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Case No: 78775
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ORIGINAL

EFTA SURVEILLANCE
AUTHORITY

IN THE EFTA COURT

APPLICATION

submitted pursuant to Article 31(2) of the Agreement between the EFTA States on the
Establishment of a Surveillance Authority and a Court of Justice by

THE EFTA SURVEILLANCE AUTHORITY

represented by Carsten Zatschler and Auður Ýr Steinarsdóttir,
acting as Agents,

applicant,

AGAINST

THE KINGDOM OF NORWAY

defendant,

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 (PFOA), Norway has breached its obligation arising from the Act referred to at point 12zc of chapter XV of Annex II to the EEA Agreement (*Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*) as adapted by way of Protocol 1 thereto, and/or its obligations under the Agreement on the European Economic Area.

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1 INTRODUCTION

1. By the present Application, the EFTA Surveillance Authority (“ESA”) seeks a declaration that Norway has breached its obligations under the REACH Regulation,¹ and/or its obligations under the EEA Agreement, 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 a substance commonly referred to as “PFOA”.²
2. PFOA is a synthetic chemical that does not occur naturally in the environment. It is used as a processing aid in the manufacture of fluoropolymers, which have numerous applications due to their fire resistance and ability to repel oil, stain, grease and water, the most well-known example being polytetrafluoroethylene, commercially known as Teflon. PFOA is also used in the photographic and imaging industry.
3. 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 REACH is permissible only in certain narrowly defined circumstances, provided for under the REACH Regulation. As such, REACH harmonises the restriction process itself, depriving States of the possibility of acting unilaterally. In particular, it is not open to EEA States to unilaterally bypass the harmonised restriction process provided for in Articles 68 and 69 of REACH, which would jeopardise the uniform high level of protection of human health and the environment as well as the free movement of substances which REACH was adopted to ensure.

¹ Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement, incorporated by EEA Joint Committee Decision No 25/2008 of 14 March 2008 (*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 (“REACH” or “the Regulation”*).

² Scientifically known as perfluorooctanoic acid or pentadecafluorooctanoic acid. Identified with CAS (Chemical Abstract Service Registry) number 335-67-1 and European Community (EC) number 206-397-9. The CAS number is the substance numerical identifier assigned by the Chemical Abstract Service, a division of the American Chemical Society. The EC number is the numerical identifier for substances in the EC inventory, which is a combination of three independent and legally approved European lists of substances from the previous EU chemicals regulatory frameworks [EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European List of Notified Chemical Substances) and NLP (No-Longer Polymers)]. Both are widely used chemical identifiers. See information on the website of the European Chemicals Agency: <http://echa.europa.eu/substance-information/-/substanceinfo/100.005.817>, enclosed as **Annex A.1** to this Application.

4. The specific background to the present Application concerns national legislation which has been adopted in Norway to restrict PFOA, a substance which, while it has been manufactured since the 1940s in industrial quantities, has been the subject of significant and increasing concerns. It is important to stress that, by this Application, ESA in no way seeks to question the necessity of regulating PFOA as a substance. It is instead an important procedural matter which has prompted ESA to bring the present infringement action: when an EEA State identifies a risk to health or the environment arising from a substance covered by REACH, it is essential for the functioning of the system established by REACH that those concerns are acted upon within the framework of that system, rather than resulting in unilateral action.
5. As will be explained in further detail below, REACH lays down detailed rules on the procedures to be followed which are designed to ensure that all stakeholder interests are duly taken into account, and that a uniform, high level of protection is achieved throughout the EEA. Unilaterally imposed restrictions are, against that background, not only prone to hinder the free movement of substances within the internal market sought to be ensured by REACH as a whole, and the free movement clause in its Article 128 in particular, but also undermine the achievement of health and environmental protection objectives of REACH by removing any incentive on individual States to share their dossiers through REACH to ensure equally high protection throughout the internal market.
6. That is why ESA in the present proceedings challenges the fact that Norway took unilateral action on PFOA, adopting itself a national restriction on the substance rather than applying the REACH mechanism. The point of principle raised by this Application – whether it is open to EEA States to unilaterally bypass the harmonised restriction process provided for in Articles 68 and 69 of REACH – is of systematic importance for the functioning of REACH as a whole.

2 LEGAL FRAMEWORK

2.1 The EEA Agreement

7. Article 3 of the EEA Agreement requires the EEA States to guarantee the effective application of EEA law:

“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”

8. Article 11 of the EEA Agreement prohibits quantitative restrictions on imports and all measures having equivalent effect between the Contracting Parties.
9. Article 13 of the EEA Agreement provides for an exception from Article 11. It reads as follows:

“The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties.”

2.2 The REACH Regulation

10. REACH stands for the Registration, Evaluation and Authorisation of Chemical substances. A main objective of the REACH regime is the creation of a single, comprehensive, overarching registration system designed to identify relevant risk management measures based on hazard and risk information on new and existing chemical substances manufactured in or imported into the EEA.
11. As is clear from Article 1 and Recital 1 of REACH, it is intended to ensure a high level of protection of human health as well as the environment. Among its key aims is the free circulation of substances throughout the internal market, on their own, in mixtures and articles, while enhancing competitiveness and innovation. Recital 2 of REACH further makes it clear that “[t]he 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”.

