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ORIGINAL

ATTORNEY GENERAL – CIVIL AFFAIRS

To the EFTA Court

Oslo, 10 October 2016

STATEMENT OF DEFENCE

BY

THE NORWEGIAN GOVERNMENT

represented by Mr Ketil Bøe Moen, Advocate, Office of the Attorney General (Civil Affairs), and Ms Ingunn Skille Jansen, Senior Adviser, Department of Legal Affairs, Ministry of Foreign Affairs, acting as agents, submitted pursuant to Article 35 of the Rules of Procedure of the EFTA Court, in

Case E-9/16 EFTA Surveillance Authority v the Kingdom of Norway

in which the EFTA Surveillance Authority has submitted an application pursuant to the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

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1 INTRODUCTION

1. By application to the EFTA Court (the Court) of 3 August 2016, the EFTA Surveillance Authority (ESA) is seeking a declaration that Norway has breached its obligations under Regulation No 1907/2006 (REACH)[1] and/or under the EEA Agreement 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 0.1%[2] or more by weight of perfluorooctanoic acid (PFOA).

2. The Norwegian Government (the Government) is invited to lodge a Defence by 10 October 2016, cf. the Court's letter of 10 August 2016.

3. The case thus concerns the possibility for Norway to regulate so called PFOA in consumer products. At the end of the time period prescribed in the Authority's reasoned opinion, the situation was characterized by the following, which seems undisputed: i) PFOA is a substance causing very high concern to human life and health, as well as to the environment; ii) there was no EU/EEA wide regulation of PFOA in consumer products; and iii) there was an ongoing process within the European Chemicals Agency (ECHA) of possible future regulations of PFOA. The situation is the same as of today.

4. It is under these circumstances that ESA's application must be assessed. ESA has forwarded three pleas, all of which should be rejected by the Court. The Government hence respectfully requests the Court to declare the application as unfounded, see section 6 below.

5. 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 Title VIII of REACH is *in principle available*. As a secondary plea, ESA submits that Norway has breached Article 3 EEA, read in conjunction with Article 128(1) of REACH, by adopting national restrictions despite having *initiated* the procedure under Article 69(4) of REACH.

6. The Government finds both pleas to be unfounded, see sections 3.1 and 3.2. The Government submits that the harmonising effect of the Title VIII procedure will occur only when there has been adopted an EU/EEA wide restriction covering the same subject matter in the form of an Annex XVII entry. EEA States cannot, until such a restriction is adopted, be precluded from adopting national restrictions, cf. Article 128(2) of REACH. The procedure as such is not harmonised with the effect of excluding national measures. Consequently, Norway has not breached the REACH Regulation, neither before nor after initiating the restriction procedure under REACH Title VIII. Article 3 EEA on loyal

[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, referred to at point 12zs of chapter XV of Annex II to the EEA Agreement.
[2] ESA writes several times that the concentration limit is 0.001% by weight. This may perhaps seem to rest on a misunderstanding, see section 2.1 below.

cooperation does not alter this conclusion. Indeed, Norway has actively and loyally applied the REACH procedure.

7. ESA submits, as a third plea, that the restriction on PFOA in consumer products as introduced by the Norwegian Product Regulation breaches Articles 11 and 13 of the EEA Agreement as the restriction – in ESA's view – does not comply with the principle of proportionality.

8. As set out in section 3.3 below, the Government submits that the restriction is indeed proportionate as it is appropriate and necessary in ensuring the objectives of public health and the environment. It is demonstrated, in particular, that ESA does not seem to fully recognize the thorough and comprehensive risk assessments that have been undertaken, demonstrating, inter alia, that the same level of protection cannot be achieved with less restrictive measures.

9. Before turning to the legal assessment, the Government will in section 2 supplement the Authority on the legal and factual background.

2 FACTUAL AND LEGAL BACKGROUND

2.1 The relevant time of assessment and national regulation

10. The legal and factual background of the case is set out accurately by ESA on most points. It is nevertheless necessary to make some supplementary remarks.

11. ESA's position is that this case should be assessed on the basis of the national legislation as it stood at 8 September 2015, i.e. the time limit set in the reasoned opinion.[3] However, the time limit to answer the reasoned opinion was extended by ESA until 16 October 2015.[4] By extending the time limit, ESA prolonged the period that Norway was given to comply with the reasoned opinion. It must accordingly be this new limit – 16 October 2015 – that the case must be assessed against when ESA subsequently chooses to bring an action before the Court, cf. the second paragraph of Article 31 SCA.

12. Originally, the Norwegian Product Regulation Section 2-32 contained a somewhat broader regulation. It included a prohibition against PFOA as a substance or mixture in consumer products with a concentration limit of 0.001% by weight. This part of the regulation was, however, repealed by an amendment of § 2-32 of the Regulation 25 September 2015. This was made to implement Regulation (EU) No 317/2014 that had entered into force in the EEA on 11 July 2015. This amendment was explained in Norway's reply of 16 October 2015 to the reasoned opinion.[5]

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[3] Application, paragraph 49.
[4] E-mail from ESA 1 September 2015, extending the time limit to 30 September 2015, and letter from ESA 18 September 2015, further extending the time limit to 16 October 2015, **Annex B.1** to this Defence.
[5] Application, Annex A.15.

13. The relevant national legislation is therefore the one applicable after this amendment. This is no longer restrictions on PFOA as a substance or mixture in itself, but PFOA in articles (products). It is unclear whether this is appreciated by ESA as the reference is still made to the repealed concentration limit of 0.001% for PFOA as a substance or mixture.[6]

14. The main principle is now – as it was on 16 October 2015 – that consumer products cannot be manufactured, imported, exported or sold if the product's individual components are containing PFOA of 0.1% by weight or more, cf. the first paragraph of section 2-32 of the Product Regulation.[7] For textiles, carpets and other coated consumer products the limit value is 1 µg/m², cf. the first paragraph.[8]

15. Several industry associations representing the textile and sports industry reported to the Norwegian Environment Agency that their members had difficulties in complying with the regulation by 1 June 2014, which was the deadline set in the regulation. In order to comply with the regulation, many products would be destroyed or sold to other countries where the use of PFOA was not restricted.

16. This was considered to be unfortunate alternatives seen from health and environmental perspectives. Destruction of the products would not really lower the risks of PFOA from these products. Therefore, and because the content of PFOA in these products was low, it was accepted to allow the sale and import until 1 January 2018 of products that were proved to be manufactured before 1 June 2014. This is further set out in section 3.3.4 below (paragraphs 97-103), explaining why this delayed implementing date for products already produced does not call into question the appropriateness of the regulation.

17. Regulation 1 June 2004 No 922, as later amended (Forskrift om begrensning I bruk av helse- og miljøfarlige kjemikalier og andre produkter (produktforskriften), FOR-2004-06-01-922). Section 2-32 is enclosed as **Annex B.1** to this Defence in Englis translation.

2.2 The risks of PFOA and relevant assessments and scientific research

18. ESA does not contest the necessity of regulating PFOA based on the risks related to this substance.[9] It seems nevertheless appropriate to inform the Court in some more detail on these risks, in particular because it may be useful in order for the Court to assess the alternative plea related to the proportionality of the Norwegian regulation (section 3.3), but also because it is relevant in ensuring an interpretation of REACH that fully appreciate the objective of a high level of protection of health and environment, cf. Article 1(1) of REACH (section 3.1 below).

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[6] For instance in paragraph 1 of the Application.
[7] Regulation 1 June 2004 No 922, as later amended (Forskrift om begrensning i bruk av helse- og miljøfarlige kjemikalier og andre produkter (produktforskriften), FOR-2004-06-01-922). Section 2-32 is enclosed as **Annex B.2** to this Defence in English translation.
[8] For simplicity, reference is in this Defence primarily made to the 0.1% by weight concentration limit.
[9] Application, paragraph 4.

