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EFTA SURVEILLANCE AUTHORITY

REASONED OPINION

delivered in accordance with Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice concerning Norway's breach of Regulation 1907/2006

EFTA SURVEILLANCE AUTHORITY

1 Introduction

1. On 27 August 2013[1], the Norwegian Government informed the EFTA Surveillance Authority ("the Authority") that a regulation prohibiting perfluorooctanoic acid ("PFOA") in certain consumer goods in Norway had been adopted on 27 May 2013 ("the Products Regulation")[2].

2. PFOA is a synthetic chemical that does not occur naturally in the environment. It is used as processing aid in the manufacture of fluoropolymers, which have numerous applications including their fire resistance and ability to repel oil, stain, grease and water. It is also used in the photographic and imaging industry.

3. Draft regulations to introduce a ban on PFOA in consumer products had previously been submitted to the Authority in the context of the draft technical regulations procedure laid down in Directive 98/34[3] ("DTR"), first in 2007[4] and then again in 2010[5]. The Authority issued comments on both these draft regulations. In both sets of comments, the Authority questioned the compatibility of the proposed Norwegian regulations with existing harmonised EEA legislation applicable to products intended for use by consumers.

4. The European Commission also issued comments on the 2010 Norwegian notification in the context of the DTR procedure[6]. Having received no reply to those comments and being concerned that its comments had not been taken into account by the Norwegian Government, the European Commission issued further comments on 1 March 2013[7]. These comments made it clear that, if adopted, the notified measures would have a negative impact on the free movement of goods within the EEA.

5. On 30 October 2013, the Authority's Internal Market Affairs Directorate ("the Directorate") addressed a pre-31 letter to Norway, setting out its concerns regarding the prohibition on PFOA[8]. The issue was then discussed with representatives of the Norwegian Government at the package meeting which took place in Oslo on 21-22 November 2013. Norway's response to the pre-31 letter, dated 10 January 2014, was received by the Authority on 13 January 2014[9]. The prohibition was further discussed during the package meeting which took place in Oslo on 16-17 October 2014.

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[1] Document No 681074.
[2] Regulation No 550 of 27 May 2013 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).*
[3] Comments were issued following the procedure established by *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.*
[4] Notification 2007/9016/N. Comments by the Authority can be found in Document No 435537.
[5] Notification 2010/9019/N. Comments by the Authority can be found in Document No 590181.
[6] Communication from the Commission – C(2011)1982. Document No 591458.
[7] Communication from the Commission – SG(2012) D/50637 Procedure for the provision of information EC-EFTA Notification: 2010/9016/N, 2010/9017/N, 2010/9018/N, 2010/9019/N, Document No 627029.
[8] Document No 687170.
[9] Document No 695408 (Norway's reference No 12/3557).

6. On 14 January 2015, the Authority issued a letter of formal notice to Norway[10]. By letter dated 10 March 2015, the Authority received a request from Norway to extend the time limit to submit observations in the case[11]. The Authority granted an extension of the deadline to respond to the letter of formal notice until 11 April 2015[12]. On 15 April 2015, the Authority received Norway's formal observations on the letter of formal notice by letter dated 13 April 2015[13].

2 Relevant national law

7. The addition of section 2 paragraph 32 to the Norwegian Product Regulation makes it illegal, from 1 June 2014, to manufacture, import, export and sell consumer products containing PFOA and certain salts and esters of PFOA[14] as a pure substance or in a mixture when the mixture contains 0.001% or more of the chemical[15]. 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 PFOA[16], is present in amounts equal to or greater than 1 $\mu g/m^2$.

8. From 1 June 2014, it is prohibited to manufacture, import, export and sell consumer products containing PFOA and certain salts and esters of PFOA when the content of the substance in the product's individual components is greater than or equal to 0.1% weight.

9. 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 do not apply to food packaging, materials in direct contact with food and medical equipment.

10. The prohibitions shall not apply to spare parts for consumer products that are made available for sale before 1 June 2014.

