacco products that were not already harmonised in Directive 2014/40/EU[23], based on a specific assessment of which aspects were harmonised and which were not.[24]

75. In addition, case-law pre-dating the REACH Regulation supports this position. In relation to previous legislation, namely the Marketing Directive (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 the Risk Evaluation Regulation (Regulation (EEC) No 793/93), the ECJ clarified that the inclusion of a substance within the scope of the Directive did not preclude national legislation until the substance was actually regulated on the Community level.[25] Furthermore, the fact that the procedure for such regulation was initiated under the Risk Evaluation Regulation was held to be immaterial as regards the freedom of Member States to adopt national legislation, as this procedure did not harmonise the use of the substance.[26] Although the REACH Regulation has enhanced the regulation of the procedure, the wording of Article 128(2) of the REACH Regulation reflects this established state of law.

76. The Norwegian Government also refutes ESA's reading of Article 69(4) of the REACH Regulation. Although the Norwegian Government believes that the procedure under that Article should be the main approach, an approach Norway has followed, this does not mean that an EEA State is obliged to notify its concerns without any delay, as submitted by ESA. Preparing an Annex XV dossier is very demanding and time consuming, due to the amount of documentation and assessments required. ESA's apparent contention that all EEA States, even if they are concerned about several potentially harmful substances that may call for EEA-wide actions, are in a constant breach of Article 69(4) of the REACH Regulation simply because they have not yet been able to prioritise the task of preparing a dossier is refuted by Norway.

77. Were an obligation to notify ECHA and prepare the Annex XV dossier to exist, this should not imply that the procedure as such is harmonised. An obligation of that kind may

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[22] Reference is made to the Opinion of Advocate General Sharpston in C-472/14, *Canadian Oil*, EU:C:2015:809, points 38 and 39.

[23] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws regulations and administrative provisions of the Member States concerning the manufacture presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ 2014 L 127, p. 1)

[24] Reference is made to the judgment in C-547/14, *Philip Morris Brands SARL et al*, EU:C:2016:325, paragraphs 73 to 80.

[25] Reference is made to the judgment in *Toolex*, cited above, paragraph 30.

[26] Ibid., paragraphs 31 to 32.

go hand in hand with a freedom for the EEA State to apply national regulations until the final assessment is made on an EEA-wide level. A different interpretation would render Article 128(2) of the REACH Regulation more or less ineffective, contrary to its own wording and legal history.

78. Moreover, according to the Norwegian Government, as long as the substance poses national concerns only, the EEA State must be entitled to regulate it without using the procedure under Title VIII of the REACH Regulation. This further indicates that national legislation cannot as such be precluded until it is clarified that Community-wide regulations will be adopted. As long as the EEA State proposes national legislation, even if this is supplemented by an Annex XV dossier, this national regulation should be respected, provided it is compatible with the general free movement provisions.

79. Norway submits that Articles 128 and 129 of the REACH Regulation must be read together. Article 128(2) applies only to situations where the substance is not harmonised by REACH, i.e. in situations where there are no relevant requirements set out under the REACH procedures. This is contrasted with Article 129 of the REACH Regulation, which allows, exceptionally, national measures to be taken unilaterally even if the substance in question is "satisfying the requirements" already established under the REACH procedure. The possibility for EEA States to adopt national measures is wider in the absence of harmonising measures (Article 128(2)) than in the case where harmonising measures have already been adopted (Article 129).[27] Article 129 of the REACH Regulation is thus similar to Article 114(5) of the Treaty on the Functioning of the European Union ("TFEU"), since both provisions set out the relevant options provided the substance in question has been regulated by EEA-wide measures included in Annex XVII to the REACH Regulation.

80. With regard to the objectives of the REACH Regulation, Norway concedes that restrictions on an EEA-wide basis are more efficient than restrictions on a national basis, unless the substance only raises national concerns. Norway fully supports the prioritisation of the REACH approach as the main approach, and has actively contributed to these processes, namely by preparing, together with Germany, the PFOA dossier. In its view, what is crucial, however, is whether a prohibition of national measures until a possible EU/EEA-wide regulation is adopted will more effectively protect human health and the environment than a right to adopt restrictive, national measures within this time frame, given that procedures that may lead to EU/EEA-wide regulations are often long and complicated, as the present PFOA procedure exemplifies.