19. PFOA is widely recognized as a substance harmful to health and the environment. PFOA is listed on the Candidate List for substances of very high concern (SVHC) both for reprotoxic and PBT-properties.[10]

20. The Norwegian impact assessment made before adopting the national regulation, submitted to ESA in December 2010,[11] states that PFOA is persistent, reprotoxic and has chronic toxicity. Furthermore, it states that *"even if the substance does not meet the B criterion in the narrow sense, the detection of PFOA in blood in the general population, with a half-life of about four years as well as the potential for long-range transport and presence in wild animals, gives us similar reason for concern"* as for PBT substances[12]. It states that since PFOA is a PBT-like substance or a substance of equal concern, it is impossible to establish an acceptable level for substances with such properties in the environment, and emissions and exposure should be limited to the greatest extent possible.

21. The impact assessment further documents the concerns regarding PFOA`s wide-spread occurrence in the environment, the presence in biota in the Arctic and in particular the time trend data in the Arctic. An average annual increase of 2.3% in PFOA levels were shown in East Greenland polar bears from 1984 to 2006.[13]

22. Likewise, the impact assessment documents the concerns regarding the available data at that time on occurrence of PFOA in humans, including the transferal of PFOA via the placenta to the foetus in the uterus and to babies via breast milk[14]. The concern about the exposure of humans to PFOA, including the foetus and infants, was further strengthened with more recent publications from scientists in the National Institute of Public Health of Norway.[15]

23. New evidence regarding adverse health effects of PFOA was published in 2012 by the C8 Science Panel.[16] They found that serum PFOA is positively associated with diagnosed high cholesterol (hypercholesterolemia). They also found that inflammatory bowel disease (combining ulcerative and Crohn`s disease) showed a positive trend of increased risk. In addition, some recent publications have demonstrated an overall reduction in birth weight associated to PFOA exposure in humans.[17]

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[10] PBT means persistent, bioaccumulative and toxic.
[11] Application, Annex A.5.
[12] *Impact assessment of regulating perfluorooctanoic acid (PFOA) and individual PFOA salts and esters in consumer products* (2010), Annex A.5, at section 2.4. It should be noted that the REACH PBT criteria (Annex XIII of REACH) were revised in 2011 by Commission Regulation (EU) No 253/2011 of 15 March 2011, allowing more emphasis on weight of evidence. PFOA was identified as an SVHC fulfilling the PBT-criteria in in 2013.
[13] Impact assessment 2010, Annex A.5, at section 2.3. Reference is inter alia made to Dietz et al. 2008, **Annex B.3** to this Defence.
[14] Impact assessment 2010, Annex A.5, section 2.3, with reference to several scientific studies, including Haug et al. 2009; Fromme et al. 2009; and Monroy et al. 2008, **Annexes B.4, B.5 and B.6** to this Defence.
[15] E.g. Gützkow et al. 2012; and Haug et al. 2011, **Annexes B.7 and B.8** to this Defence.
[16] C8 Science Panel probable link reports, 2012, available here: http://www.c8sciencepanel.org/prob_link.html.
[17] E.g. Chen et al., 2012,; Maisonet et al., 2012; and Whitworth et al. 2012, **Annexes B.9, B.10 and B.11** to this

24. As set out below, the Government cannot see that it is necessary for the purpose of the present case to forward these and other underlying, scientific analyses. However, based on ESA's submissions, and for the Court's information, a selection of these documents, as set out in the previous paragraphs with footnotes, is annexed to this Defence.

2.3 The process under REACH – time frame and updated documents

25. In the Application, it may appear as if a process under REACH starts at the latest 12 months before a dossier with a proposal for a regulation is sent to ECHA under Article 69(4).[18] This is, however, not the case and ESA's submissions related to the impact of Article 69(4) are thereby also inaccurate.

26. ESA describes the procedure under the REACH Regulation in section 2.2.1, but does not provide information about the process leading up to identifying a risk and a possible decision to initiate the restriction. The process may start by a risk management option analysis (RMOA)[19]. The RMOA has been established as an informal procedure allowing for cooperation between the Member State and the Commission in order to discuss the need for managing the risk and which type of provision would be the most appropriate, e.g. authorisation, restrictions or other Community wide measures.

27. According to REACH Article 69(4), the restriction dossier must be submitted at the latest 12 months after the official Registry of Intention is forwarded to ECHA. Based on the heavy work load in preparing a dossier, it is far from unusual that the EU/EEA States in question start working with the comprehensive documentation needed for a restriction dossier long before they notify the intention to ECHA. Indeed, that is also the procedure recommended in the ECHA guidance to prepare an Annex VX dossier:[20]

> *It is highly recommended to go through such workload considerations prior to notifying the Agency about the intention of completing an Annex XV dossier due to the restricted timeframe within which the Annex XV dossier has to be completed.*

28. Developing a restriction proposal is indeed a very time-consuming process. The required information for a restriction dossier is extensive and it is a heavy workload to undertake for a state, cf. the list of requirements in the REACH regulation Annex XV.

29. For PFOA, the work started with preparation of the classification and labelling dossier which in itself takes several years (submitted in 2010, on public consultation in 2011, adopted in 2014). Germany and Norway submitted an RMOA (Analysis of the most Appropriate Risk Management Option) for PFOA in 2011. It was concluded that PFOA should be considered as a substance of very high concern according to Article 57 c) REACH

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[18] Application, for instance at paragraph 18.

[19] Described on ECHA's website: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/rmoa.

[20] Guidance for the preparation of an Annex XV dossier for restrictions, ECHA 2007, at p. 27, available here: https://echa.europa.eu/documents/10162/13641/restriction_en.pdf.

due to its reprotoxicity and according to Art 57 d) due to its PBT-properties. It should thus be included in the candidate list for substances of very high concern. Furthermore, it was assessed that a restriction would be a better way to manage the risk than inclusion in Annex XIV (the authorisation procedure). In the RMOA the way forward was described as follows:[21]

> *The Annex XV-Dossier for identifying the SVHC-properties for PFOA will be prepared by Germany and Norway and will be sent to ECHA in 2012. In 2013, PFOA could be included into the Candidate List. The Annex XV-Dossier for restriction will be prepared by Germany and Norway and will be announced on the ROI in April 2013 and will be sent to ECHA in April 2014. A restriction of PFOA in Europe-27/EEA is possible in 2015.*

30. An important step in the REACH procedure is the adoption of opinions by the Risk Assessment Committee (RAC) and the Socio-Economic Committee (SEAC). These opinions were delivered on 8 September 2015 and 4 December 2015, and they both support a very strict, EEA wide restriction on PFOA.[22] Both RAC and SEAC propose restrictions that are wider in scope than the contested Norwegian regulation and stricter since the set concentration limits are proposed to be set substantially lower. See section 3.3.5 below.

31. These opinions were sent by ECHA to the European Commission along with relevant background documents. Within three months of receipt of the Committees' opinions, the Commission is supposed to prepare a draft amendment of the list of restrictions. Such a draft amendment is, however, still not finalised by the Commission.

32. There is also one more detailed point that should be mentioned in relation to the introductory parts of the Application. The Annex XV dossier to ECHA proposing PFOA to be identified as a substance of very high concern showed that PFOA met the criteria not only in Article 57(c) due to its reprotoxicity, but also the criteria in Article 57(d) due to its PBT-properties. The latter is not reflected by ESA.[23]

2.4 The global approach

33. Finally, and for the sake of completeness, it is notable that EU in 2015 submitted a proposal for the listing of PFOA, its salts and PFOA-related compounds to the Stockholm Convention on Persistent Organic Pollutants (POPs). This implies that there is presently an extensive, ongoing procedure, initiated by the European Union, to consider not only an

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[21] For these and all other relevant documents regarding the proposal (including RAC and SEAC opinions, cited below) see https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1908/term. The Norwegian-German proposal is available here: https://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7.