12. One of the main reasons for creating REACH was the large number of substances manufactured and placed on the market in Europe over the years, sometimes in very high amounts, combined with insufficient information on the hazards these substances pose to human health and the environment. It was considered necessary to fill these information gaps by establishing a coherent system in order to ensure that the industry is able to assess hazards and risks of new and existing chemical substances manufactured in or imported into the EEA, and to identify and implement the risk management measures to protect humans and the environment.
13. In principle, it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment.
14. REACH aims to improve the protection of human health and the environment through early identification of the intrinsic properties of chemical substances. REACH introduces four stand-alone but complementary procedures for the risk management of hazardous substances: registration, evaluation, authorisation and restriction of chemicals. For present purposes, it is the restriction process which is relevant.

2.2.1 Restriction

15. REACH establishes a restriction process to manage risks that are otherwise not adequately addressed in the legislation. Under the restriction regime, it is possible to restrict the manufacture, placing on the market (including import) or use of certain substances. The scope of the restriction can vary: for example, certain substances may be made subject to specific limitations, e.g. a prohibition on their use in children's toys or food contact materials, while others may see an outright ban imposed on their importation or manufacture in the EEA.
16. A restriction is defined under REACH as "any condition for or prohibition of the manufacture, use or placing on the market".³ The REACH provisions on restrictions,

³ Article 3(31) REACH.

notably Title VIII (Articles 67 to 73) and Annex XVII, have applied since 1 June 2009 throughout the EEA.⁴

17. According to Article 68(1) of REACH:

“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 (...)”

18. Where such a risk is identified, a restriction must be adopted following the procedure set out in Title VIII of REACH. Article 69(4) REACH provides:

“If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a preparation 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.”

19. The dossier which must be prepared by the EEA State concerned in conformity with Annex XV of REACH (“the Annex XV dossier“) should demonstrate that there is an unacceptable risk to human health or the environment that needs to be addressed at the EEA level and identify the most appropriate set of risk reduction measures. If that is the case, the State concerned is obliged to initiate the restriction process.

20. Proposals for restrictions can also be prepared by ECHA at the request of the Commission (Article 69(1) of REACH).

⁴ The following link to ECHA’s website provides an overview of the restriction process: <http://echa.europa.eu/web/guest/regulations/reach/restrictions/restriction-procedure/restrictions-process>. The graph provided therein is enclosed as **Annex A.2** to this Application.

21. To prevent duplication of work, a State must notify ECHA of its intention to prepare an Annex XV dossier for a restriction. ECHA will maintain a list of Annex XV dossiers for restrictions that are planned or underway. For substances on this list, no other such dossier shall be prepared (Article 69(5) of REACH).
22. Where the restriction process outlined above culminates in a decision by the Commission to restrict a substance, this restriction is registered in Annex XVII of REACH, which contains a list of all restricted substances, specifying which particular uses are restricted.

2.2.2 Free movement and safeguard clauses

23. Title XV of REACH, entitled “Transitional and Final Provisions” contains a Free movement clause in Article 128, as well as a Safeguard clause in Article 129.
24. Article 128(1) REACH guarantees the free movement of products that are within the scope and in compliance with the Regulation, by forbidding States from regulating them further. The second paragraph provides for a limited transitional exception to this rule. Article 128 reads as follows:

“1. Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a preparation 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.”

25. REACH also contains an over-arching safeguard mechanism in Article 129, which 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 preparation 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 point (a) of paragraph 2, 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 point (a) of paragraph 2, the Commission shall consider whether this Regulation needs to be adapted.”

26. When Article 129 is invoked, the relevant EEA EFTA State must immediately inform ESA, which then has 60 days either to authorise the provisional measure or require the State to revoke the provisional measure.⁵

2.3 National regulation of PFOA

27. In Norway, following amendments adopted on 27 May 2013, section 2, paragraph 32, of Regulation No 922 of 2004 relating to restrictions on the use of chemicals and other products hazardous to health and the environment (“the Norwegian Product Regulation”)⁶ makes it illegal, from 1 June 2014, to manufacture, import, export and sell consumer

⁵ Article 129(2) REACH, as adapted by Protocol 1 to the EEA Agreement.

⁶ Regulation amending the Regulation relating to restrictions on the use of chemicals and other products hazardous to health and the environment, No 922 of 1 June 2004 (as amended): *Forskrift om endring i forskrift om begrensning i bruk av helse- og miljøfarlige kjemikalier og andre produkter (produktforskriften) 1 Juni 2004 nr. 922 (FOR-2004-06-01-922)*. The text in Norwegian of § 2-32 is available under the following link: http://lovdata.no/dokument/SF/forskrift/2004-06-01-922/KAPITTEL_2#§2-32.

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.

28. Further, as from the same date, it is prohibited to manufacture, import, export and sell textiles, carpets and other coated consumer products when the content of PFOA, and certain salts and esters of PFOA⁷, is present in amounts equal to or greater than 1 µg/m².
29. The prohibition also covers the manufacture, import, export and sale of 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.
30. The prohibitions mentioned above apply from 1 January 2016 for a) adhesive, foil or tape in semiconductors and b) photographic coatings for film, paper or screen. The prohibitions on the other hand do not apply to food packaging, materials in direct contact with food and medical equipment. The prohibitions do not apply to spare parts for consumer products that were made available for sale before 1 June 2014.
31. Section 2, paragraph 32, of the Norwegian Product Regulation was amended on 27 May 2014 in order to allow products which were manufactured before the ban entered into force to remain on sale until 1 January 2018.

