JUDGMENT OF THE COURT
14 July 2017

(REACH Regulation (EC) No 1907/2006 – Chemical substances – Perfluorooctanoic acid (PFOA) – Free movement – Restrictions procedure – Legal basis)

In Case E-9/16,

EFTA Surveillance Authority, represented by Carsten Zatschler, Auður Ýr Steinarsdóttir and Marlene Lie Hakkebo, members of its Department of Legal & Executive Affairs, acting as Agents,

applicant,

v

The Kingdom of 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,

defendant

APPLICATION for a declaration that Norway has failed to fulfil its obligations arising from the Act referred to at point 12zc of Chapter XV of Annex II to 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)), as adapted under its Protocol 1, and/or its obligations under the Agreement, by maintaining in force a national provision such as Section 2-32 of the Norwegian Product Regulation which bans the manufacture, import, export and sale of consumer products containing certain concentrations of perfluorooctanoic acid,

THE COURT,

composed of: Carl Baudenbacher, President and Judge-Rapporteur, Per Christiansen and Ása Ólafsdóttir (ad hoc), Judges,

Registrar: Gunnar Selvik,

having regard to the written pleadings of the applicant and the defendant, and the written observations of the German Government, represented by Thomas Henze and David Ferdinand Klebs, acting as Agents; the Swedish Government, represented by Anna Falk, Director, and Hanna Shev, Legal Adviser, Ministry for Foreign Affairs, acting as Agents; and the European Commission ("the Commission"), represented by Emmanuel Manhaeve and Ken Mifsud-Bonnici, members of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of the applicant, represented by Carsten Zatschler and Marlene Lie Hakkebo; the defendant, represented by Ketil Bøe Moen; the German Government, represented by David Klebs; and the Commission, represented by Ken Mifsud-Bonnici, at the hearing on 2 March 2017,

gives the following

Judgment

I Introduction

1 By an application lodged at the Court Registry on 5 August 2016, the EFTA Surveillance Authority ("ESA") brought an action under 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"), seeking a declaration that Norway has breached its obligations under the Act referred to at point 12zc of Chapter XV of Annex II to the Agreement on the European Economic Area ("the EEA Agreement" or "EEA"), that is Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1) ("the REACH Regulation") and/or its obligations under the Agreement, by maintaining in force a national regulation prohibiting the manufacture, import, export and sale of consumer products containing certain concentrations of perfluorooctanoic acid ("PFOA"). Norway contests the action.

2 PFOA is a synthetic chemical used as a processing aid in the manufacture of fluoropolymers, as well as in the photographic and imaging industry. It is widely recognised as a substance harmful to health and the environment.

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 in the EEA Agreement by Joint Committee Decision No 25/2008 of 14 March 2008 (OJ 2008 L 182, p. 11), which added it as point 12zc of Chapter XV of Annex II (Technical Regulations, Standards, Testing and Certification) to the Agreement. The decision entered into force on 5 June 2008. From 1 June 2009, the REACH Regulation was applicable in its entirety in the EEA.

5 Article 1 of the REACH Regulation reads:

> *Aim and scope*
>
> 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.*
>
> 2. *This Regulation lays down provisions on substances and mixtures within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.*
>
> 3. *This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect*

human health or the environment. Its provisions are underpinned by the precautionary principle.

6 Article 67(1) of the REACH Regulation reads:

A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

7 Article 68(1) of the REACH Regulation reads:

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 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.

...

8 Article 69 of the REACH Regulation reads:

Preparation of a proposal

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.*

5. *The Agency shall maintain a list of substances for which a dossier conforming to the requirements of Annex XV is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction. If a substance is on the list, no other such dossier shall be prepared. If it is proposed by either a Member State or the Agency that an existing restriction listed in Annex XVII should be re-examined a decision on whether to do so shall be taken in accordance with the procedure referred to in Article 133(2) based on evidence presented by the Member State or the Agency.*

...

9 Article 128 of the REACH Regulation reads:

Free movement

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.*

10 Article 129 of the REACH Regulation reads:

Safeguard clause

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.*

2. *The Commission shall take a decision in accordance with the procedure referred to in Article 133(3) within 60 days of receipt of the information from the Member State. This decision shall either:*

   (a) authorise the provisional measure for a time period defined in the decision; or

   (b) require the Member State to revoke the provisional measure.