[22] *Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related Substances*, ECHA/RAC/RES-O-0000006229-70-02/F and ECHA/SEAC/RES-O-0000006229-70-03/F, 8 September 2015 and 4 December 2015, referred to as Opinions from RAC and SEAC, **Annex B.12** to this Defence.

[23] Application, paragraphs 37-39. To be added to the list of substances of very high concern (SVHC), substances must meet *one or more* of the criteria set out in Article 57(a)-(f) of REACH.

EU/EEA wide restriction on PFOA, but a global restriction. This illustrates the very high concern related to PFOA and products containing PFOA.

3 LEGAL ASSESSMENT

3.1 The Government's response to ESA's primary plea

34. As set out above, ESA submits that Norway is prevented by the REACH Regulation from adopting national regulations on PFOA since the restriction procedure provided for in Title VIII of REACH is in principle available. This prohibition against national legislation exists, according to ESA, until a procedure under REACH has concluded that there is no need for an action on an EEA wide basis.

35. Whereas the Government fully acknowledges the harmonising effect of final, EEA wide regulations, by means of Annex XVII entries, it cannot follow ESA's assessment of the harmonising effect of the *procedure* that may – or may not – lead to such regulations. The Government's position is that it is entitled to maintain or introduce restrictions on a substance or on products with a 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. The mere initiation of this procedure does therefore not imply that all EEA States are prohibited from regulating the substance nationally.[24]

36. The possible harmonising effect of the *availability of the procedure* set out in Title VIII, must be assessed in the light of Article 128 in particular. Under the first paragraph of that Article, EEA States may, "subject to paragraph 2", not unilaterally impose restrictions on a substance "falling within the scope of [the] Regulation" as long as the substance complies with the Regulation itself or with implementing measures. The harmonising effect of REACH is however not absolute, as clarified by Article 128(2), that should be recalled:

> *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.*

37. The REACH Regulation does therefore not harmonise a substance only because a substance falls within the wide scope of the Regulation. National rules to protect workers, human health and the environment are only prohibited if the Regulation does indeed "harmonise the requirements on manufacture, placing on the market or use" of a substance. These concepts of "manufacturing", "placing on the market" and "use" of a substance, as further defined in Article 3 nos 8), 12) and 24, all indicate that the

[24] The implications of having initiated the restriction procedure under REACH are assessed by ESA in its secondary plea, see therefore also section 3.2 below.

harmonising effect relates to the use of the substance (in a wide sense of the word) by producers, suppliers or consumers, respectively. It therefore presupposes that an actual regulation of the substance in question exists. If not, there is no harmonisation of "the requirements on" the manufacturing, placing on the market or use of a substance.

38. Conversely, if no such regulation exists, EEA States are not precluded from adopting national legislation. Notably, no reference is made in Article 128 to the harmonising effect of the restriction *procedure* that may eventually lead to a situation where – to use the words of Article 128(2) - the REACH Regulation *does* "harmonise the requirements on manufacture, placing on the market or use".

39. It is noted, moreover, that Article 128(2) refers to both maintaining existing rules and laying down new national rules, both of which may be legitimate provided that the manufacturing, placing on the market and the use of the substance has not been harmonised. The room for such national rules regarding hazardous substances would be very limited should ESA's understanding be correct.

40. That is, however, not in conformity with the intention of that Article. Article 128(2) did not figure in the Commissions original proposal.[25] It was introduced during the legislative process by the Council. Debates within the Council *"reiterated the importance of retaining national capability to respond to challenges and of retaining capability to evaluate substances likely to constitute a risk to health and/or the environment."*[26]

41. A majority within the Council supported including the additional provision of what became Article 128(2).[27] The EU legislator has therefore stated that the intention of Article 128(2) is to ensure *national capability* to respond to challenges related to substances falling within the scope of REACH. The Government submits that ESA does not fully respect this intention of the provision with its very narrow interpretation of Article 128(2).

42. The Court of Justice has handed down two recent judgments that shed interesting light on the scope of the harmonisation provided by the REACH Regulation, giving further support to the interpretation of Article 128(2) submitted in this Defence.

43. *Lapin* concerned a situation where Finland had issued derogations from EU regulations adopted under REACH, more particularly derogations from explicit provisions on arsenic compounds already in place in Annex XVII to REACH.[28] The ECJ held that it followed from Article 128(2) of REACH that the European Union legislator intended to harmonise the requirements in "certain cases". That included the situation referred to in Article 67(1), i.e. the situation for which Annex XVII already contained a restriction on the same substance.[29]

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[25] COM(2003) 644 final, Article 125.
[26] Press Release on the 2665th Council meeting, Competitiveness (Internal Market, Industry and Research) , Luxembourg 6 and 7 June 2005, C/05/133, p. 9.
[27] See Opinion in *Canadian Oil Company Sweden AB*, C-472/14, EU:C:2015:809, paragraph 32 with references.
[28] Judgment in *Lapin*, C358/11, EU:C:2013:142, paragraphs 20-21.
[29] *Lapin*, paragraph 33 and Article 67 REACH, first paragraph, first sentence.

44. The situation was hence that there already existed parallel, EU wide regulations, and the wording of Article 67(1) therefore prohibited further, national restrictions.[30] As there was harmonised legislation in place covering the same subject matter as the national regulation, the ECJ could conclude that Article 128(2) was inapplicable.[31] It is striking, however, that the wording of every relevant paragraph is chosen to reflect the fact that there already existed EU wide regulations. There is no mentioning of a possible harmonising effect *irrespective of* EU wide action, for instance because arsenic as such is a substance falling within the scope of REACH. On the contrary, the natural reading of the judgment and the way it is phrased rather indicates that the manufacturing, placing on the market or use of a substance is *not* harmonised without EU wide regulations, meaning that States are allowed, under Article 128(2), to adopt national legislation provided they are compatible with EU/EEA law.

45. The judgment in *Canadian Oil Company* confirms that it is "*apparent from [Articles 128(1) and 128(2)] that the EU legislature intended to harmonise those requirements only in certain cases*".[32] The ECJ concludes that the harmonisation carried out by REACH did not exclude a national registration system such as the Swedish, coming in addition to the registration requirements under REACH.[33]

46. This is further explained by Advocate General Sharpston, who recalls that *Lapin* concerned a situation where requirements were already taken on Community-wide basis, excluding a different, national regulation. She continued that the same would apply for substances "duly authorised by the Commission", i.e. another situation where final, Community regulation had already been adopted.[34] Again, the wording of her Opinion indicates that the harmonising effect under the REACH procedures is the consequence of final measures taken at EU level, and not of the mere existence of a procedure for adopting such measures.

47. She contrasted this to the situation in the case before her, as that case concerned the degree of harmonisation regarding *registration* of substances, where there was no provision comparable to those on restrictions or authorisations adopted on EU level.[35] This would equally apply, the Government submits, in the present case until there is indeed a final decision taken on EU/EEA level regarding PFOA in consumer products.

48. The Government submits, furthermore, that also case law from before the adoption of the REACH Regulation supports this position. REACH rests on previous EU legislation, such as Directive 76/769/EEC (the Marketing Directive) and Regulation (EEC) No 793/93 (the Risk Evaluation Regulation). The ECJ has clarified that the fact that a substance fell within the scope of a directive like the Marketing Directive, did not preclude national legislation until

[30] *Lapin*, paragraphs 34-35.
[31] *Lapin*, paragraph 37.
[32] Judgment in *Canadian Oil Company Sweden AB*, C-471/14, EU:C:2016:171, paragraph 27.
[33] *Canadian Oil Company*, paragraph 38.
[34] Opinion in *Canadian Oil Company*, paragraph 38.
[35] Opinion in *Canadian Oil Company*, paragraph 39.

the substance was actually regulated on the Community level.[36] Moreover, the fact that the procedure for such regulation was initiated under the Risk Evaluation Regulation was immaterial for the freedom of Member States to adopt national legislation as this procedure did not harmonise the use of the substance.[37] The wording of Article 128(2) of REACH echoes this established state of law. Even though the REACH Regulation has further enhanced the regulation of the procedure of harmful substances, the Government cannot see that this important division of competence and duties between the EEA States on the one hand and the Community procedure on the other is altered radically as proposed by ESA.