2.4 EEA regulation of PFOA

2.4.1 Restriction process

32. On 19 February 2014, together with Germany, Norway notified its intention to ECHA to submit an Annex XV dossier under the restriction process to ECHA proposing an EEA wide restriction on PFOA. That dossier was formally submitted on 17 October 2014.⁸
33. Following submission, the dossier was subject to scrutiny by the Risk Assessment Committee ("RAC")⁹ as foreseen in Article 70 of REACH in order to determine whether it was in conformity with the requirements of Annex XV of REACH. Once that had been

⁷ Those salts and esters are identified with the following CAS numbers: CAS No. 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5.

⁸ The information note submitted with the dossier is available via the following link: <http://echa.europa.eu/documents/10162/3b6926a2-64cb-4849-b9be-c226b56ae7fe>

⁹ RAC prepares the opinions of ECHA related to the risks of substances to human health and the environment in certain REACH and CLP (Classification, Labelling and Packaging) processes (including restriction and authorisation processes).

established, the dossier was subject to public consultation. The deadline for comments in the public consultation was 17 June 2015. Subsequently, the Socio-Economic Committee (“SEAC”)¹⁰ adopted its opinion in line with Article 71 of REACH. A schematic timeline of the restriction process is provided in **Annex A.3** to this Application.¹¹

34. The restriction procedure is as things stand at present not yet finalised. ESA understands that the relevant committees within ECHA, the RAC and the SEAC, submitted their reports to the Commission in January 2016.¹² According to recent informal information received from the Commission, it is currently preparing a draft amendment of Annex XVII. The ultimate outcome of this procedure in any event has no bearing on the present action.

2.4.2 Authorisation process

35. By way of further background, it may be noteworthy that PFOA is also currently a candidate substance for authorisation under REACH. The aim of the authorisation process, as stated in Article 55 of REACH, is:

“to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.”

36. Authorisation is a procedure intended to control the risks arising from substances of very high concern (“SVHC”)¹³ and to phase them out in favour of suitable alternatives. Where an SVHC is subject to an authorisation, it may not be placed on the market for use in the EEA unless companies (and their registered users) have been specifically authorised to do so. Authorisation will only be granted where it can be demonstrated that the risks are

¹⁰ SEAC prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in certain REACH processes (including restriction and authorisation processes).

¹¹ Timeline from page 6 of “REACH Restriction Regime, The Basics”, April 2011. Available at: <http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/REACH-Restriction-Regime-the-basics.pdf>.

¹² Information on these reports is available at: <http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1908/term>.

¹³ For the sake of good order, it must be noted that substances that have been identified as being of very high concern (SVHC) under the authorisation procedure can be made subject to the restriction procedure if the authorisation procedure is not considered to sufficiently address possible risks to human health or the environment caused by those substances. The authorisation procedure is limited to substances that have been identified as SVHCs, but the restriction procedure on the other hand is not limited to SVHCs.

adequately controlled, that the socio-economic advantages outweigh the risks and that no suitable alternatives are available.¹⁴ The authorisation regime is set out in Title VII of REACH.

37. Before a substance can be subject to authorisation, it must first be added to the candidate list.¹⁵ To be added to the list, substances must meet the criteria set out in Article 57(f) of REACH. Any EEA State may prepare a dossier in accordance with relevant legislation for substances which, in its opinion, meet the criteria set out in Article 57 (Article 59(3)). According to Article 59(2) of the Regulation, ECHA may also prepare dossiers at the request of the Commission.
38. Once on the candidate list, ECHA submits a recommendation to the Commission, which then decides whether the substance is to be included in the Authorisation list set out in Annex XIV of REACH.
39. On 4 February 2013, Germany submitted an Annex XV dossier to ECHA proposing that PFOA be identified as a SVHC as it met the criteria of Article 57(c) REACH. This was based on RAC's findings. PFOA was accepted onto ECHA's candidate list for authorisation on 20 June 2013, but it has not yet been listed in Annex XIV of REACH.¹⁶
40. For the sake of clarity, it must be noted that, as they are designed as two stand-alone regimes, authorisation and restriction are not mutually exclusive. It is therefore important to ensure proper interaction between them.¹⁷ However, the acceptance of PFOA onto the candidate list for authorisation has no further bearing on the present action.

¹⁴ Article 60 REACH.

¹⁵ Article 59(1) REACH.

¹⁶ ECHA press release, ECHA/PR/13/26, available at http://echa.europa.eu/view-article/-/journal_content/title/echa-updates-the-candidate-list-for-authorisation-with-six-new-substances-of-very-high-concern-svhcs-.

¹⁷ See also recital 80 of REACH, which states that “[t]he proper interaction between the provisions on authorisation and restriction should be ensured in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment. [...]” See also “Regulating Chemical Substances under REACH: The Choice between Authorization and Restriction and the Case of Dipolar Aprotic Solvents”, by Lucas Bergkamp and Nicolas Herbatschek. Available at: https://www.reachpsforum.eu/files/Uploads/Documents/REACH/Regulating_Chemical_Substances_under_REACH.pdf.