The principle of loyal cooperation under Article 3 EEA

81. It is clear that, under Article 3 EEA and the principle of loyal cooperation, EU/EEA States cannot issue only national restrictions if the substance in question causes an EU/EEA

[27] Reference is made to the Opinion of Advocate General Sharpston in *Canadian Oil*, cited above, point 33 and footnote 21.

wide concern, having the obligation to initiate the procedure under Article 69(4) of the REACH Regulation. However, in order to respect the precautionary principle and the principle of ensuring a high level of protection for human health and the environment, an overarching principle of EEA law in light of which all EEA legislation should be interpreted,[28] national measures should be permitted pending the outcome of the procedure under the REACH Regulation, which can be excessively long.

82. The Norwegian Government submits moreover that Article 3 EEA cannot imply that EEA States are prohibited from adopting national measures only because the procedure under Title VIII of the REACH Regulation has been initiated. The wording, legal history and case-law on Article 128(2) of the REACH Regulation demonstrate that only restrictions adopted through the REACH procedure prevent national measures with the same scope. There is no indication that the mere initiation of the procedure under Title VIII should be a decisive factor.

83. Article 3 EEA has limitations established by secondary legislation. It requires a loyal application of the REACH Regulation, but cannot preclude legislation which that Regulation allows. Consequently, EEA States may legitimately adopt national measures until EEA-wide harmonisation is established. The contrary conclusion would entail a radical extension of the harmonising effects of an EEA regulation simply by reference to Article 3 EEA.

84. Furthermore, the Norwegian Government avers that it prepared, together with Germany, an extensive Annex XV dossier. The preparation of the dossier began in 2011 with the submission of an analysis of the most appropriate risk management options. Hence, it is clear the procedure laid down in the REACH Regulation was loyally applied.

85. The reference made by ESA to *Commission* v *Sweden* is not relevant here, since that case concerned a situation where the Community and Member States had shared competence, and any unilateral approach by the latter could compromise the principle of unity in the international representation of the Community. In the present case, there is no shared power and principle of unity comparable. Furthermore, Norway's actions would not bind the EU/EEA legislature, nor compromise the possibility to adopt EEA-wide measures.[29] The Norwegian Government thus submits that a national procedure in parallel with the initiation of the REACH procedure cannot be prohibited by Article 3 EEA.

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[28] Reference is made to the judgment in C-14/06 and C-295/06, *European Parliament and Denmark* v *European Commission*, EU:C:2008:176, paragraph 75.

[29] Reference is made to the judgment in *Commission* v *Sweden*, cited above, paragraph 102, in which the ECJ found that the Union could not be bound by a national measure. Reference is made in addition to paragraphs 83, 89 to 91, 92 to 94 and 104 of the same judgment.

National measures are justified by legitimate objectives and are proportionate, appropriate and necessary to attain them (this title relates to the third plea, which has been withdrawn by ESA by letter of 16 February 2017)

86. The national measure at issue constitutes a restriction under Article 11 EEA. However, the Norwegian Government submits that it is justified by the legitimate objectives of public health and the environment, and it is proportionate as it is appropriate and necessary in ensuring the fulfilment of those aims. ESA's third plea must be assessed therefore under the general provisions on the free movement of goods under the EEA Agreement.

87. ESA's objections relate to the necessity and proportionality of the national measures at issue, and the documentation provided by Norway. ESA does not seem to have due regard, however, to the impact assessment issued along with the introduction of national measures, which details the risk assessment and assessment of the necessity of the measures, including concentration limits and alternative measures. Norway avers that it forwarded to ESA a comprehensive impact assessment of December 2010 in paper version, and that the report prepared by Germany and Norway for proposing an EEA-wide restriction on PFOA was also submitted, in the form of an electronic reference. Moreover, in response to the Application, Norway added other relevant documents to the Defence, which should be seen as a proof of loyalty.[30] In Norway's assessment, ESA appears not to fully take into account the risks PFOA poses to human health and the environment.