49. ESA, on its part, argues that Article 69(4) of REACH deprives States of the possibility of addressing uncontrolled risks through unilateral restriction measures without first having followed the complete procedure under Title VIII of REACH.[38] ESA refers, in particular, to the wording of that provision, stating that States "shall" notify ECHA if it considers that a substance poses risks to human health and the environment that are not adequately controlled and need to be addressed on a Community-wide basis. The State "shall" thereafter prepare a dossier within 12 months.

50. The Government does not share this understanding of Article 69(4).

51. First, whereas the Government believes that the procedure under Article 69(4) should be the main approach – certainly applied by Norway also in the present case – this does not necessarily mean that a State is obliged to notify its concerns without any delay, as submitted by ESA. As set out in section 2.3 above, preparing an Annex XV dossier with the aim of introducing a new restriction is very demanding and time consuming, in particular because of the amount of documentation and assessments required. Clearly, many EEA states are concerned about several potentially harmful substances that may call for EEA wide actions. However, only some EU/EEA States do take the responsibility of providing a dossier and only in relation to some of the substances that may cause concern. ESA seems to argue, in effect, that all these EEA States are in a constant breach of Article 69(4) of REACH only because they have not yet been able to prioritize the task of preparing a dossier. That seems to be an unsound and unpractical interpretation that – indeed – is also contrary to the guidance from ECHA, cited in paragraph 26 above.

52. Second, even if there would be an obligation to notify ECHA and prepare the Annex XV dossier, this should not imply that the procedure as such is harmonised. Such a possible obligation may go hand in hand with a freedom for the State to apply national regulations until the final assessment is made on EEA wide level. Another interpretation would, as set out above, make Article 128(2) more or less ineffective, contrary to the wording and legal history of that provision.

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[36] See, in particular, judgment in *Toolex*, C-473/98, EU:C:2000:379, paragraph 30.
[37] *Toolex*, paragraphs 31-32.
[38] Application, paragraphs 55-56.

53. Third, some concerns may be of a local or national concern. Article 69(4) only relates to the need for action if there is a genuine EEA wide concern, cf. also Article 68(1). As long as the substance poses national concerns only, the EEA State must be entitled to regulate the substance without using the procedure under Title VIII of the REACH Regulation, provided compatible with the EEA Agreement. This further indicates that national legislation cannot as such be precluded until it is *clarified* that there will be adopted Community-wide regulations. As long as the EEA State proposes a *national* legislation, even if this is supplemented by an Annex XV dossier, this national regulation should be respected, provided compatible with the general free movement provisions.

54. ESA finds, moreover, that the Government's position on Article 128(2) is strange as – ESA submits – it would imply that an EEA State could introduce regulations in non-urgent situations more easily than under the safeguard clause in Article 129 and deprive Article 129 of its field of application.[39]

55. The Government fails to follow ESA's reasoning. Articles 128 and 129 must be read together. Article 128(2) only applies to situations where the substance is *not* harmonised by REACH, i.e. in situations where there are no relevant requirements set out under the REACH procedures. This is contrasted with Article 129 allowing, exceptionally, national measures to be taken unilaterally *even if* the substance in question is "satisfying the requirements" already established under the REACH procedure. The two situations are clearly different, and it is not a surprising position from a systematic point of view that the possibility for EEA States to adopt national measures are wider *without* harmonising measures (Article 128(2)) than *with* already adopted, harmonising measures (Article 129). The opposite position would be the surprising one.

56. As Advocate General Sharpston puts it after having recalled that States are allowed by Article 128(2) to introduce unilateral measures if there is no harmonised rule under the REACH procedure:[40]

> *By contrast, Member States are entitled to adopt safeguard measures derogating from the harmonised rules only under the strict procedural and substantive conditions set out in Article 129 of the REACH Regulation.*

57. Article 129 of REACH rather seems to resemble Article 114(5) TFEU, i.e. the safeguard clause in TFEU for environmental protection based on new scientific data. These two provisions provide for the relevant options provided that the substance in question has been regulated by EEA wide measures included in Annex XVII of REACH.[41]

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[39] Application, paragraph 63.
[40] Opinion in *Canadian Oil Company*, paragraph 33 and footnote 21.
[41] To this effect, see *Lapin*, paragraph 37.

58. Finally, ESA also submits that its interpretation is supported by the overall objectives of the REACH Regulation; to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market, cf. Article 1(1). ESA argues that the possibility for national regulations until restrictions are adopted on an EU/EEA wide level will undermine the achievement of health and environment by removing incentives to prepare dossiers through the REACH system.[42]

59. It is recalled at the outset that the principle of high level of protection of human health and the environment, based inter alia on the principles of precaution and preventive action, is an overall principle of EEA law that all EEA legislation must be interpreted in light of.[43]

60. The Government agrees that restrictions on an EEA wide basis are more efficient than restrictions on a national basis, unless the substance only causes national concerns. Norway fully supports that the REACH approach should be the main approach. Indeed, Norway contributes actively in these processes and has undergone the comprehensive task of preparing the PFOA dossier together with Germany.

61. The question is, however, whether a prohibition against any national measure until a possible EU/EEA wide regulation is adopted will more effectively protect human health and the environment than a right to adopt restrictive, national measures within this time frame.

62. The procedure that may lead to EU/EEA wide regulations are often long and complicated, as the present PFOA procedure exemplifies. Even if it is universally accepted that a substance causes great concern, it may last years before the REACH procedure is concluded. In this period of time, it will certainly better ensure the protection of human health and the environment if national regulations may be maintained or introduced.

63. As for the longer term effects, including incentives, ESA's argument could have been valid if there were no obligation what so ever on the EU/EEA States to make efforts under the REACH procedure. However, even if it may be unclear exactly what obligations may be derived from Article 69(4) of REACH, it seems clear that States cannot issue only national restrictions if the substance in question causes an EU/EEA wide concern. The general principle of loyal cooperation, enshrined in Article 3 EEA, must imply that an EU/EEA State under such circumstances must initiate the procedure under Article 69(4) in due cause. Moreover, EEA States must respect the precautionary principle and the principle of high level of protection of human health and the environment. There would therefore be clear incentives to use also the REACH procedure.

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[42] Application, paragraphs 5 and59.
[43] Judgment in *European Parliament and Denmark v European Commission*, Joined Cases C-14/06 and C-295/06, EU:C:2008:176, paragraph 75.

64. The best effects for the protection of human health and the environment, and indeed therefore the best way to respect the said principles both in the short and longer term, would be to allow for national measures pending the outcome of the procedure under REACH.

3.2 The Government's response to ESA's secondary plea

65. ESA submits, as its secondary plea, that Norway has breached Article 3 EEA, read in conjunction with Article 128(1) of REACH, by adopting national restrictions despite having initiated the procedure under Article 69(4) of REACH, i.e. at the moment when Norway notified to ECHA its intention to submit an Annex XV dossier on 19 February 2014.

66. It is undisputed that Article 3 EEA requires EEA States to take all appropriate measures to ensure fulfilment of the obligations under the EEA Agreement and likewise to abstain from measures which could jeopardize the attainment of its objectives.[44] These requirements must, however, be seen against the background of the relevant EEA obligations at hand. Under the circumstances of the present case, and in particular based on Article 128(2) of REACH, Article 3 cannot imply that EEA States are prohibited from adopting national measures only because the procedure under Title VIII of REACH is initiated.