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

3 Relevant EEA law

3.1 EEA Agreement

12. Article 3 of the EEA Agreement states that:

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[10] Document No. 722134.
[11] Document No. 750357.
[12] Document No. 750455.
[13] Document No. 754015.
[14] 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.
[15] The text in Norwegian of § 2-32 can be found under this link: http://lovdata.no/dokument/SF/forskrift/2004-06-01-922/KAPITTEL_2#§2-32.
[16] See footnote 10 for a list of the salts and esters covered by paragraph 2-32 of the Norwegian Product Regulation.

"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."

13. Article 11 of the EEA Agreement states that:

"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties."

14. Article 13 of the EEA Agreement states that:

"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."

3.2 REACH

15. In the EEA, chemicals are regulated by the Act referred to at point 12zc of Chapter XV of Annex II to the EEA Agreement *(Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended* ("REACH")).

16. REACH 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 in articles, while enhancing competitiveness and innovation[17]. The legislation provides two principal methods for the control of hazardous substances, namely authorisation and restriction.

3.2.1 Authorisation

17. Authorisation is one of the REACH processes for managing the risks of hazardous substances. Substances that are subject to authorisation may not be used in the EEA unless companies (and their registered users) have been authorised to do so.

18. The aim of the authorisation process, as stated in Article 55 of REACH, is:

[17] Recital 2 of REACH makes it clear that *"[t]he efficient functioning of the internal market can be achieved only if requirements for substances do not differ significantly from Member State to Member State"*.

"*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*".

19. The substances that qualify for consideration for authorisation are known as 'Substances of Very High Concern' ("SVHC"). In order to be subject to the authorisation regime, substances are first required to be added to the Candidate list[18]. To be added to the list, substances must meet the criteria set out in Article 57(f) of REACH. Once on the Candidate list, the European Chemicals Agency ("ECHA") submits a recommendation to the European Commission, who then decides on the eventual inclusion of the substance on the Authorisation List which is set out in Annex XIV of REACH.

3.2.2 Restriction

20. REACH establishes a restriction process in order to regulate the manufacture, placing on the market or use of certain substances, either on their own or in mixtures or in articles. Such activities may be limited or even banned, if necessary. A restriction is defined under REACH as "*any condition for or prohibition of the manufacture, use or placing on the market*"[19]. The REACH provisions on restrictions (Title VIII and Annex XVII) have applied since 1 June 2009 throughout the European Economic Area.

21. 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 (...)"

22. Where such a risk is identified, a restriction must be adopted following the procedure set out in Title VIII of REACH[20]. Article 69(4) of REACH states:

"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."

23. The Annex XV dossier should demonstrate that there is a risk to human health or the environment that needs to be addressed at the EEA level and should identify the most appropriate set of risk reduction measures. If this dossier demonstrates that

[18] Article 59(1) REACH.
[19] Article 3(31) REACH.
[20] Title VIII of REACH covers Articles 67 to 73 of the Regulation.

action on an EEA-wide basis is necessary, beyond any measures already in place, the State shall submit it to ECHA in the format outlined in Annex XV, in order to initiate the restrictions process. Proposals for restrictions can also be prepared by ECHA at the request of the European Commission.

24. To prevent duplication of work, a State is requested to notify ECHA that it proposes 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).

25. 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.

3.2.3 Possibility of introducing unilateral national restrictions under REACH

26. 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 regulating them further. Article 128(2) provides for a limited exception to this rule. Article 128 states:

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."*

27. REACH also contains an over-arching safeguard clause in Article 129(1) which states:

"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."

28. When Article 129 is invoked, the relevant EFTA State must immediately inform the Authority, which then has 60 days to either authorise the provisional measure or to require the State to revoke the provisional measure[21].

3.3 Regulation 1272/2008

[21] Article 129(2) REACH.

29. *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* ("the CLP Regulation")[22] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EEA through classification and labelling of chemicals. 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 Community level. Under Article 37 of the CLP Regulation, Member States may submit proposals for the harmonised classification and labelling of a substance.

Current status of PFOA in the EEA

30. Following submission by Norway of an Annex XV dossier for a harmonised classification and labelling for PFOA and its salts, the Committee for Risk Assessment ("**RAC**"), the body responsible for preparing the opinions of ECHA on the risks of substances to human health and the environment under both REACH and CLP, concluded that PFOA should be classified as toxic for reproduction category 1B[23] in accordance the CLP Regulation. This corresponds to classification as toxic to reproduction category 2 in accordance with Directive 67/548/EEC[24].