3. *If, in the case of a decision as referred to in paragraph 2(a), the provisional measure taken by the Member State consists in a restriction on the placing on the market or use of a substance, the Member State concerned shall initiate a Community restrictions procedure by submitting to the Agency a dossier, in accordance with Annex XV, within three months of the date of the Commission decision.*

4. *In the case of a decision as referred to in paragraph 2(a), the Commission shall consider whether this Regulation needs to be adapted.*

11 Annex XVII to the REACH Regulation contains restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. Substances classified as carcinogenic, mutagenic or reproductive toxicant are listed in entries 28 to 30 of Annex XVII. It follows from the annex that these substances shall not be placed on the market or used as substances, as constituents of other substances, or in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than a certain concentration limit.

12 By Commission Regulation (EU) No 317/2014 of 27 March 2014 (OJ 2014 L 93, p. 24), PFOA was added to entry 30 of Annex XVII to the REACH Regulation as a substance that is toxic to reproduction. That entry contains no restriction on PFOA in articles. Regulation No 317/2014 was inserted in point 12zc of Chapter

XV of Annex II to the EEA Agreement by Joint Committee Decision No 180/2015 of 10 July 2015 (OJ 2017 L 8, p. 9), which entered into force on 11 July 2015.

National law

13 In May 2013, Norway amended 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") to include PFOA.

14 Section 2-32 of the present Norwegian Product Regulation makes it illegal, from 1 June 2014, to manufacture, import, export and sell (1) 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 1μg/m2 (one microgram per square metre), and (2) 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 per cent of weight.

15 The prohibitions on manufacture and export apply from 1 January 2016 for adhesive, foil or tape in semiconductors, and photographic coatings for film, paper or screen. The prohibitions on import and sale apply from 1 January 2018 for products that were produced before the prohibition on manufacture entered into force. 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.

16 Before an amendment in September 2015, Section 2-32 also contained a prohibition on the manufacture, import, export and sale of 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 per cent or more of the chemical. However, that prohibition was repealed in order to implement Commission Regulation (EU) No 317/2014. Thus, Section 2-32 only concerns the presence of PFOA in consumer products, and not PFOA as a pure substance or in a mixture.

III Pre-litigation procedure

17 On 27 August 2013, the Norwegian Government informed ESA that it had amended the Norwegian Product Regulation by introducing in Section 2-32 restrictions on the manufacture, import, export and sale of consumer products containing PFOA and certain salts and esters of PFOA.

18 On 30 October 2013, ESA sent a letter to Norway setting out its concerns regarding the national restriction on PFOA. Norway replied by letter of 10 January 2014. The restriction was further discussed at meetings in Oslo in 2013 and 2014.

19 On 17 October 2014, Germany and Norway submitted a joint dossier to the European Chemicals Agency ("the Agency") under Article 69(4) of the REACH Regulation, proposing an EEA-wide restriction of PFOA, including PFOA in articles.

20 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 and/or the EEA Agreement by maintaining in force Section 2-32 of the Norwegian Product Regulation. On 15 April 2015, Norway submitted its observations on the letter of formal notice, rejecting ESA's view.

21 On 8 July 2015, ESA delivered a reasoned opinion, maintaining the conclusions set out in its letter of formal notice. Pursuant to the second paragraph of Article 31 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. Upon a request from Norway, the deadline for complying with the reasoned opinion was extended to 16 October 2015.

22 On 16 October 2015, Norway responded to the reasoned opinion, maintaining its position and providing some additional comments. Norway explained that it had repealed the part of Section 2-32 concerning PFOA as a substance or mixture. However, the remaining restrictions on PFOA in articles were upheld.

IV Procedure and forms of order sought

23 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 2-32] 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. 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.

24 On 20 October 2016, Norway submitted a statement of defence, requesting the Court to declare that:

1. The application is unfounded.

2. The EFTA Surveillance Authority bears the costs of the proceedings.

25 On 22 November 2016, ESA submitted its reply. On 20 December 2016, the Commission and the German Government submitted written observations. On 21 December 2016, the Swedish Government submitted written observations. On 22 December 2016, Norway submitted its rejoinder.

26 By letter of 16 February 2017, ESA informed the Court that it withdrew the plea alleging a failure to fulfil obligations arising from Article 11 EEA. ESA nevertheless maintains that it should be awarded the costs in respect of this plea, as the withdrawal was, in its view, essentially due to evidence that Norway should have presented during the pre-litigation procedure.