67. It is recalled from section 3.1 above that Article 128(2) of REACH allows EEA States to adopt national rules in cases where REACH does not harmonise the requirements on manufacture, placing on the market or use of a substance. As demonstrated, the wording, legal history and case law calls for the conclusion that only restrictions finally adopted through the REACH procedure prevents national restrictions with the same scope. None of the sources presented indicates that the mere initiation of the procedure under Title VIII of REACH should be a decisive factor. Indeed, there is no more harmonisation of the requirements on the use etc. of a substance after the procedure has been initiated than before.

68. Consequently, the relevant question is whether Article 3 EEA prohibits EEA States from adopting legislation even when the relevant secondary legislation allows such national legislation. That question should be answered in the negative.

69. Article 3 EEA represents an important principle, but nevertheless has its limits. Those limits must, as a rule, be found in the relevant secondary legislation. As long as the interpretation of REACH presented by the Government is correct, EEA States may legitimately adopt national measures until an EEA wide harmonisation is established, *in casu* concerning PFOA in consumer products. Article 3 EEA requires a loyal application of REACH, but cannot preclude adoption of national legislation that REACH allows. That

[44] Cf. the EFTA Court case law cited in the application, footnote 46.

would be tantamount to extending radically the harmonising effect of an EEA Regulation, simply by invoking Article 3 EEA. Such an interpretation would not respect the limits of harmonisation set in the relevant piece of legislation, determined by the EU legislators.

70. Indeed, the Norwegian Government has applied the REACH procedure loyally. Together with Germany, Norway has invested huge recourses in collecting relevant scientific data and preparing for an extensive Annex XV dossier, as set out in 2.3 above. The cooperation between Norway and Germany towards an EEA wide restriction started already with submitting an analysis of the most appropriate risk management options (RMOA) in 2011, which was before the adoption of national measures. Further, the preparations for an Annex XV dossier started before the notification was sent ECHA in February 2014. It must be recalled that the time needed for the preparation of an Annex XV dossier in a case like the present, is longer than the 12 months prescribed in Article 69(4) of REACH. It is therefore common, and also recommended by ECHA, that the work with regulating a substance is initiated before the intention is notified under Article 69(4).

71. The Government is not aware of any case law calling for the interpretation proposed by ESA.

72. ESA relies on *Commission v Sweden*[45] concerning the Stockholm Convention on Persistent Organic Pollutants. That case is, however, not comparable to the present case and cannot provide a legal basis for ESA's position. It concerns a situation where the Community and its Member States had shared competence, implying a particular obligation of close cooperation flowing from the requirements of unity in the international representation of the Community.[46]

73. Sweden had in that case taken unilateral measures with regard to the listing of substances in an Annex to the Stockholm Convention. That was contrary to an established common practice within the European Union.[47] The unilateral approach would have direct consequences for the Union and could, for instance, imply that the Union would be bound by Sweden's approach, against the interests of the Union.[48] Such a situation was likely to compromise the principle of unity in the international representation of the Union and its Member States and weaken the Union's negotiating power with regard to the other parties to the Convention.[49]

74. These factors are absent in the present case. There is no shared power and principle of unity comparable to those of international relations within the European Union. Moreover, Norway's action would not bind the EU/EEA legislator or in other way

[45] Judgment in *European Commission v Sweden*, C-246/07, EU:C:2010:203.
[46] Paragraph 83.
[47] Paragraphs 89-91.
[48] Paragraphs 92-94 and 102.
[49] Paragraph 104.

compromise the possibility to adopt EEA wide measures. Indeed, the ECJ held that the situation could not be compared with that of national measures:[50]

> *In that regard, the assertion by the Kingdom of Sweden and the interveners that a proposal to list a substance in the Annex to an international convention which is binding on the Union is equivalent to a national measure that is more stringent than a minimum Union measure and is permitted by Article 176 EC cannot be accepted. The Union could be bound by an amendment to an Annex to the Stockholm Convention whereas it is not bound by such a national measure.*

75. The Government submits, on this background, that a national procedure in parallel with the initiation of the REACH procedure cannot be prohibited by Article 3 EEA. Hence, also ESA's secondary plea should be dismissed as unfounded.

3.3 The Government's response to ESA's third plea

3.3.1 Introduction

76. ESA submits, as its third plea, that the restrictions on PFOA introduced by the Norwegian Product Regulation are in any event unlawful under the general rules on the free movement of goods in the EEA Agreement. It is argued that the measure is not proportionate in ensuring the aims pursued.

77. The national measure – prohibition of the production, import, export and sale of consumer products containing more than 0,1% PFOA by weight – constitutes a restriction under Article 11 EEA. However, the Government submits that it is justified by the legitimate objectives of public health and the environment, and that it is proportionate as it is appropriate and necessary in ensuring the fulfillment of these aims.

78. ESA's objections against the justification seem to relate, at least primarily, to the necessity of the national measure and the documentation provided by Norway. The Government is of the opinion that ESA in this regard does not sufficiently appreciate the comprehensiveness of the documents forwarded, in particular the impact assessment issued in relation with the introduction of the national regulation. This document deals with most of the elements that ESA seems to believe is missing, such as a risk assessment and an assessment of the necessity of the measure, including an assessment of the chosen concentration limit and possible alternative measures.[51]

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[50] Paragraph 102.
[51] Impact assessment 2010, Annex A.5 of the application.

79. Moreover, the Government provided a link to the full risk assessment of the Norwegian-German proposal under REACH Title VIII.[52] This assessment is dismissed by ESA with the argument that the proposed concentration limit therein differs from the limits in the Norwegian provisions.[53] That represents a line of argument that is difficult to follow, however. First, the risk assessment under the REACH procedure includes far more than an assessment of the concentration limits and is hence relevant for more than that particular aspect of the necessity test. Second and importantly, the proposal under Title VIII of REACH was *stricter* than the Norwegian regulation in several aspects, including the concentration limit.[54] Hence, Norway provided to ESA a risk assessment substantiating the need for stricter regulations than those of the contested provision. ESA has not explained why an assessment calling for a *lower concentration limit* (i.e. a stricter restriction) of a hazardous substance is irrelevant in order to demonstrate that the *higher limit* (i.e. a less strict restriction) in the Norwegian regulation goes beyond what is necessary in order to achieve the public health and environmental objectives.

80. Finally in this introductory section, it must be recalled that subsequent risk assessments under the REACH procedure confirm the appropriateness and necessity of a prohibition against substances with PFOA and regulations that are at least as strict as the contested decision. As already set out above, both the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have by consensus under the REACH procedure concluded that the measures proposed by Norway and Germany, with a few amendments, are the most appropriate measure to address the risks of PFOA and that there are no relevant alternative regulations.[55]

81. These aspects are further set out below.

3.3.2 Legitimate objectives

82. PFOA is a substance of very high concern, as set out in section 2.2 above. Indeed, it has been concluded, for instance, that PFOA may damage the unborn child, cause damage to organs, cause serious eye damage, is harmful if inhaled, and that it is suspected of causing cancer.[56] The hazardous nature of PFOA is not disputed by ESA.[57]

83. ESA accepts that the national regulation may in principle be justified by the objective of public health. The ECJ and the EFTA Court have indeed constantly regarded health and life to rank foremost among interests protected by Article 13 EEA.[58]

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[52] The Norwegian-German proposal: https://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7 Link to all relevant documents under the REACH procedure: https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1908/term.

[53] Application, footnote 60.

[54] See e.g. section 3.3.5 below.

[55] Opinion by RAC and SEAC, enclosed as **Annex B.12** to this Defence.

[56] Application, Annex A.1.

[57] Application, paragraphs 4 and 86.

[58] Case E-4/04 *Pedicel* [2005] EFTA Ct Rep 1, paragraph 52, and Case E-16/10 *Philip Morris* [2011] EFTA Ct.