88. ESA does not dispute the hazardous nature of PFOA and hence accepts that the national regulation may in principle be justified by public health. Health and life have been regarded to rank foremost among interests protected by Article 13 EEA.[31] In addition, the national restriction is justified by the protection of the environment, which can constitute an overriding requirement whether falling within or outside the scope of Article 13 EEA.[32]

89. With regard to the proportionality of the measures, Norway contends that, according to settled case-law, it is for each EEA State to decide the degree of protection they wish to ensure, and in which way they will do so.[33] National restrictions, whether based on public health or environmental objectives, must, in accordance with the principle of proportionality, be appropriate for ensuring attainment of the objectives pursued and must not go beyond what is necessary in order to attain those objectives.[34] Where there is

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[30] See paragraph 67.

[31] Reference is made to *Pedicel*, cited above, paragraph 52, and Case E-16/10 *Philip Morris*, cited above, paragraph 77.

[32] Reference is made to the judgment in C-573/12, *Ålands Vindkraft*, EU:C:2014:2037, paragraphs 77 and 80, and the judgment in *Parliament and Denmark* v *Commission*, cited above, paragraph 75.

[33] Reference is made to Case E-16/10 *Philip Morris*, cited above, paragraphs 77 and 80, and case-law cited.

[34] Reference is made to the judgment in *Ålands Vindkraft*, cited above, paragraph 76, and Case E-16/10 *Philip Morris*, cited above, paragraph 81.

uncertainty as to the existence or extent of risks to human health, an EEA State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. An EEA State may thus take the measures that reduce, as far as possible, a public health risk.[35]

90. As to the appropriateness of the measures, the Norwegian Government argues that it was reasonable to assume that the national measures would be able to contribute to the protection of human health or the environment. The extent to which a measure contributes to the protection of legitimate aims is not as such relevant under the test of appropriateness.[36] Moreover, contrary to the submissions made by ESA, Norway avers that a risk assessment was sent to ESA with all the relevant scientific measures showing that PFOA is dangerous to human health and indeed a substance of very high concern.[37] It observes that, according to recital 70 in the preamble to the REACH Regulation, for such substances, "measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with the view to minimising the likelihood of adverse effects". Moreover, detailed assessments relating to the chosen concentration limit were included, as well as consideration of less restrictive, albeit less effective, national measures.

91. A restrictive measure cannot be regarded as appropriate or suitable if it does not pursue its objectives in a consistent and systematic manner.[38] ESA levels this criticism at the Norwegian Product Regulation, since it contains a transitional rule allowing products containing PFOA produced before 1 June 2014 to be imported and put on the market until 1 January 2018. Norway counters that criticism by arguing, first, that there is nothing to indicate that these measures constitute a means of arbitrary discrimination or disguised restrictions to trade and, second, that the transitional rule makes sense from the point of view of proportionality[39] and protection of health and environment. It was introduced in response to industry concerns that it would be difficult to achieve the deadline of 1 June 2014.

92. Norway contends that the exception is objectively limited, since all products produced before 1 January 2014 will be subject to the restriction four years later. It would not have been a good solution from a health and environmental perspective to ban these

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[35] Reference is made to Case E-16/10 *Philip Morris*, cited above, paragraph 82 and case-law cited.

[36] Reference is made to the judgment in C-434/04, *Ahokainen*, EU:C:2006:609, paragraph 39, and the Opinion of Advocate General Poiares Maduro in the same case, EU:C:2006:462, point 24.

[37] Reference is made to the classification of PFOA as a CMR substance under Directive 67/548/EEC, now Regulation (EC) No 1272/2008 and Regulation (EU) No 944/2013. Moreover, PFOA is a PBT-like substance, with PBT properties, as follows from the RAC and SEAC Opinions in the REACH restriction procedure.

[38] Reference is made to the judgment in C-28/09, *European Commission* v *Austria*, EU:C:2011:854, paragraph 126.