2.4.3 The CLP Regulation

41. Finally, to provide the fullest possible context to the Court, it can be noted that the REACH Regulation is complemented by the so-called “CLP Regulation” (for “Classification, Labelling and Packaging”),¹⁸ which ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EEA through classification and labelling of chemicals. While REACH governs what substances can be used in the EEA, the CLP Regulation lays down rules concerning information which must be provided in relation to them. In most cases, it will be the suppliers of products that decide on their classification. However, for some particularly hazardous substances, the decision on the classification of a chemical is taken at EEA level. Under Article 37 of the CLP Regulation, EEA States may submit proposals for the harmonised classification and labelling of a substance.
42. Following submission by Norway of a dossier prepared in accordance with Annex VI of the CLP Regulation for a harmonised classification and labelling for PFOA and its salts, the Committee for Risk Assessment (RAC) concluded that PFOA should be classified as toxic for reproduction category 1B¹⁹ in accordance with the CLP Regulation.²⁰
43. PFOA was included in Annex XVII of REACH with effect from 1 January 2015.²¹ Entries 28 to 30 of Annex XVII of REACH prohibit the sale to the general public of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR) above specified concentration limits. Specifically, Regulation 317/2014 inserted PFOA into

¹⁸ Regulation (EC) No 1272/2008 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. Act incorporated into the EEA Agreement at point 1 of Chapter XV of Annex II by EEA Joint Committee No. 106/2012 of 15 June 2012.

¹⁹ Committee for Risk Assessment, decision of 2 December 2011 available at http://echa.europa.eu/documents/10162/13579/rac_pfoa_adopted_opinion_en.pdf. A reproductive toxicant is a chemical substance that is capable of producing effects on either the male or female reproductive system. For further details, see: http://scorecard.goodguide.com/health-effects/explanation.tcl?short_hazard_name=repro.

²⁰ This corresponds to classification as toxic to reproduction category 2 in accordance with *Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances* referred to at point 1 of Chapter XV of Annex II to the EEA Agreement (“Directive 67/548”).

²¹ *Commission Regulation 317/2014 of 27 March 2014 amending the REACH Regulation as regards Annex XVII (CMR Substances)*. Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement, incorporated into the EEA Agreement by Joint Committee Decision No 180/2015 of 10 July 2015, which entered into force on 11 July 2015.

Appendix 6 of Annex XVII to REACH as toxic for reproduction category 1B in the EU with a limit value of 0.3% by weight²². This is a generic concentration limit which applies to CMR substances and must not be confused with any limit value which may be set under the restriction procedure under Title VIII of REACH. Again, none of these matters have a specific bearing on the present action, and these details are only provided by way of general background to the Court.

3 PRE-LITIGATION PROCEDURE

44. On 27 August 2013, the Norwegian Government informed ESA that a regulation amending the Norwegian Product Regulation through the introduction of restrictions on the manufacture, import, export and sale of consumer products containing PFOA and certain salts and esters of PFOA had been adopted on 27 May 2013.
45. 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 (“DTR”) procedure laid down in Directive 98/34,²³ first in 2007 and then again in 2010.²⁴ ESA issued comments on both of these draft regulations.²⁵ In both sets of comments, ESA questioned the compatibility of the proposed Norwegian regulations with existing harmonised EEA legislation applicable to products intended for use by consumers.
46. The Commission also issued comments on the 2010 Norwegian notification in the context of the DTR procedure.²⁶ Having received no reply to those comments and being concerned that its comments had not been taken into account by the Norwegian Government, the Commission issued further comments on 1 March 2013.²⁷ These comments made it clear

²² In relation to the concentration limit of 0.3% by weight which applies to PFOA, the second indent of paragraph 1 of Entry 28-30 of Annex XVII to REACH was modified in the EU with effect from 1 June 2015 by Article 59(7)(b)(i) of the CLP Regulation so that it refers to “*the relevant generic concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008*”. The specified concentration limit is to be found in Table 3.7.2 in Annex I to the CLP Regulation which refers to the 0.3% by weight concentration limit.

²³ *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 and of rules on Information Society services.*

²⁴ The notifications submitted by Norway are enclosed as **Annexes A.4** and **A.5** to this Application.

²⁵ **Annexes A.6** and **A.7** to this Application.

²⁶ **Annex A.8** to this Application.

²⁷ **Annex A.9** to this Application.

that, if adopted, the notified measures would have a negative impact on the free movement of goods within the EEA.

47. On 30 October 2013, ESA sent a pre-31 letter to Norway,²⁸ setting out its concerns regarding the prohibition on PFOA. Norway replied by letter dated 10 January 2014.²⁹ The prohibition was further discussed during package meetings in Oslo in 2013 and 2014.
48. On 14 January 2015, ESA issued a letter of formal notice to Norway, concluding that Norway had failed to fulfil its obligations under the Regulation.³⁰ On 15 April 2015, Norway submitted its formal observations on the letter of formal notice to ESA.³¹
49. On 8 July 2015, ESA delivered a reasoned opinion, maintaining three of the conclusions set out in its letter of formal notice.³² Pursuant to the second paragraph of Article 31 of the Surveillance and Court Agreement (“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. It is accordingly that date – 8 September 2015 – at which the infringement has to be assessed.
50. By letter of 16 October 2015, Norway responded to the reasoned opinion, maintaining its position and providing some additional comments.³³ As Norway still maintained the national provisions in question by the deadline set in the reasoned opinion, ESA decided to bring the matter before the EFTA Court pursuant to the second paragraph of Article 31 SCA.³⁴

4 THE INFRINGEMENTS

51. ESA’s primary plea is that a unilateral national prohibition of a chemical substance by an EEA State is precluded where one is concerned with a substance covered by REACH and the restriction procedure provided for in Articles 67 and 68 of REACH is available.