27 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

28 The oral hearing was held on 2 March 2017. Since Judge Páll Hreinsson was prevented from sitting after the closure of the oral procedure, the Court, by letter of 8 May 2017, informed the parties and the other participants of the oral hearing that an ad hoc Judge would be appointed in accordance with Article 30(4) SCA to replace Judge Hreinsson and to complete the Court. In the same letter, the parties and the other participants of the hearing were given the opportunity until 12 May 2017 to request the reopening of the oral procedure. By letters of 12 May 2017, the parties informed the Court that they would not request to be heard again. Accordingly, on 16 May 2017, the Court informed the parties and the other participants of the hearing that it had appointed Ása Ólafsdóttir to act as an ad hoc Judge in the present case and that it had decided to proceed to judgment without reopening the oral procedure.

V Pleas and arguments submitted to the Court

29 The applicant 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 restrictions procedure, and it is thus not open to EEA States to bypass this procedure. Otherwise, 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, would be jeopardised.

30 The applicant's primary plea is that a unilateral national prohibition of a chemical substance by an EEA State is precluded when the restrictions procedure provided for in Articles 67 and 68 of the REACH Regulation is available. The secondary and alternative plea is that, even if the availability in principle of the REACH restrictions procedure is insufficient to preclude unilateral action, unilateral action is certainly precluded once the REACH restrictions procedure has actually been triggered.

31 ESA submits that Article 128(1) of the REACH Regulation guarantees the free movement of substances within the scope of and compliant with that regulation. EEA States are thus prevented 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 restrictions procedure laid down in that regulation. National action is only possible once it is clear that EEA-wide action is not necessary.

32 However, the fact that the restrictions 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 the REACH system. 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 overarching system for the regulation of chemical substances in the EEA.

33 ESA observes that Norway, together with Germany, submitted an Annex XV dossier to the Agency on 17 October 2014. However, the unilateral national restrictions at issue 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.

34 In ESA's view, 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) to justify its conduct.

35 According to ESA, Article 128(2) of the REACH Regulation is intended to address two specific situations. First, it applies to cases where the REACH Regulation itself contained no harmonisation of the requirements on manufacture, placing on the market or use in the transitional period when the regulation was introduced. Second, the provision allows EEA States to regulate substances more strictly for reasons not covered by the REACH Regulation, subject to the general free movement provisions of the EEA Agreement.

36 ESA contends that, 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. 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.

37 Furthermore, according to ESA, it would seem strange from a systematic point of view if Article 128(2) of the REACH Regulation could be relied upon generally by EEA States in order to introduce new restrictions 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. If Norway's reading of Article 128(2) were correct, it would deprive Article 129 of its field of application.

38 ESA moreover disputes Norway'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. Articles 68(1) and 69(4) of the REACH Regulation set out the exhaustive character of the harmonising effect of both the restrictions procedure 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 restrictions procedure itself.

39 Consequently, in ESA's view, Norway has not produced any convincing legal arguments as to why unilateral measures were necessary in the case of PFOA. By maintaining in force a provision such as Section 2-32 of the Norwegian Product Regulation, Norway has breached its obligations under Article 128(1) of the REACH Regulation.

40 The defendant 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. Norway 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.

41 Norway submits that 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 regulation is not absolute. A substance is not harmonised under the REACH Regulation only because it falls within the wide scope of that regulation. National rules to protect workers, human health and the environment are only prohibited if the REACH Regulation harmonises 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 substance itself. If no regulation exists, EEA States are not precluded from adopting national legislation.

42 Norway observes that Article 128(2) of the REACH Regulation refers to both maintaining existing rules and laying down new national rules. The provision was not part of the Commission's original proposal, but the Council introduced it during the legislative process as a means to ensure national capability to respond to challenges related to substances falling within the scope of the REACH Regulation.

43 The defendant also refutes ESA's reading of Article 69(4) of the REACH Regulation. The procedure laid down in that article should be the main approach, an approach Norway has followed. However, this does not mean that an EEA State is obliged to notify its concerns without any delay, as submitted by ESA, since the preparation of an Annex XV dossier is very demanding and time consuming. Were an obligation to notify the Agency and prepare the Annex XV dossier to exist, this should not imply that the procedure as such is harmonised. It should rather 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 legislative history.

44 Moreover, 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 EEA-wide regulations will be adopted.

45 Norway submits in addition 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, that is, 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, in a manner similar to Article 114(5) of the Treaty on the Functioning of the European Union. The possibility for EEA States to adopt national measures is

wider in the absence of harmonising measures (Article 128(2) of the REACH Regulation) than in cases where harmonising measures have already been adopted (Article 129 of the REACH Regulation).