[39] On the proportionality of measures with reference to the objectives pursued, reference is made to the judgments in C-262/02, *Commission* v *France*, EU:C:2004:431, paragraphs 35 and 36; C-429/02, *Bacardi France*, EU:C:2004:432, paragraph 4; and C-137/09, *Josemans*, EU:C:2010:774, paragraph 79.

existing products, with the implication that they should either be destroyed or sold to countries without a comparable regulation. In addition, a full ban would have been more burdensome for those who had already manufactured the products than for other producers, capable of immediately adapting to the new provisions. Since both public health and environmental consequences of PFOA occur, to a large extent, as the product is produced, the use of products containing the substance or their transformation into waste would not significantly change their negative impact on health and environment. These conclusions are in line with those proposed by RAC and the Committee for Socio-Economic Analysis ("SEAC"). What is of paramount importance is stopping the further production of PFOA or substances that can turn into PFOA.

93. Norway stresses that it is within the discretion of the EEA State to determine how strict a restriction should be.[40] Limiting a restriction through derogations or transitional rules does not imply the measure is inconsistent;[41] the latter is true only if the measure is clearly ineffective, or where the EEA State does not provide any reasons for seemingly contradictory national legislation.[42] In the case at hand, the transitional rule contributes to the reduction of the total emissions of PFOA into the environment and the total exposure to PFOA to humans. It is a first step towards phasing out PFOA in the environment, which operates in parallel to the proposed EEA-wide ban under the REACH procedure that Norway and Germany have triggered.

94. Turning to the necessity of the measures, the Norwegian Government submits that the regulation is indeed necessary, as the objectives of public health and the environment cannot be protected as effectively with less restrictive measures.[43] The conclusions of the 2010 impact assessment have been confirmed by the recent opinions of the RAC and SEAC under the REACH procedure. Moreover, the regulation is limited to consumer products, a scope that is based on the dangers of exposure to PFOA in small quantities as found in many products. Were only a specific range of products included, the positive effects of the regulation (reduction of the global exposure) would be hindered. The Norwegian Government also notes that the restriction proposed at EEA level has a wider scope, extending to all products, not only consumer ones.

95. With regard to the concentration limits, Norway contends that, since all exposure to PFOA is harmful, the lower the limit set, the more efficient the protection of health and the environment. It is also true that the concentration limit proposed in the risk assessments under the REACH procedure aimed at an EEA-wide ban of PFOA is significantly lower

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[40] Reference is made to the judgment in C-262/02, *Commission* v *France*, cited above, paragraphs 33 to 36.

[41] Reference is made to the judgments in *Toolex*, cited above, paragraph 46, and *Commission* v *Austria*, cited above, paragraph 134.

[42] Reference is made to the judgments in C-243/01, *Gambelli*, EU:C:2003:597, paragraphs 67 to 69, and *Hartlauer*, cited above, paragraph 61.

[43] Reference is made to Case E-3/06 *Ladbrokes* [2007] EFTA Ct. Rep. 86, paragraph 58.

than in the Norwegian regulation.[44] However, in Norway's view, ESA fails to explain why an assessment calling for a lower concentration limit is irrelevant for the purposes of demonstrating that a higher limit, i.e. a less strict restriction (such as the one taken up by the national measures), does not goes beyond what is necessary to achieve public health and environmental objectives.[45]

96. Furthermore, alternative measures, such as information campaigns, taxes, collection schemes, voluntary agreements between industry and the authorities or labelling,[46] were assessed before adopting the national restrictions, but were found to be inappropriate or at least less efficient. The overall conclusion, after a careful balancing of interests in light of what was practically and technically possible, was that the proposed restriction was indeed necessary in order to achieve the desired level of protection until there is EEA-wide restriction.

97. In conclusion, the Norwegian regulation does not go beyond what is necessary, as the same level of protection cannot be achieved as efficiently with less restrictive means.