²⁸ Document No 687170. **Annex A.10** to this Application.

²⁹ Document No 695408. **Annex A.11** to this Application.

³⁰ Document No. 722134. **Annex A.12** to this Application.

³¹ Document No. 754015. **Annex A.13** to this Application.

³² Document No. 759496. **Annex A.14** to this Application.

³³ Document No. 776683, **Annex A.15** to this Application.

³⁴ College Decision No. 040/15/COL, adopted on 17 February 2016, Document No. 779018.

52. ESA's secondary plea, which is in the alternative, is that, even if it were not sufficient for the REACH restriction procedure to be in principle available to preclude unilateral action, once the REACH restriction procedure has been actually triggered, unilateral action is certainly precluded.
53. In any event, according to ESA's third plea, the restrictions on PFOA as introduced by the Norwegian Product Regulation constitute a breach of the provisions in the EEA Agreement on the free movement of goods.
54. These three pleas are addressed below in order.

4.1 Primary plea: Unilateral action is precluded where the REACH restriction procedure is available

55. Article 128(1) of REACH guarantees the free movement of products that are within the scope of and in compliance with the Regulation, by forbidding States from prohibiting, restricting or impeding the manufacturing, import, placing on the market or use of such products.
56. Any EEA State wishing to impose restrictions on PFOA would have had to invoke the restriction process laid down in Articles 67 to 73 of REACH. The language of Article 69(4) of REACH is unequivocal. The provision clearly provides that if a State considers that a substance presents a risk to human health or the environment that is not adequately controlled "*it shall notify the Agency...*" (emphasis added). In such circumstances, States are obliged to prepare an Annex XV dossier under Article 69(4) within 12 months of the notification to ECHA. This language does not leave any room to interpret the provision as being optional.
57. As such, Article 69(4) REACH thus in effect deprives States of the possibility of addressing uncontrolled risks through unilateral national restriction measures, without first having followed the restriction procedure under Title VIII of REACH. As long as different rules relating to the manufacture, import, export and sale of a substance (PFOA in this case) remain in place across the EEA, the objective of REACH to ensure the free circulation of substances on the internal market cannot be met. It is only when it is established, on the

basis of an Annex XV dossier, that the identified risks do not require action on an EEA wide basis, that national restrictions may be introduced.³⁵

58. On 17 October 2014, together with Germany, Norway submitted an Annex XV dossier to ECHA. However, in breach of Article 128(1) of REACH, Norway had already unilaterally imposed national restrictions, which form the basis of the present action. A national legal provision such as section 2, paragraph 32, of the Norwegian Product Regulation clearly qualifies as a restrictive measure³⁶ under Article 128(1) REACH.

59. REACH is intended to “*ensure a high level of protection of human health and the environment*”³⁷. This is to be achieved, inter alia, through the restriction process established by Title VIII of REACH. As already pointed out by way of introduction, in order for the REACH system to work efficiently, it is important that all the parties involved respect the processes under the Regulation and refrain from taking unilateral action.

60. Norway has not advanced any cogent legal arguments during the pre-litigation procedure as to why unilateral measures were necessary to address PFOA. The provisions of REACH in principle permit unilateral national measures where a State believes there is an urgent need for action, using the safeguard provisions of Article 129 of REACH. That clause was however never invoked in the present case by Norway.

61. Instead, Norway has, in the pre-litigation procedure, sought to justify its conduct by reference to the second paragraph of Article 128 of REACH. In ESA’s submission, that is a provision which already on its face does not apply in circumstances such as those of the present case. Article 128(2) of REACH provides a narrow exception to the free movement provisions established by Article 128(1) and is intended to address two specific scenarios. Firstly, cases where REACH itself contained no harmonisation of the requirements on manufacture, placing on the market or use in the transitional period when REACH was introduced. Secondly, to regulate substances more strictly for reasons not covered by REACH – subject of course to the general free movement provisions of the EEA Agreement. The provision has, according to information received from the Commission, in

³⁵ REACH Article 68(1).

³⁶ According to Article 3(33) of the Regulation, a restriction means “*any condition for or prohibition of the manufacture, use or placing on the market.*”

³⁷ REACH Article 1(1).

practice only ever been applied to deal with pre-existing restrictions in Member States at the point when REACH was introduced and it has never been invoked in the way that Norway now has purported to seek to justify the introduction of new national rules.

62. As an exception from the general free movement provision in Article 128(1), it is clear that Article 128(2) must be interpreted narrowly in any event.
63. Furthermore, from a systematic point of view, it would seem strange if Article 128(2) could be relied upon by EEA States generally to introduce new regulations in non-urgent situations more easily and subject to fewer checks by the Commission/ESA than those provided for under the safeguard clause in Article 129 of REACH. Article 129 of REACH requires States wishing to take unilateral action to immediately inform the Commission (or ESA as regards the EEA EFTA States),³⁸ 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/ESA is then bound to take a decision on the matter within 60 days and may require the State to revoke the provisional measure. Moreover, Article 129(3) expressly requires for the submission of an Article XV dossier if the Commission/ESA authorises a provisional measure. If Norway's reading of Article 128(2) were correct, it would deprive Article 129 of its field of application.
64. Norway has argued that harmonisation can only be achieved when there is a restriction by means of an Annex XVII entry, and not merely by the availability of the restrictions procedure provided for in Title VIII.³⁹ Hence, it has argued that the harmonisation contemplated by Article 128(2) takes place "*only when an actual regulation of the substance in question exists*".⁴⁰ Norway has further argued that if a State's discretion to introduce national legislation exists only in the exceptional circumstances envisaged by Article 129 of REACH, Article 128(2) would be deprived of "*its proper purpose*".
65. Norway's position in this regard is misconceived. The provisions of Articles 68(1) and 69(4) REACH clearly set out the exhaustive character of the harmonising effect of both the restriction process and its outcome (i.e. entry into Annex XVII). Whenever there is an

³⁸ Article 129(2) REACH, as adapted by Protocol 1 to the EEA Agreement.