31. On 4 February 2013, in the context of the authorisation process, 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[25].

32. On 19 February 2014, together with Germany, Norway notified its intention to ECHA to submit an Annex XV dossier to ECHA which proposed an EEA wide restriction on PFOA. That dossier was formally submitted on 17 October 2014.[26]

33. At the EU level, *Commission Regulation 317/2014 of 27 March 2014 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR Substances)* ("Regulation 317/2014") amended Appendix 6 of Annex XVII REACH to include PFOA. Entries 28 to 30 of Annex XVII REACH prohibit the sale to the general public of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR) above specified concentration limits. The effect of Regulation 317/2014 is that, from 1 January

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[22] Act incorporated into the EEA Agreement at point 1 of Chapter XV of Annex II.

[23] Committee for Risk Assessment, decision of 2 December 2011 available at http://echa.europa.eu/documents/10162/13579/rac_pfoa_adopted_opinion_en.pdf

[24] *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.*

[25] 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-

[26] Following submission, the dossier is subject to scrutiny by the RAC to determine whether it is in conformity with the requirements of Annex XV of REACH. Only once it is deemed to conform with Annex XV will the dossier be subject to public consultation. The deadline for comments in the public consultation was 17 June 2015. The information note submitted with the dossier can be found here: http://echa.europa.eu/documents/10162/3b6926a2-64cb-4849-b9be-c226b56ae7fe

2015, PFOA was inserted into Appendix 6 of Annex XVII to REACH as toxic for reproduction category 1B in the EU with a limit value of 0.3% by weight[27].

34. Regulation 317/2014 has not yet been incorporated into the EEA Agreement. The Authority understands that Norway sought an adaptation text for this Act and that this process is ongoing. However, the status of Regulation 317/2014 in the EEA is not material to the Authority's assessment in the current case.

4 The Authority's Assessment

4.1 Harmonisation of Title VIII procedure under REACH

35. The Authority considers that the exhaustive character of the harmonisation process is clear from the language of both Articles 68(1) and 69(4) of REACH. Whenever there is an unacceptable risk to either human health or the environment which needs to be addressed on a EEA wide basis, Article 68(1) states that "*Annex XVII shall be amended...pursuant to the procedure set out in Articles 69 to 73*".

36. In the view of the Authority, the language of Article 69(4) is unequivocal. The provision clearly states that if a State considers that there is 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).

37. As such, Article 69(4) 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. It is only when, on the basis of the Annex XV dossier, it is established that the identified risks do not require action on an EEA wide basis, that national restrictions may be introduced.

38. In its observations on the letter of formal notice, Norway states that it is unclear whether Article 69(4) imposes an obligation on States to initiate harmonisation procedures in appropriate cases, and suggests that this provision may be optional. The Authority does not see that this language leaves any room to interpret the provision as being optional and cannot therefore share Norway's argument.

39. In addition, in its observations on the letter of formal notice and with reference to Article 69(4), Norway states that "*it is far from clear that the provision confers to the State an obligation to notify promptly its intentions" (sic)*. Norway seems to argue that as there is no deadline attached to the notification of a dossier under Article 69(4) REACH that this somehow opens the door to permitting unilateral measures. Once more, the Authority cannot agree with this reasoning. It is the Authority's view that where a State fails to comply with the obligation to prepare

[27] 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.

an Annex XV dossier, as required by Article 69(4) REACH, despite having identified an uncontrolled risk, this must be seen as a breach of that provision.

40. In attempting to rebut the Authority's interpretation of Article 69(4) of REACH, Norway also seems to suggest, in its response to the letter of formal notice, that one of the reasons for its introduction of unilateral measures on PFOA is the inefficiency of the REACH process, in particular the establishment of an EEA-wide regulation of PFOA under REACH. The Authority notes that Norway does not make any attempt to further clarify what it means by inefficiency. In any case, the Authority cannot agree with such argumentation.