European Commission

Introductory remarks

98. The Commission contends that, from the date of its entry into force, Title VIII of the REACH Regulation has "occupied the field" with regard to restricting the free movement of chemical substances within the European Union. Any restriction of the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article in the EU must be brought about by means of a REACH restriction, initiated by a Member State or the Commission.

99. Norway has submitted an Annex XV dossier, but has adopted, at the same time, a national restriction without awaiting the conclusion of the process at EU level, or without following, in the alternative, the safeguard procedure. It has thus breached the "harmonised process" established by the REACH Regulation. The Commission thus supports ESA in its first plea by which it seeks a declaration that Norway has failed to fulfil its obligations arising from point 12zc of Chapter XV of Annex II to the EEA Agreement.

Article 128(2) of the REACH Regulation

100. The Commission submits that Norway's interpretation of the harmonising effect of the REACH Regulation in relation to restrictions is too narrow. The fact that Member States are obliged to initiate the REACH restriction procedure upon identifying risks which

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[44] The draft Commission Regulation on PFOA was voted on by the REACH Committee on 7 December 2016.

[45] Reference is made to the judgment in *Bacardi France*, cited above, paragraph 40.

[46] For a detailed discussion, see paragraphs 116 to 122 of the Defence.

need to be addressed proves that, in relation to manufacture, placing on the market and use of a substance, the REACH Regulation does indeed harmonise all requirements regarding the introduction of restrictions. Limiting the scope of the harmonisation of restrictions to cases where "an actual regulation of the substance in question exists" would exclude the harmonising effect of applications for restrictions assessed under Regulation No 793/93 or an Annex XV dossier which did not result in a restriction because no unacceptable risk was found.

101. Article 128(2) of the REACH Regulation should be read as a restatement of the principle that Member States remain free to act in areas which are not harmonised under EU law. The provision's scope of application in the specific area of restrictions is very limited, for example, when certain conditions under Annex XVII entries leave discretion to Member States. It should not be read as limiting the harmonisation effects under the REACH restrictions or undermining the free movement clause in Article 128(1). The Council debates on the original proposal for the REACH Regulation on which Norway relies relate merely to evaluation under Title VI, in respect of which Member States have direct competence without the need to rely on Article 128(2) of the REACH Regulation.

102. In the Commission's view, Norway misinterprets *Lapin*. The case of *Lapin* concerned only the interpretation of a specific entry in Annex XVII to the REACH Regulation, thus it is not surprising that there is no mention of a possible harmonising effect irrespective of EU-wide action. This does not mean that the Title VIII restriction procedure cannot be considered one of the "certain cases" referred to by the ECJ.

103. According to the Commission, the references to *Canadian Oil* and the Opinion of Advocate General Sharpston in that case are equally problematic, since both focus on the contrast between the degree of harmonisation achieved by the REACH Regulation with respect to restrictions and authorisations, and the degree of harmonisation achieved with respect to registration of substances. They conclude that the scope of harmonisation achieved by REACH registration does not preclude a national registration which is not a precondition to placing on the market, relates to different information from that required by the REACH Regulation and contributes to its objectives. There is nothing in the judgment or Opinion to suggest that, in relation to restrictions, only Annex XVII entries constitute harmonisation measures.[47]

104. Title VIII of the REACH Regulation harmonises both the restrictions in Annex XVII and the entirety of the restriction process. If Member States consider that a substance poses an uncontrolled risk, they are obliged to notify ECHA and to prepare an Annex XV dossier. Only if there is no EU interest, in view of the dossier, can a Member State introduce a national restriction.

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[47] Reference is made to the Opinion of Advocate General Sharpston in *Canadian Oil*, cited above, point 49.

On the interface between Articles 128(2) and 129 of the REACH Regulation

105. In the Commission's view, the safeguard procedure in Article 129 of the REACH Regulation should be triggered, as far as entries in Annex XVII are concerned, if Member States consider that, in order to protect human health or the environment, urgent action is essential to make the manufacture, placing on the market or use of a substance which is subject to restriction under Annex XVII subject to new conditions. Immediately after the enactment of such provisional measure, the Member State is obliged to notify the Commission, ECHA and other Member States, justifying it, and submitting the scientific or technical information on which the measure is based. If the provisional measure is authorised, an Annex XV dossier must be prepared.