³⁹ Norway's reply to ESA's reasoned opinion, dated 16 October 2015, **Annex A.15** to this Application.

⁴⁰ Norway's reply to the letter of formal notice, enclosed as **Annex A.13** to this Application.

unacceptable risk to either human health or the environment which needs to be addressed on an EEA wide basis, Article 68(1) states that “*Annex XVII shall be amended...pursuant to the procedure set out in Articles 69 to 73*”.

66. The circumstance that PFOA had not been added to Annex XVII of REACH following a procedure under Title VIII, has therefore no bearing for the applicability of the exception provided in Article 128(2) REACH due to the harmonising effect of the restriction procedure itself.
67. There is no case law from the EFTA Court or the CJEU interpreting the scope of harmonisation under REACH. However, Norway has sought to rely on the judgment of the CJEU in Case C-473/98 *Kemikalieinspektionen and Toolex Alpha AB* (“Toolex”)⁴¹ to support its view on the interpretation of REACH in the pre-litigation procedure. That case arose from a challenge to the Swedish decision to ban the substance trichloroethylene, which had been classified as a category 3 carcinogen under Directive 67/548. In its judgment, the CJEU upheld the ban on the basis that it was necessary to protect human life, despite uncertainties surrounding the substance in question.
68. There is a clear distinction between the scope of the legislation which was under scrutiny in that case, and that of REACH. In *Toolex*, the CJEU made it clear that the relevant legislation in force at that time regarding the classification,⁴² marketing⁴³ and risk evaluation of substances⁴⁴ did not harmonise the conditions under which substances could be marketed and only laid down certain minimum requirements. On this basis, the legislation in force at that time did not prevent States from regulating the marketing of substances that fell outside its scope.
69. Recital 2 of REACH makes it clear that “[t]he 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”. In terms of trade in chemicals, REACH

⁴¹ Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB*, EU:C:2000:379.

⁴² Directive 67/548, referred to above.

⁴³ 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 (“Directive 76/769/EEC”). Directive 76/769/EEC was repealed on 31 May 2009 on the entry into force of REACH.

⁴⁴ Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (“Regulation 793/93”).

harmonises the law across the EEA in a way that differs fundamentally from the chemicals legislation that was in force at the time of the CJEU's judgment in *Toolex*.

70. During the pre-litigation procedure, Norway sought to rely on paragraphs 31 to 32 in *Toolex*, which refer to Regulation 793/93⁴⁵. Regulation 793/93 introduced a consistent and coherent system for evaluating the risks related to chemical substances. However, it is clear from paragraph 31 of the judgment that Regulation 793/93 “*neither imposes obligations nor harmonises rules on the use of substances in general or trichloroethylene in particular*”. As such, given the fundamental differences in the scope of Regulation 793/93 and REACH, ESA does not consider that the judgment in *Toolex* supports Norway's arguments as regards the scope of harmonisation under the latter Regulation.

71. Accordingly, ESA submits that the restrictions procedure under Title VIII of REACH 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 REACH.

4.2 Secondary plea: Breach of Article 128 of REACH and Article 3 EEA – Unilateral action is precluded where the REACH restriction procedure is triggered

72. In the alternative, if the Court were to conclude that the restriction procedure under Title VIII of REACH itself does not have a harmonising effect, it is ESA's submission that Norway is in breach of Article 3 of the EEA Agreement read in conjunction with Article 128(1) of REACH.

73. ESA submits that in any event the initiation of the Title VIII procedure represents a point of departure for EEA action, which implies that Norway is under a duty of close co-operation with the EEA States and Institutions in order to ensure that the aims of REACH, in particular the effective functioning of the internal market, can be upheld. In the present

⁴⁵ *Ibid.*

case, this is the moment when Norway notified ECHA of its intention to submit an Annex XV dossier in respect of PFOA on 19 February 2014.

74. Article 3 of the EEA Agreement 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.⁴⁶ Article 128(1) of REACH, read together with Article 3 of the EEA Agreement, requires Norway to refrain from introducing unilateral national legislation to regulate PFOA until the restriction procedure initiated by Norway and Germany has been finalised.
75. In ESA's submission, Norway's decision to restrict PFOA under national law demonstrates that it had identified PFOA as presenting an uncontrolled risk to the environment and human health. Having identified such a risk, ESA considers that Norway was under an obligation to follow the restriction process set out in Title VIII of REACH, in particular the requirements of Article 69(4).
76. Norway has alleged procedural deficiencies as a reason for taking unilateral measures. However, the effectiveness of the system depends precisely to a large extent on the effective cooperation of the EEA States. Although Article 69(4) of the REACH Regulation does not specify a deadline for States to notify an intention to prepare an Annex XV dossier, it is clear that such notification must be done promptly in order to ensure the effective functioning of the system. It is exactly if EEA States were free to take unilateral action that the effectiveness of the REACH system would be undermined as a whole: there would be no incentive for EEA States to address deficiencies identified, and a lack of cooperation through REACH would invariably make it impossible to achieve the same high level of protection throughout the EEA which the system was set up to achieve.
77. It must be emphasized that the effectiveness of the REACH system and the level of protection across the EEA depends on swift action from the EEA States. Early notification also prevents duplication of work within the EEA. The objectives of the REACH system