46 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. It notes, however, that procedures which may lead to EEA-wide regulations are often long and complicated, as the present PFOA procedure illustrates. The precautionary principle and the principle of ensuring a high level of protection for human health and the environment are overarching principles of EEA law, in light of which all EEA legislation should be interpreted. Therefore, national measures should be permitted pending the outcome of the procedure under the REACH Regulation.

47 Norway acknowledges that, under Article 3 EEA and the principle of loyal cooperation, EEA States cannot issue only national restrictions if the substance in question causes an EEA-wide concern, since they are obliged to initiate the procedure under Article 69(4) of the REACH Regulation. However, this 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. Article 3 EEA 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.

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

49 The German Government essentially supports the position of Norway. Germany submits that it is important not to underestimate the need for protection in relevant cases. Whilst the REACH system is most sophisticated in terms of achieving a well-considered balance between appropriate protection and the free movement of goods, in many cases it lacks measures designed to provide preliminary protection. If a high level of protection is to be upheld, national governments must be given the opportunity to act quickly and establish supplementary national legislation.

50 Germany submits that both ESA’s primary plea and secondary plea are not in line with Article 128(2) of the REACH Regulation. The wording of Article 128(2) explicitly refers to the protection of workers, human health and the environment and the manufacture, placing on the market and use of a substance. Those are precisely the aims and subjects of the regulation and particularly its risk management sections. It therefore allows EEA States to regulate a substance with the same aims and instruments as long as the REACH Regulation does not contain any specific requirements on that substance. The term requirements

means that the REACH Regulation must impose actual requirements on a substance, by way of authorising or restricting it under Annexes XIV or XVII.

51 According to Germany, Article 69 of the REACH Regulation does not harmonise the requirements on manufacture, placing on the market or use. It merely regulates the procedure for amending Annex XVII. Any other interpretation would deprive Article 128(2) of its meaning.

52 The Swedish Government submits that Article 129 of the REACH Regulation constitutes a derogation clause which allows for unilateral national measures in situations where the procedure in Articles 68 and 69 would otherwise apply. It follows from Article 129(3) that the safeguard clause is the starting point for a restrictions procedure. However, the restrictions 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.

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

54 Sweden considers that the restrictions 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. The restrictions procedure limits the possibility for EEA States to introduce national bans when there is an unacceptable risk to human health or the environment arising 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 EEA State must notify the Agency and prepare a dossier under Article 69(4).

55 Sweden contends that the harmonising effect must 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 measures under REACH have actually been adopted. The mere initiation of a restrictions 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.

56 The Commission essentially supports ESA’s arguments and submits that Norway’s interpretation of the harmonising effect of the REACH Regulation in relation to restrictions is too narrow. Limiting the scope of 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 the previous regulatory framework or an Annex XV dossier which did not result in a restriction because no unacceptable risk was found.

57 The Commission submits that Article 128(2) of the REACH Regulation should be read as a restatement of the principle that EEA States remain free to act in areas which are not harmonised under EU law. It should not be read as limiting the harmonising effects under the REACH Regulation or undermining the free movement clause in Article 128(1).

58 In the Commission's view, the safeguard clause in Article 129 of the REACH Regulation should be triggered if EEA States consider that urgent action is essential to make the manufacture, placing on the market or use of a substance which is subject to a restriction under Annex XVII subject to new conditions.

59 According to the Commission, the restrictions procedure established by Title VIII of the REACH Regulation has itself a harmonising effect and is designed to preserve the *status quo* pending the evaluation of the need for EEA-wide action. In this regard, the safeguard clause in Article 129 of that regulation also applies in cases where an EEA State intends to introduce an urgent restriction for a substance for which no entry in Annex XVII exists yet.

VI Findings of the Court

60 Article 1(1) of the REACH Regulation establishes that the regulation's purpose 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.

61 According to its Article 1(3), the REACH Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that substances they manufacture, place on the market or use do not adversely affect human health or the environment. The REACH Regulation's provisions are underpinned by the precautionary principle.

62 The REACH Regulation establishes a comprehensive framework for the registration and evaluation of chemical substances, the authorisation of substances of very high concern, and the restriction of substances that pose an unacceptable risk to human health or the environment.

63 Title II of the REACH Regulation concerns the registration of substances. Article 5 provides that substances on their own, in mixtures or in articles shall generally not be manufactured or placed on the market unless they have been registered in accordance with the relevant provisions. In order to register a substance, the registrant must provide the Agency with information about the properties and hazards of the substance, including how it can be used safely. The Agency undertakes a completeness check of each registration without assessing the quality or the adequacy of any data or justifications submitted to it.