84. In addition, the national restriction is justified by the protection of the environment, as set out above. It is well established that restrictions may be justified by overriding requirements relating to protection of the environment, whether falling within or outside the scope of Article 13 EEA.[59]

3.3.3 Proportionality – introduction

85. As health and life of humans rank foremost among the interests protected by Article 13 EEA, it is settled case law that it is for each EEA State to decide what degree of protection they wish to assure. 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 both 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. As EEA States are allowed a certain margin of discretion in this regard, protection may vary from one EEA State to another.[60]

86. National restrictions, whether based on public health or environmental objectives, must, in accordance with the principle of proportionality, be appropriate for ensuring attainment of the objectives pursued and must not go beyond what is necessary in order to attain those objectives.[61]

87. As held just above, the power to determine the degree of protection that a State wishes to afford to public health and the way in which that protection is to be achieved, must be taken into account in assessing whether the measure is appropriate and necessary. It is, moreover, settled law that where there is uncertainty as to the existence or extent of risks to human health, an EEA State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. An EEA State may take the measures that reduce, as far as possible, a public health risk.[62]

3.3.4 Appropriateness

88. It is not entirely clear to what extent ESA contests that the first element of proportionality – that the measure is appropriate in ensuring at least one legitimate objective – is complied with. ESA states, for instance, that it does not dispute "in principle" that PFOA is a serious hazardous substance, but may seem to question whether the public health risks are sufficiently documented.[63]

Rep. 330, paragraph 77.
[59] Judgment in *Ålands Vindkraft AB*, C-573/12, EU:C:2014:2037, paragraphs 77 and 80: and in *European Parliament and Denmark v European Commission*, Joined Cases C-14/06 and C-295/06, paragraph 75.
[60] *Philip Morris*, paragraphs 77 and 80, with further references.
[61] *Ålands Vindkraft*, paragraph 76, and *Philip Morris*, paragraph 81.
[62] *Philip Morris*, paragraph 82, with further references.
[63] Application, paragraphs 86 and 89.

89. The Government submits that the national regulation is clearly appropriate. This requires that it was reasonable to assume that the measure would be able to contribute to the protection of human health or the environment.[64] The Government cannot see that this could be called into question on the basis of the information and scientific evidence available at the time of adopting the national measure, as already forwarded to ESA. The conclusion is further strengthened with new scientific evidence and new risk assessments made under REACH Title VIII.

90. ESA claims that the impact assessment forwarded to ESA 20 December 2010 did not address the issues of "substantiated justification" and that it has not received any "risk assessment or other scientific or technical evidence from Norway".[65] It therefore seems necessary to recall essential extracts of the document forwarded to ESA,[66] that indeed addresses these and other relevant matters, documented with a long list of scientific references set out in Section 8 of the report. See also section 2.3 above.

91. In section 2.4 of the report, there is a separate risk assessment related to health and environmental impact. This sections starts by recalling that PFOA is a substance of very high concern with respect to its health and environmental properties. Further, reference is made to the procedure of classifying PFOA as dangerous to human health because of its risk of causing cancer, damage to the reproductive system and chronic toxicity (CMR) under former Directive 67/548/EEC , now Regulation (EU) No. 1272/2008 (CLP). This procedure was later concluded by Regulation (EU) No. 944/2013 which established harmonised classification for PFOA as reproductive toxicant 1B.

92. The report continues by referring to the occurrence of PFOA, set out in more detail earlier in the report, with numerous scientific references. The report summarizes in section 2.4 parts of these findings:

> *PFOA is present in the blood and has a very long half-life (about four years, RPS Advies, 2010). The occurrence in blood in the general population and exposure of foetuses through umbilical cord blood and infants through breast milk are serious reasons for concern. Small children may also be exposed through direct contact with dust from carpeting and textiles. Breathing, swallowing of air or dust may be a significant contributor to the exposure of PFOA, especially for small children.*

93. It is emphasised, moreover, that PFOA is a PBT-like substance. These are substances for which there already exist well-established principles of evaluation. For instance, there is a consensus opinion that one cannot find an acceptable level of concentration. The following is stated in section 2.4:

> *Since PFOA is a PBT-like substance or a substance of equal concern, it not possible to establish acceptable levels for concentrations of the substance in the environment*

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[64] *Philip Morris*, paragraph 83.
[65] Application, paragraphs 91 and 94.
[66] Application, Annex A.5.

with certainty. Regulating PFOA therefore cannot be based solely on the traditional risk assessment methods. The dispersion of substances which do not degrade and which are stored in living organisms constitutes a special problem, because accumulation in the environment is difficult to reverse and their long-term effects may be difficult to predict. For substances with such properties, emissions and exposure need to be limited as much as possible.

94. These findings have been further strengthened in the years after the impact assessment from 2010, inter alia because PFOA is regarded as having PBT properties, and not *only PBT-like* properties. Reference is made to the opinions by RAC and SEAC annexed to this Defence.[67]

The restriction proposal is based on the PBT properties of PFOA. No relevant quantitative environmental risk assessment can as such be conducted for PBT substances (REACH Guidance R.11.1 page 10, version 2.0, 2014), so the overall intention is to minimize emissions. Any environmental exposure has the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects on the food chain). Information on environmental emissions (supported by environmental monitoring data) for PFOA and PFOA-related substances are therefore used as a proxy for potential risk.

(...)

The PBT properties of PFOA are not discussed further in this opinion as there is already an EU agreement on PFOA fulfilling the PBT criteria, that is, that PFOA is persistent, bioaccumulative and toxic (see Section B.4.3 of the restriction proposal and the Member State Committee (MSC) opinion for identification of PFOA as an SVHC, June 2013). There is no indication of new data challenging the 2013 opinion from MSC.

95. It is hence common ground within the relevant scientific environments that PFOA is a substance of very high concern, that it has so called PBT properties meaning that there cannot be established an acceptable level of concentration, and that the actual exposure to nature is a main source of information of the risk assessment. It follows from the REACH Regulation, inter alia from Recital 70, that for such substances, *"measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with the view to minimising the likelihood of adverse effects."*[68]

96. The impact assessment, in line with this, describes the occurrence of PFOA in more detail, inter alia in section 2.3. It continues with the range of application of PFOA and relevant alternatives than using PFOA (section 3). Moreover, there are detailed assessments of the chosen concentration limit and whether it is possible to adopt less restrictive, albeit

[67] **Annex B.12** to this Defence, at pp. 11 and 12.
[68] See also section 3.3.5 below on the necessity of the Norwegian restriction.

effective, national measures. These aspects are assessed under the necessity section below. That section will also include the summary in section 7.4 of the impact assessment, even though that summary is also relevant for the appropriateness of the national restriction.

97. The impact assessment hence provided a solid basis for the conclusion that the contested national regulation was indeed appropriate to ensure the objectives of public health and the environment. Reference is throughout the report made to scientific research, but the Government did not forward the underlying research documents. The Government fails to see that there is, under the conditions of the present case, a legal requirement to forward these documents in order for the national restriction to be substantiated. However, in order to provide the Court with an even more comprehensive basis, the Government has forwarded a selection of the relevant scientific documentation, as set out in section 2.3 above.[69]

98. ESA also submits that the Norwegian Product Regulation does not appear to pursue the objective of public health in a coherent and systematic manner and that it therefore cannot be considered appropriate for attaining that objective.[70] The reason for this submission is that the regulation was amended in 2014 as regards the entry into force of the regulation. Products containing PFOA that had already been produced by 1 June 2014 are allowed to be imported and put on the market until 1 January 2018, as set out in section 2.2 above.

99. The Government strongly contests that this transitional rule can call into question the appropriateness of the Norwegian regulation.

100. First, allegations like these are, when it comes to the free movement of goods, normally assessed under the last sentence of Article 13 EEA. Nothing indicates, however, that the regulation constitutes a means of arbitrary discrimination or a disguised restriction on trade.