⁴⁶ See, for example Cases E-6/13, *Metacom AG v Rechtsanwälte Zipper & Kollegen*, [2013] EFTA Ct. Rep. 856, paragraph 69, E-25/13 *Engilbertsson v Íslandsbanki*, [2014] EFTA Ct. Rep. 524, paragraph 159; and E-15/12 *Jan Anfinn Wahl v the Icelandic State* [2013] EFTA Ct. Rep. 534, paragraph 54, and the case-law cited therein.

would not be achieved if the EEA States considered it a secondary option to national regulation.

78. On 19 February 2014, together with Germany, Norway notified ECHA of its intention to initiate the restriction process. This was nine months after the national legislation was adopted, and following ESA's pre-31 letter of 30 October 2013 reminding Norway of its obligations under the REACH Regulation. On 17 October 2014, this dossier was finally submitted.
79. Parallels with the case currently under consideration may be drawn from the findings of the CJEU in Case C-246/07 *Commission v Sweden*⁴⁷. That case was brought by the Commission to challenge Sweden's unilateral decision to propose the addition of the substance PFOS to the Stockholm Convention on Persistent Organic Pollutants.⁴⁸ At the time of Sweden's proposal there was not yet a formal proposal from the European Union regarding PFOS, but there was a common strategy regarding this substance. The CJEU, upholding the Commission's challenge, found that Member States are "*subject to special duties of action and abstention*" where proposals, although not yet adopted, represent a point of departure for concerted Community action⁴⁹. While it is clear that the substance of Case C-246/07 does not concern the EEA Agreement, the initiation of the restriction process under Title VIII of REACH represents, by analogy, a point of departure for concerted EEA action which precludes unilateral action by States.
80. Accordingly, ESA takes the view that Norway is in breach of Article 3 of the EEA Agreement read in conjunction with Article 128(1) of REACH by maintaining in force a national provision such as section 2, paragraph 32, of the Norwegian Product Regulation after notifying ECHA of its intention to submit an Annex XV dossier in respect of PFOA on 19 February 2014 and thereby initiating the restriction procedure under Title VIII of REACH.

⁴⁷ Case C-246/07 *European Commission v Kingdom of Sweden* [2010] ECR I-03317.

⁴⁸ The Stockholm Convention on Persistent Organic Pollutants, adopted on 22 May 2001, is an international environmental treaty that aims to eliminate or restrict the production and use of persistent organic pollutants.

⁴⁹ Case C-246/07, cited above, at paragraph 74.

4.3 Third plea: Breach of Article 11 EEA – Unjustified restriction on the free movement of goods

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

4.3.1 The measure constitutes a restriction

82. The free movement of goods is a fundamental freedom under the EEA Agreement. This is expressed in the prohibition, as set out in Article 11 of the EEA Agreement, on quantitative restrictions on imports between EEA States and all measures having equivalent effect.

83. The prohibition on PFOA introduced by the amendments to the Norwegian Product Regulation 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.

4.3.2 Justification under Article 13 of the EEA Agreement

84. Article 13 of the EEA Agreement provides for certain exceptions to the general ban on quantitative import restrictions in Article 11 EEA. The protection of public health is explicitly recognised in Article 13 EEA as justification for a restriction of the principle of free movement of goods.

85. It is settled case-law that the health and life of humans rank foremost among the assets or interests protected by Article 13 EEA.⁵⁰ In the absence of harmonised rules, where there is uncertainty as to the current state of scientific research, it is for the EEA States, within the limits of the EEA Agreement, to decide what degree of protection they wish to assure and the way in which that will be achieved⁵¹. It is however settled case-law that the exemptions from Article 11 EEA laid down in Article 13 EEA must be interpreted strictly.⁵² Any

⁵⁰ See judgment in Case E-16/10 *Philip Morris Norway v. Norway* [2011] EFTA Ct Rep. 330, paragraph 77, and the case-law cited therein.

⁵¹ Case E-4/04 *Pedicel AS v Sosial- og helsedirektoratet*, [2005] EFTA Ct. Rep. 1, paragraph 55. See also Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103.

⁵² Case E-1/94 *Ravintoloitsijain Liiton Kustannus Oy Restamark*, [1994-1995] EFTA Ct. Rep. 15, paragraph 56; Case E-5/96, *Ullensaker Kommune v Nille AS*, [1997] Efta Ct. Rep. 30, paragraph 33.

national rule likely to have a restrictive effect on imports can only be accepted if it is proportionate.⁵³

86. During the pre-litigation procedure, Norway took the position that PFOA is a serious hazardous substance.⁵⁴ As already mentioned, ESA does not dispute this in principle. Norway has however failed to provide ESA with sufficient evidence in order to demonstrate the proportionality of the measures taken.