106. According to the Commission, the procedure established by Title VIII has itself a harmonising effect. In this regard, the safeguard clause also applies in cases where a Member State intends to introduce an urgent restriction for a substance for which no entry in Annex XVII exists yet. The "safeguard" element relates merely to the need to tackle urgent matters, in spite of the existence of a harmonised procedure for initiating restrictions. The only time Article 129 of the REACH Regulation has been invoked was in relation to a substance for which there was no entry in Annex XVII, and which, following the Article 129 procedure, is now regulated by an entry.[48]

107. The Commission thus agrees with ESA in its argument that a different reading of Article 128(2) of the REACH Regulation would lead to the anomalous situation where national restrictions in non-urgent cases could be implemented more easily than urgent proposals for restriction under Article 129 of the REACH Regulation. This is confirmed also by the Commission Communication on the Council's Common Position (COM(2006) 375 final), according to which the only exceptions to the REACH regime are measures adopted under Article 114(4) to (6) TFEU and Article 129 of the REACH Regulation.

Article 69(4) of the REACH Regulation

108. Insofar as a risk has been identified, it is the Commission's view that the Member State concerned is precluded from addressing that risk via national measures without notification to ECHA and the preparation of an Annex XV dossier. If a Member State introduces a national restriction, this demonstrates that it has identified a risk – thus meaning that it should follow the procedure in Article 69(4) of the REACH Regulation.

109. The restriction procedure in Title VIII of the REACH Regulation "is designed to preserve the status quo pending the evaluation of the need for Union-wide action". In urgent cases, Member States can have recourse to Article 129 of the REACH Regulation. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical

[48] Entry 65 on inorganic ammonium salts.

regulations and of rules on Information Society services (OJ 2015 L 241, p. 1) ("Directive (EU) 2015/1535") contains an analogous procedure by establishing a standstill period for national technical regulations in non-harmonised areas, which have to be notified to the Commission in draft.

110. With regard to the Norwegian Government's submission that the Title VIII procedure should not be used for concerns relating to substances that are local or national in nature, the Commission underlines that, while the risk might be localised, the substance concerned may be traded across EEA borders, which can lead to distortions of the internal market, hence calling for EEA-wide action.

Previous legislation and *Toolex*

111. The Commission shares ESA's views on why *Toolex* is not relevant for the present case.

Slowness of the REACH procedure

112. The Commission reiterates its view that Article 129 of the REACH Regulation is not limited to cases where a substance is already regulated by an entry in Annex XVII. Rather, this expedited procedure can be used when a Member State has justifiable grounds to believe that urgent action is needed, ensuring that the risk will be assessed EU-wide and in line with the objectives of the REACH Regulation.

The German Government

113. Germany considers the case at issue not a simply a dispute on the scope of the REACH Regulation but as raising the question of how to maintain a constant and appropriate level of protection against dangerous substances in the light of fast-developing scientific discoveries, and slow-moving REACH risk-management procedures. It adds that, while it is preferable to find long-term solutions within the available legislative framework, if a high level of protection is needed and is to be upheld, national governments must be given the opportunity to act quickly and establish supplementary national legislation.

114. It appears to be suggested by ESA that as soon as the REACH restriction procedure was made available, Member States were precluded from enacting national legislation. This would thus correspond to 1 June 2007, the date on which the REACH Regulation entered into force and the procedure became available. The German Government supports Norway's contention that Article 128(2) of the REACH Regulation expressly allows the Member States to maintain or lay down national rules to protect workers, human health and the environment in cases where the Regulation "does not harmonise the requirements on manufacture, placing on the market or use".

115. The purpose of the REACH Regulation is, according to Article 1 thereof, to ensure a "high level of protection of human health and the environment". This objective is

hindered if the procedural provisions concerning the addition of new substances in the restriction process block Member States from maintaining or laying down national rules concerning substances. It remains essential for the Member States to be able to protect human health and the environment from risks at national level as long as the protection is not provided for by specific measures under REACH.