101. Second, even if the case law cited by ESA may be applied also in the context of the free movement of goods, the Government cannot understand that anything suggests that the public health and environmental objectives are not pursued coherently and systematically. Leaving aside the paradox that ESA with its argument suddenly calls for a stricter regulation whereas the regulation elsewhere seems to be too strict for ESA,[71] the point is that the transitional rule simply makes good sense from a principle of proportionality and the protection of health and environment.

102. The transitional rule was, as explained above, introduced after industry concerns that it would be difficult to reach the deadline of 1 June 2014. Lots of products with PFOA had

[69] **Annexes B.3 – B.11** to this Defence.
[70] Application, paragraph 96.
[71] To make a restriction less strict can hardly be incoherent, see, to this effect, judgment in *Bacardi France SAS*, C-429/02, EU:C:2004:432, paragraph 40.

already been produced, implying that the alternative was either to destruct the products or to sell them to states without a comparable regulation. This was assessed by the Norwegian Directorate of the Environment, concluding that both of these options would be unfortunate for the environment.[72] Indeed, both the public health and environmental consequences of PFOA occur to a large extent as the product is produced. PFOA is a man-made substance that does not exist naturally. It is formed in different ways during the production processes. Using the product or making them into waste would therefore not significantly change their negative impact on health and environment. Thus, there is no inconsistency in accepting products with PFOA that were already produced.

103. Indeed, the same approach is suggested on EU level. Both the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) propose different transitional rules, extending the time limit for the entry into force of the Norwegian-German proposal for an EEA wide restriction. Some of these transitional rules are suggested only for products already produced, based on an assessment that this would be appropriate and proportional to the aims pursued.[73]

104. It would be highly paradoxical if the comparable Norwegian measure would be found inappropriate and inconsistent.

3.3.5 Necessity

105. ESA submits, finally, that the Norwegian provision fails to meet the necessity requirement, in particular, it seems, based on the allegedly lack of explanation of the scope of the regulation and the set concentration limits.

106. The Government submits that the regulation is indeed necessary as the objectives of public health and the environment cannot be protected just as effectively with less restrictive measures,[74] bearing in mind also the margin of appreciation described in section 3.3.3.

107. Again, reference should in particular be made to the impact assessment from 2010 assessing these matters thoroughly, assessments that are confirmed in the recent opinions under the REACH procedure.

108. The contested regulation concerns consumer products. It is hence wide in the sense that all types of products are included, but limited to products for consumers. This scope of the regulation is based on the risks related to PFOA. PFOA is found in small quantities in many different products. It is the sum of exposure that may be harmful to health and the environment. This implies that it would reduce the positive effects of the regulation if only

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[72] Letter of 4 March 2014 from the Norwegian Environment Agency to the Ministry of Climate and Environment, in Norwegian and with an unofficial translation of the summary, **Annex B.13** to this Defence.
[73] It is suggested, for instance, to include a derogation for "spare parts, if the spare parts are already produced at the date of entry into force, and the date of production can be demonstrated", see **Annex B.12** at p. 9.
[74] E.g. Case E-3/06 *Ladbrokes* [2007] EFTA Ct. Rep. 86, paragraph 58. See also the Application, paragraph 95.

a specific range of products were included. Moreover, even if also the use of PFOA within the industry etc. causes concern, the risks related to consumers, including children, must be regarded as higher.

109. These aspects are set out in the impact assessment, inter alia as part of the conclusion in section 7.4:[75]

> *Products are the most important application area for PFOA. It is not acceptable for such serious priority substances as PFOA to be present in consumer products. Consumer products are an important source of uncontrolled dispersion of priority substances into the environment. It is therefore critically important that the use of products with such priority substances be limited. Consumer products are particularly important, since consumers lack the requisite knowledge about the health-related and environmental problems associated with their use and the waste disposal of these substances. Consumers also do not have the requisite knowledge and ability to protect themselves against emissions. The entire population, including vulnerable groups such as children, is therefore exposed to emissions from consumer products, either directly or indirectly via the environment.*

110. It is noted that the restriction proposed on EEA level has a wider scope than the Norwegian restriction. It is proposed that the EEA measure should cover all products, not only consumer products, with some derogations only. This is summarised as follows:[76]

> *RAC concludes that based on the available information on transformation, all PFOA-related substances seem to degrade to PFOA in amounts >0.1% per year, and therefore are relevant to include in the proposed restriction. Importantly, there was no information provided in the public consultation showing that there are substances with linear or branched perfluoroheptyl- or perfluorooctylderivatives (beside the exceptions already defined in the proposal10) that cannot degrade or be transformed into PFOA.*
>
> *RAC therefore recommends that the proposed restriction should encompass an open-ended list of PFOA-related substances, similar to the current EU restriction of PFOS.*

111. When it comes to the concentration limit, it is recalled from section 2 above that there was originally a separate regulation for PFOA in mixtures (set at 0.001% by weight), whereas the presently applicable regulation only concerns PFOA in articles (consumer products) with a limit of *0.1% by weight*. The impact assessment demonstrates – as also held above – that the characteristics of PFOA mean that all exposure is potentially harmful. The lower the limit is set, the more efficient will the regulation be for health and environmental purposes. The concentration limits were set to ensure an efficient

[75] Impact assessment (2010), Annex A.5, section 7.4.
[76] Opinions from RAC and SEAC (2015), **Annex B.12,** p. 16.

regulation, without, however, making it too burdensome and costly in relation to products with very limited content of PFOA. They were also based inter alia on the knowledge the Norwegian authorities had of limits that from an analytical point of view were possible to detect.

112. Reference is also here made to the summary and conclusions in section 7.4 of the impact assessment.[77]

> *The documentation shows that PFOA has PBT-like properties. Because PFOA is a potential PBT-like substance, acceptable concentration levels of such substances in the environment cannot be established with certainty. The key challenge is the general dispersion of PFOA into the environment from many different products throughout their entire useful lives, through usage and as waste. This particularly applies to textiles, impregnation agents, ski waxes and carpets, where the emission can be significant. PFOA in products will be able to leak out into the environment once the products end up as waste.*
>
> *Dispersion of substances that degrade slowly (persistent) and are stored in living organisms (bioaccumulate) constitutes a special problem because it is difficult to reverse accumulation in the environment, and the long-term effects can be difficult to predict. The precautionary principle therefore suggests that measures should be implemented.*

113. Notably, the concentration limit is set significantly lower in the proposed restriction under REACH than the limit set in the Norwegian regulation. The proposed limits in the Opinions from the Committee for Risk Assessment (RAC) and the Committee for Socio-economic analysis (SEAC) are 25 ppb for PFOA or its salts, 1000 ppb for any single PFOA-related substance and 1000 ppb for the sum of all PFOA-related substances as constituents of other substances. The same limits apply in mixtures and in articles.[78] The Norwegian limit for PFOA in consumer articles (0.1% by weight) corresponds to 1 000 000 ppb, i.e. a substantially higher level than under the REACH proposal. The Norwegian measure is hence also on this point less restrictive than the pending REACH proposal.

114. The RAC and SEAC opinions are based (with minor amendments) on the Norwegian – German proposal. When these REACH restriction limits were proposed, they were based on new knowledge on the possible limits of detection, which had then been lowered significantly. In addition, PFOA had at that time been identified as a PBT substance[79], meeting the criteria in Article 57 of REACH, calling for as low limits as possible, cf. the Preamble of REACH, at Recital 70, and Annex I, at paragraph 6.5.

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[77] Impact assessment (2010), Annex A.5, section 7.4.
[78] Ppb = parts per billion. See Opinions of RAC and SEAC (2015), **Annex B.12**, at pp. 4-10.
[79] And not only a "PBT-like" substance as set out in the impact assessment from 2010, set out in section 3.3.4 above.