4.3.3 The measure is not proportionate

87. An assessment of whether the principle of proportionality has been observed in the field of public health must take account of 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 that protection is to be achieved.⁵⁵
88. Nevertheless, national rules or practices which restrict a fundamental freedom under the EEA Agreement, such as the free movement of goods, or are capable of doing so, can be properly justified only 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.⁵⁶
89. In order to rely on Article 13 of the EEA Agreement, Norway must demonstrate that the risk for public health appears sufficiently established based on the latest scientific data available at the date of the adoption of the measure.⁵⁷
90. ESA submits that Norway was therefore under an obligation to provide a risk assessment, based on scientific and technical evidence, demonstrating the proportionality of the restrictive provisions.⁵⁸ In order to show the proportionality of the prohibition on PFOA, Norway is required to identify the specific risks associated with the substance and demonstrate that a ban on the product is the least restrictive measure possible.

⁵³ Case C-322/01 *Deutscher Apothekerverband*, cited above, paragraph 104.

⁵⁴ See page 6 of Norway's reply to the Letter of Formal Notice, Annex A.13 to this Application.

⁵⁵ See judgment in Case E-16/10 *Philip Morris Norway v. Norway*, cited above, paragraph 80.

⁵⁶ See Case E-16/10 *Philip Morris Norway v. Norway*, cited above, paragraph 81 and case-law cited.

⁵⁷ Case C-41/02 *Commission v the Netherlands* [2004] ECR I-11375, paragraphs 47-49.

⁵⁸ Case C-41/02 *Commission v the Netherlands*, cited above, and Case C-192/01 *Commission v Denmark* [2003] ECR I-9693.

91. Norway included an Impact Assessment of regulating PFOA in consumer products in its 2010 DTR notification of proposed measures.⁵⁹ This is however the only document submitted to ESA concerning the risks presented by PFOA and the alternatives currently available to replace the substance.⁶⁰ As ESA noted in its comments to the notification, the impact assessment does not address the issues of substantiated justification, necessity and proportionality which had originally been made in ESA's 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*".⁶¹
92. During the pre-litigation procedure, Norway argued that the 0.001 weight percent concentration for PFOA was based on the concentration limit for PFOS in Regulation (EC) No 850/2004⁶². This was chosen "[s]ince PFOA and PFOS are similar compounds with similar chemical properties and hazards".⁶³ This is the only explanation provided by Norway for the chosen concentration limit. ESA does not consider that this qualifies as a concrete risk assessment required by Article 13 EEA.
93. It was furthermore argued that the amendments to the Norwegian Product Regulation were necessary "*in order to ensure that PFOA is phased out by all actors producing and importing consumer products*", claiming that the prohibition is justified under the public health exception under Article 13 EEA.⁶⁴
94. ESA submits that Norway's reference to such broad policy objectives is not sufficient to demonstrate the adequacy of the measures as required by Article 13 EEA. Norway's identification of PFOA as a hazard does not take into account the likelihood of exposure to

⁵⁹ See **Annex A.5** to this Application.

⁶⁰ It should be noted that in its reply to the Reasoned opinion, Norway made a general reference to "*the risk assessments provided for in the Norwegian-German proposal under REACH Title VIII*", providing the following link: <http://echa.europa.eu/restrictions-under-consideration/-/substance-rev/1908/term>. See page 2 of **Annex A.15** to this Application. ESA submits that these risk assessments (which have never been formally submitted to ESA) are not of relevance since the proposed concentration limit therein differs from the limits in the contested provision of the Norwegian Product Regulation.

⁶¹ See **Annex A.8** to this Application.

⁶² **Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC** referred to at point 6 of Chapter XV of Annex II to the EEA Agreement.

⁶³ See page 5 of Norway's reply to the letter of formal notice, **Annex A.13** to this Application.

⁶⁴ See page 6 of Norway's reply to the letter of formal notice, **Annex A.13** to this Application.

a substance, and what concentrations of that substance consumers are likely to encounter in practice. Merely referring to the inherent properties of PFOA cannot be considered sufficient to satisfy the exemption under Article 13 of the EEA Agreement. ESA has not received any risk assessment or other scientific or technical evidence from Norway which would demonstrate the proportionality of the restriction on PFOA in the Norwegian Product Regulation.

95. 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. As such, a national rule banning a product cannot benefit from the derogation provided for in Article 13 if human health can be protected just as effectively by measures which are less restrictive of intra-EEA trade.

96. Furthermore, it should be noted that despite its identification of PFOA as a hazard, Norway has not attempted to explain the exemptions which apply to the Norwegian Product Regulation, in particular the amendment which allows products which were manufactured before the ban entered into force to remain on sale until 1 January 2018. The Norwegian Product Regulation to this extent does not appear to pursue the objective identified in a coherent and systematic manner and thus cannot be considered appropriate for attaining that objective.⁶⁵

97. In conclusion, 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 of the EEA Agreement. As a result, ESA considers that the Norwegian restriction on PFOA breaches Article 11 of the EEA Agreement.

5 CONCLUSION

98. On those grounds, ESA requests 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,**

⁶⁵ See Case C-169/07 *Hatlauer*, EU:C:2009:141, paragraph 55.

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 l2zc 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 l2zc 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.



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Agents of the EFTA Surveillance Authority

6 SCHEDULE OF ANNEXES

No	Description	Date	Document Number	Number of pages	Referred to in this Application at paragraph(s)
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A.8	The Commission's comments on Norway's DTR notifications 2010/9016/N, 2010/9017/N, 2010/9018/N and 2010/9019/N	21/03/2011	591458	5	46
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