116. This interpretation is supported by the wording of Article 128(2) of the REACH Regulation, which refers expressly to the protection of workers, human health and the environment, and the manufacture, placing on the market and use of a substance. It therefore allows the Member States to regulate a substance with the same aims and instruments, as long as REACH does not yet contain specific requirements on the same substance. The wording clearly suggests that a harmonising effect can only take place once "requirements" are imposed on a specific substance. The term "requirements" suggests an authorisation or restriction and the reference to "this regulation" has to be understood to mean that the Regulation itself, in particular Annex XIV (authorisation) or XVII (restriction) thereto, has been amended.

117. As long as a substance is not actually and specifically regulated under the REACH framework, Member States may maintain or introduce national rules in order to provide for the protection of workers, human health and the environment. Article 69 of the REACH Regulation does not harmonise substantive requirements for manufacture, placing on the market, or use; it merely regulates the procedure for amending Annex XVII to the REACH Regulation. Any other interpretation would deprive Article 128(2) of the REACH Regulation of any meaningful sense.

118. The German Government underlines the arguments made by Norway about the legislative history of REACH. Article 128(2) of the REACH Regulation was not included in the Commission's initial proposal for the Regulation in 2003, having been introduced during the legislative process in the Council deliberations as the result of discussions regarding the scope of the harmonising effect of the Regulation's risk management tools. It was of great importance for many Member States expressly to preserve their regulatory rights in cases where the REACH Regulation does not set out, or has not yet set out, specific requirements on the manufacture, placing on the market or use of a substance.

119. In the German Government's view, Article 128(2) of the REACH Regulation simply clarifies what Article 128(1) states. According to Article 128(1), Member States are barred from imposing restrictions only "if the substance complies with the Regulation" and a substance is only able to comply with the Regulation if and insofar as the latter contains requirements for the substance (that is, if the substance is authorised or restricted in a specific way).

120. That interpretation is not contradicted by Article 69(4) of the REACH Regulation, since that provision has to be seen as part of the procedural rules that govern the REACH process to amend existing or add further entries to Annex XVII. While Article 69(4) opens

the option for Member States to propose initiatives to supplement the European *acquis*, it cannot be understood as interfering with their rights to regulate outside harmonised areas.

121. Article 129 of the REACH Regulation, on the other hand, addresses cases of provisional measures where the Regulation already provides for harmonised requirements with respect to a substance. In the case at issue, PFOA was not regulated under the REACH framework, as no restriction had been passed. Consequently, applying Article 129 of the REACH Regulation does not make sense. It is impossible for Member States to notify the Commission about a deviation if there is nothing to deviate from. The opposing interests in relation to the free movement of goods are sufficiently ensured by the provisions of primary and secondary EU/EEA law, such as Articles 34 and 36 TFEU and Directive (EU) 2015/1535.

122. According to the German Government, ESA's understanding of "harmonising effect" is misconceived in the second plea on the same grounds as in the first. If the harmonising effect began at the time the restriction process is triggered, the aim of achieving a Community regulation in a timely manner would be jeopardised. In order to provide protection at national level, Member States would be forced to refrain from triggering the restriction process under REACH until after national rules have been adopted, which would substantially extend the duration of the restriction procedure.

123. Germany has no comments with regard to ESA's third plea, but notes that the dangers arising from PFOA have not been questioned by ESA. In addition, it would be contradictory for ESA to question such dangers, when the Commission seeks to impose even stricter restrictions and has already secured the backing of the Member States in the REACH Committee.

The Swedish Government

124. The Swedish Government submits that ESA's interpretation of Article 128 of the REACH Regulation is not consistent with the wording of the provision, especially having regard to its legislative history. The Commission's initial proposal included Article 125 (which corresponds now to Article 128(1)) as a complement to the requirements of the Regulation, covering the substances on their own, in preparations or in articles complying with the provisions of the Regulation. In 2005, the Council's legal service issued an opinion, stating that the proposed Article 125 aimed at full harmonisation of the terms for manufacturing, placing on the market and use of substances covered by the Regulation. However, a majority of the Member States found it necessary to clarify the proposal to ensure that this provision did not interfere with their possibilities to legislate in areas which were not harmonised by the Regulation. The Council thus added that Member States have the right to maintain more stringent measures on the protection of workers, human health and the environment, provided that the area is not harmonised by the Regulation, which led to the introduction of what is now Article 128(2). Consequently, the Commission's

position, that is, fully harmonised effect as concerns the scope of REACH, did not prevail in the negotiations.