115. Alternative measures were assessed before adopting the national restriction, but found to be inappropriate or at least less efficient. Reference is made, in particular, to the impact assessment section 6.[80]

116. Alternatives discussed were, first, information campaigns:

> *One might ask the question whether this problem can be solved through information campaigns directed at consumers. However, based on OECD studies and other research, experience shows that information campaigns are insufficient to reduce emissions of priority hazardous substances. The measure is too diffuse and uncertain to reach the necessary goals. Information campaigns are therefore not a relevant alternative to the proposed regulation.*

117. As a second alternative, economic measures, such as taxes, were assessed:

> *From Norway's perspective, a corresponding health and environmental effect also cannot be achieved using economic measures, such as a tax. A tax is most appropriate in cases where the only aim is to reduce the use of a substance and in cases where there is no urgent need to reduce the emissions. As a result of PFOA's health and environmentally damaging properties, it is important that we have a reduction in use and emissions that is as rapid as possible. This means that a tax is not a desirable measure. Economic measures have generally turned out to be less effective than usage and sales restrictions to achieve reductions in the sources of emission. It would also be very difficult to establish a tax system that could produce the same effect as the proposed regulation. The large number of possible use areas would make it especially complicated to design and enforce a tax system.*

118. Third, it was assessed whether it was possible to introduce measures at a later stage in the sales chain and thereby limit the scope of the restriction:

> *It is also insufficient to introduce measures at a later stage in the sales chain. Collection schemes would, for example, be less restrictive in respect of trade than a prohibition but would not produce the same health and environmental impact. Collection schemes for products containing PFOA should also cover a great number of different types of products and would therefore be difficult to implement. Regulation at the emission source is the most effective regulation method when the objective is to achieve rapid reductions in emissions. If measures are introduced at a later stage, once the products have been put on the market, it is more difficult to introduce measures that effectively prevent uncontrolled dispersion of priority substances. Furthermore, the risk of leaks and emissions would be greater once the reducing measures are introduced after the products have entered the market. It would be more effective to regulate near the source. Many consumers lack the*

[80] Impact assessment (2010), Annex A.5, section 6.

relevant knowledge about collection schemes. It is difficult enough to monitor whether consumers are using already existing collection schemes.

119. A fourth possible alternative discussed, but dismissed, was the use of voluntary agreements:

Voluntary agreements between the authorities and the industry have been effective measures in other environmental areas, among other things, in order to ensure proper waste handling. In this case, where the objective is to achieve rapid reductions in emissions and to avoid PFOA in imported consumer products, a voluntary agreement—like the one the large fluoropolymer producers have entered into—is not sufficient to ensure that PFOA is phased out by all producers of consumer products. PFOA is present in a large number of imported products. These are difficult to capture with voluntary agreements. The proposed restrictions will therefore be a more effective measure to achieve the desired result. The proposed limits on the content of PFOA were imposed on the basis of the current trend in the market and recent results.

120. Finally, labelling was also assessed:

Additionally, restrictions are a far more effective measure than labelling of products containing PFOA. It is not likely that labelling in itself will reduce the risk of dispersing or exposure of PFOA.

121. It is noted that the same conclusion is drawn in the procedure under REACH. For instance, it is concluded by the relevant committees (RAC and SEAC) that there are no real alternatives than a strict regulation on all use of PFOA covering all emission sources:[81]

PFOA is a highly persistent PBT substance with a potential for environmental long-range transport, which makes emission of PFOA and PFOA-related substances a transboundary pollution problem. Evidence from contaminated sites such as airports (where fire-fighting foams containing PFOA or PFOA-related substances have been used) shows that it is very difficult to reduce the level of pollution once it has occurred.

The uses of PFOA and PFOA-related substances are widespread and consumer articles and mixtures containing these substances are placed on the market in all EU Member States. In addition, emissions could potentially occur at every stage in the life cycle, i.e. during production, service life and disposal. EU wide action is therefore necessary to eliminate emissions of PFOA and PFOA-related substances.

[81] **Annex B.12**, pp. 26 and 28.

Therefore, any national regulatory action cannot adequately minimise emissions of PFOA and PFOA-related substances. As a consequence, risk management action is needed on an EU wide basis.

...

A restriction covering all emission sources was considered in the dossier to be the most appropriate EU wide measure to effectively reduce the emissions.

SEAC considers there is no other foreseeable option than a restriction under REACH to bring significant emission reductions in an acceptable time horizon. Therefore SEAC agrees that a restriction is the most appropriate EU wide measure to address the concern caused by PFOA releases in the environment.

122. The overall conclusion drawn before adopting the contested measure was therefore that the restriction was indeed necessary in order to achieve the desired level of protection for the period until there will be EEA wide restriction. It is stated, inter alia the following in the impact assessment, to which the Government refers:[82]

PFOA is a priority hazardous substance, and national goals have been established for the phasing out of PFOA before 2020. The proposal for regulation might result in somewhat increased costs but will mean that the emissions of PFOA to the environment will be reduced and the risk of health effects will be lowered. Seen in relation to the health and environmental effects of PFOA, we believe that the increased costs are acceptable. The proposal will have a positive effect for companies producing alternatives. Overall, our assessment is that the measure will not result in significant socio-economic costs. We are anticipating that the benefits will outweigh the costs on the basis of the expected positive effects the proposal will have for health and the environment. The proposal will enter into force on 1 January 2013[83] because it takes a couple of years from production of raw materials to production, import, export and sale of finished consumer products. The proposal also contains a time-limited exemption for applications within the area of semiconductors and photographic products for which there are currently no alternatives.

...

The proposed regulation is considered to be based on legitimate concerns (health and environmental concerns) and is considered an appropriate and necessary measure to reach the objective of reduced emissions of PFOA from consumer.

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[82] Impact assessment (2010), Annex A.5, section 7.4.

[83] The time frame was later amended so that the regulation came into force on 1 June 2014 with the exception for products already produced at that time, see 2.2 and 3.3.3 above.

123. Based on the above the Government must conclude that the Norwegian regulation does not go beyond what is necessary as the same level of protection cannot be achieved as efficiently with less restrictive means.

4 CONCLUSIONS

124. The Government respectfully requests the Court to declare that:

1. The application is unfounded.

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

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Oslo, 10 October 2016

ATTORNEY GENERAL (CIVIL AFFAIRS)

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Agent

for Ingunn Skille Jansen
Agent

LIST OF ANNEXES

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B.4	Haug, Line S. *et al.*: "Time Trends and the Influence of Age and Gender on Serum Concentrations of Perfluorinated Compounds in Archived Human Samples", Environ. Sci. Technol., 2009, 43 (6), 2131-2136	2009	6	22, 69
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B.6	Monroy, R., Morrison, K., Teo, K., Atkinson, S., Kubwabo, C., Stewart, B., *et al.* "Serum levels of perfluoroalkyl compounds in human maternal and umbilical cord blood samples". Environ. Res. 108, 56-62	2008	7	22, 69
B.7	Kristine B Gützkow, Line S Haug, Cathrine Thomsen *et al.*, "Placental transfer of perfluorinated compounds is selective – A Norwegian Mother and Child sub-cohort study". Int. Journal of Hygiene and Environmental Health 215 (2012) 216–219	2012	4	22, 69
B.8	Line S. Haug, Sandra Huber, Georg Becher, Cathrine Thomsen, "Characterisation of human exposure pathways to perfluorinated compounds — Comparing exposure estimates with biomarkers of exposure". Environment International 37 (2011) 687–693	2011	7	22, 69
B.9	Chen M-H, Ha E-H, Wen T-W, Su Y-N, Lien G-W, et al. "Perfluorinated Compounds in Umbilical Cord Blood and Adverse Birth Outcomes". PLoS ONE 7(8): e42474	2012	8	23, 69

B.10	Mildred Maisonet, Metrecia L. Terrell, Michael A. McGeehin *et al.*" Maternal Concentrations of Polyfluoroalkyl Compounds during Pregnancy and Fetal and Postnatal Growth in British Girls". Environ Health Perspect 120:1432–1437 (2012)	2012	6	23, 69
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