64 Once a substance is registered, an evaluation procedure set out in Title VI of the REACH Regulation follows. Evaluations may set in motion the authorisation procedure or the restrictions procedure.

65 Substances of very high concern may be subject to authorisation pursuant to the provisions of Title VII of the REACH Regulation. The purpose is to ensure that the risks from such substances are properly controlled and also that suitable alternative substances or technologies may progressively replace these substances.

66 Title VIII of the REACH Regulation sets out the procedure for setting restrictions on the manufacture, placing on the market or use of certain dangerous substances, mixtures and articles. That procedure may result in an entry of a substance in Annex XVII to the REACH Regulation. Article 67 provides that a substance for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.

67 Article 68(1) of the REACH Regulation provides that 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 an EEA-wide basis, Annex XVII shall be amended. The provisions for that procedure are laid down in Articles 69 to 73.

68 The Commission, the Agency or an EEA State may take the initiative to have a substance restricted if that substance poses a risk to human health or the environment that is not adequately controlled. In that case, the Agency or the EEA State must prepare an Annex XV dossier. If the dossier demonstrates that action on an EEA-wide basis is necessary, the restrictions procedure must be launched.

69 The present case concerns the lawfulness of a Norwegian restriction on PFOA in articles. Although PFOA is subject to some restrictions in Annex XVII to the REACH Regulation, the parties to the dispute agree that the annex does not cover PFOA in articles (in the following referred to only as PFOA).

70 A REACH restrictions procedure regarding PFOA has been set in motion by Norway and Germany. The parties to the dispute agree that Norway cannot maintain its national restriction on PFOA after the restrictions procedure has been finalised. At the core of the present dispute is therefore the question whether Norway may restrict PFOA pending a final decision under the REACH Regulation. Norway did not resort to the safeguard clause in Article 129, but followed Article 128(2) of the REACH Regulation.

71 Article 128(1) of the REACH Regulation sets out the rule that an EEA State 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 and complying with the REACH Regulation.

72 However, that rule is subject to Article 128(2), according to which nothing in the REACH Regulation shall prevent an EEA State from maintaining or laying down national rules to protect workers, human health and the environment, to be applied in cases where the regulation does not harmonise the requirements on manufacture, placing on the market or use of a substance.

73 Pursuant to Article 129 of the REACH Regulation, an EEA State may take appropriate provisional measures in respect of a substance, provided that urgency and justifiable grounds to protect human health or the environment exist. This applies even if the substance satisfies the requirements of the REACH Regulation. In those circumstances, however, the EEA State must inform the Commission/ESA, the Agency and the other EEA States of the national measure. The Commission/ESA must within 60 days authorise the measure or require the EEA State to revoke it. If the restriction is authorised, the EEA State concerned is obliged to submit an Annex XV dossier to the Agency within three months.

74 Norway argues that the requirements on the manufacture, placing on the market or use are harmonised under Article 128(2) only as a result of a final decision under the restrictions procedure, that is, a corresponding entry in Annex XVII. Until then, national restrictive measures are permitted subject to the free movement provisions of the EEA Agreement.

75 ESA claims, however, that the REACH restrictions procedure laid down in Title VIII of the REACH Regulation is a harmonised requirement for a substance provided that it falls within the scope of the REACH Regulation and needs to be addressed on an EEA-wide basis. According to ESA, national measures are possible under Article 129, whereas Article 128 refers to substances outside the scope of the REACH Regulation.

76 A literal interpretation of Article 128(2) and Article 129 of the REACH Regulation does not lead to clear results concerning the interplay between the two provisions. The assessment of the harmonising effects of the REACH Regulation must therefore take into account the aim and the overall system established by that regulation, while taking full account also of Article 128(2).

77 The precautionary principle, which underlies the REACH Regulation, establishes that, in case of scientific uncertainty, EEA States retain the possibility of taking protective measures without having to wait for greater risks to become apparent (see Cases E-3/00 *ESA* v *Norway* [2000-2001] EFTA Ct. Rep. 73, paragraph 25; E-04/04 *Pedicel AS v Sosial- og helsedirektoratet* [2005] EFTA Ct. Rep., 1, paragraphs 59 to 61; compare the judgment in *Commission* v *Netherlands*, C-41/02, EU:C:2004:762, paragraphs 51 to 54).