125. In light of the reference made to *Canadian Oil Company*, Sweden observes that it is common ground between the parties that the REACH Regulation is not of universal application. Indeed, this has been confirmed in Advocate General Sharpston's Opinion, according to which "the REACH Regulation harmonises the requirements on manufacture, placing on the market or use in certain cases only", adding that "the flexibility conferred on Member States [by Article 128(2)] is limited to situations where the REACH Regulation does not harmonise the requirements on manufacture, placing on the market or use of chemical substances".[49] The ECJ confirmed this view.[50]

126. With regard to Article 129 of the REACH Regulation, the Swedish Government is of the view that the provision constitutes a derogation clause which allows national measures to be taken unilaterally in situations where the procedure in Articles 68 and 69 of the REACH Regulation would otherwise apply. It follows from Article 129(3) that the safeguard clause is the starting point for a restriction procedure. However, according to the Swedish Government, the restriction procedure must only be initiated when there is a need for EEA-wide restriction or when the conditions of use, manufacture or placing on the market of a substance are harmonised by an entry in Annex XVII. The scope of Article 129 therefore corresponds to the scope of Articles 68 and 69 of the REACH Regulation.

127. On the other hand, Article 128(2) of the REACH Regulation allows Member States to adopt national legislation when a Union-wide restriction is not needed, and when the conditions of use, manufacture or placing on the market of a substance are not harmonised by an entry in Annex XVII. Hence, the two provisions apply to different situations.

128. Sweden considers that the restriction procedure has a certain harmonising effect, since the REACH Regulation aims to ensure a high level of protection of human health and the environment, and the free movement of substances. Moreover, the heading of Article 68 of the REACH Regulation reads "Introducing new and amending current restrictions", which does not support the conclusion that the restriction process is limited to substances already regulated. Rather, it points to the need to amend Annex XVII when the risks of certain substances need to be addressed on a Community-wide basis.

129. The wording of Article 69(4) of the REACH Regulation is clear in stating that a Member State should only submit the dossier to ECHA if it shows proof that Community-wide action is necessary. It is thus for the Member State concerned to decide if the dossier shows the need for EEA-wide restrictions, and hence if a submission to ECHA is required. Accordingly, the restriction procedure limits the possibility for Member States to introduce national bans when there is an unacceptable risk to human health or the environment arising

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[49] Reference is made to the Opinion of Advocate General Sharpston in *Canadian Oil*, cited above, points 32 to 33.

[50] Reference is made to the judgment in *Canadian Oil*, cited above, paragraphs 26 to 27.

from the manufacture, use or placing on the market of a substance which needs to be addressed on an EEA-wide basis. In this case, the Member State must notify ECHA and prepare a dossier under Article 69(4).

130. If the dossier does not demonstrate the need for EEA-wide action, the Member State may introduce national legislation, provided that the conditions of use, placing on the market or manufacture are not harmonised by an entry in Annex XVII. Before adopting the legislation, the Member State is nonetheless required to notify the proposal to the Commission under Directive (EU) 2015/1535.

131. It moreover follows from Article 128(2) of the REACH Regulation that the harmonising effect is to be assessed in light of what is actually regulated and the objective sought by such regulation. The manufacture, placing on the market or use of a substance cannot be considered regulated until the measures under REACH have actually been adopted. The mere initiation of a restriction process cannot have the effect of obliging EEA States to revoke existing national rules, since the process may result in the assessment that the risk does not need to be addressed at EEA-wide level.

132. Sweden makes no observations with regard to the third plea.

Carl Baudenbacher
Judge-Rapporteur