78 An EEA State may indeed have legitimate concerns for reasons of human health or the environment to introduce or maintain national measures pending the outcome of the REACH restrictions procedure. A substance, the requirements of which have not yet been harmonised, may give rise to sufficiently serious concern for an EEA State temporarily to apply a national measure until the

REACH restrictions procedure is brought to an end. Under such circumstances, Article 128(2) of the REACH Regulation will accommodate such concerns and may efficiently support the precautionary principle in order to maintain a high level of protection for human health and the environment.

79 It is clear from the *travaux préparatoires* that Article 128(2) was not part of the Commission's proposal. The provision was inserted by the Council during the legislative procedure. Accordingly, the REACH Regulation recognises a need to retain national capabilities to respond to challenges and to evaluate substances likely to constitute a risk to health and environment (compare the Opinion of Advocate General Sharpston in *Canadian Oil and Rantén*, C-472/14, EU:C:2015:809, point 32, with further references). The provision thus supplements the safeguard clause in Article 129 and gives the EEA States the right to adopt national measures regarding substances where requirements have not yet been harmonised under the REACH Regulation's restrictions procedure.

80 An interpretation of Article 128(2) to the effect that a national measure is permitted pending a final decision under the REACH restrictions procedure is not disruptive of the overall REACH system, since such measure will be provisional and cannot be maintained in contravention of the final outcome of the REACH restrictions procedure. Furthermore, in cases where an EEA State adopts a national measure, the restrictions procedure must be triggered, if not already under way, as a consequence of the obligation on the EEA State to initiate the procedure under Article 69(4) of the REACH Regulation. Moreover, it follows from Article 3 EEA that the EEA State must fulfil this obligation without delay. A failure to do so may prompt ESA or the Commission to initiate infringement proceedings.

81 According to ESA, it is confusing that Article 128(2) of the REACH Regulation would make it easier for an EEA State to introduce national restrictions in non-urgent situations than under Article 129 in urgent situations. However, whereas Article 129 may be used in cases where the restrictions procedure has been brought to an end, this is not the case when applying Article 128(2). An EEA State is generally free to adopt national measures in areas not harmonised at the EEA level. However, such national measures will be subject to the fundamental freedoms of EEA law.

82 The harmonised requirements mentioned in Article 128(2) of the REACH Regulation are those resulting from a finalised restrictions procedure, not the harmonised procedural rules governing the restrictions process itself. Contrary to ESA's submissions, the mere fact that a substance falls within the scope of the REACH Regulation and needs to be addressed on an EEA-wide basis cannot prevent an EEA State from acting under Article 128(2). Such an interpretation would render the content of Article 128(2) nugatory.

83 It follows that an EEA State may lay down under Article 128(2) a national measure regarding a substance for which the REACH restrictions procedure has not yet been finalised. Furthermore, this interpretation recognises properly the

intention underlying the inclusion of Article 128(2) in the REACH Regulation. Nevertheless, when a national measure is taken it is incumbent on the EEA State to initiate the REACH restrictions procedure without delay; such measure will be provisional and subject to ESA's or the Commission's supervision. Moreover, in cases of violation of EEA law, the EEA State may be obliged to provide compensation for loss and damage caused to individuals and economic operators in accordance with the principle of State liability under EEA law (see Case E-18/11 *Irish Bank* [2012] EFTA Ct. Rep. 592, paragraph 125 and case law cited).

84 The Court therefore holds that the requirements on manufacture, placing on the market or use mentioned in Article 128(2) of the REACH Regulation are harmonised only when a substance has been subject to a final decision under the REACH restrictions procedure. Since PFOA in articles had not been subject to such a final decision at the end of the period set in ESA's reasoned opinion, Norway did not breach its obligations under the REACH Regulation by invoking Article 128(2) as a basis for laying down in national law a provisional restriction on PFOA in articles.

85 Consequently, the application must be dismissed.

VII Costs

86 Under Article 66(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Norway has been successful, and has requested that ESA be ordered to pay the costs. The Court finds that none of the exceptions in Article 66(3) applies, also in relation to the costs incurred on the plea that was withdrawn. ESA must therefore be ordered to pay the costs. The costs incurred by the German Government, the Swedish Government and the Commission, which have submitted observations to the Court, are not recoverable.

On those grounds,

THE COURT

hereby:

1. **Dismisses the application.**

2. **Orders the EFTA Surveillance Authority to bear the costs of the proceedings.**

Carl Baudenbacher Per Christiansen Ása Ólafsdóttir

Delivered in open court in Luxembourg on 14 July 2017.

Birgir Hrafn Búason
Acting Registrar

Carl Baudenbacher
President