41. Norway also claims, in its observations on the letter of formal notice, that the geographic scope of any restriction, i.e. whether or not it is to be EEA wide, is of significance in assessing whether the procedure under Title VIII REACH should be initiated. On the question of geographic scope, the Authority notes that Article 68(1) REACH refers to an unacceptable risk "*which needs to be addressed on a Community-wide basis*". Article 69(4) however introduces an element of discretion, by making it clear that the provision only applies "*[i]f a Member State considers*" that the risk is not adequately controlled and needs to be addressed. As such, the Authority considers that the discretion of the State only relates to the identification of an uncontrolled risk, and not to the question of whether the restriction process should be initiated. Moreover, the assessment of the appropriate level at which to address the risk, i.e. EEA wide or at the national level, is a matter for the Annex XV dossier. The Authority would re-iterate that where a State has identified an uncontrolled risk that would call for national legislation, it is under an obligation to follow the procedure established in Article 69(4) REACH.

4.1.1 Conclusion

42. In the Authority's opinion, Norway's decision to restrict PFOA under national law clearly demonstrates that it had identified PFOA as presenting an uncontrolled risk to the environment and human health. Having identified such a risk, the Authority 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). Norway's failure to follow the restriction process must be considered as a breach of its obligations under REACH.

4.2 Effect of Article 128(2) REACH

43. The Authority notes the arguments of Norway, set out first in its letter of 10 January 2014 and then restated in its observations on the letter of formal notice, that Article 69(4) does not have a harmonising effect. This is because this provision must be read in the context of Article 128(2). According to Norway, Article 128(2) is to be interpreted as meaning that REACH does not harmonise a substance simply because it falls within the scope of that Regulation. Instead, national rules intended to protect workers, human health and the environment are only prohibited where REACH harmonises requirements on the manufacture, placing on the market or use of a substance.

44. It is Norway's view that the harmonisation contemplated by Article 128(2) takes place *"only when an actual regulation of the substance in question exists"*[28]. As such, until the restriction procedure under REACH is concluded, States must be allowed to adopt unilateral national legislation. Norway argues 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*".

45. The Authority does not share Norway's interpretation on the scope of Article 128(2) REACH. In the Authority's view, 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). As such, REACH harmonises the restriction process itself, depriving States of the possibility of acting unilaterally. It is clear from the provisions of REACH that unilateral national measures are only permitted where a State believes there is an urgent need for action, using the safeguard provisions of Article 129 of REACH. Norway has not substantiated any legal arguments, either in its response to the pre-31 letter or in its comments on the letter of formal notice, as to why unilateral measures were necessary to address PFOA.

46. The Authority also cannot agree with Norway's claim that, by interpreting REACH as exhaustively harmonising the restriction process, Article 128(2) is deprived of meaning. The Authority notes that the provision of Article 128(2) allows the EEA States to regulate substances more strictly for reasons not covered by REACH, subject of course to the general free movement provisions of the EEA Agreement.

47. Norway's interpretation of Article 128(2) risks undermining one of REACH's key features, namely the free circulation of substances on the internal market and undermines the purpose of the EEA wide restriction process. The Authority agrees that REACH is also intended to "*ensure a high level of protection of human health and the environment*"[29]. This is to be achieved, inter alia, through the restriction process established by Title XVII.

48. In its observations on the letter of formal notice, Norway correctly observes that there is no case law from either the EFTA Court or the Court of Justice of the European Union ("CJEU") on the interpretation of scope of harmonisation under REACH. Despite this, Norway seeks to rely on the judgment of the CJEU in Case C-473/98 *Kemikalieinspektionen and Toolex Alpha AB* ("Toolex")[30] to support its view on the interpretation of REACH. 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 67/584/EEC[31]. 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.

49. The Authority would like to re-iterate its views on the Toolex case, as set out in the letter of formal notice. There is a clear distinction between the scope of the

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[28] Norway's observations and comments to the letter of formal notice, 13 April 2015.
[29] REACH Article 1(1).
[30] Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB*, EU:C:2000:379.
[31] *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* ("Directive 67/548/EEC"), incorporated into the EEA Agreement at Annex II, Chapter XV point 1.

legislation which was under scrutiny in that case, and that of REACH. In *Toolex*, the CJEU made it clear that since the relevant legislation in force at that time regarding the classification[32], marketing[33] and risk evaluation of substances[34] did not harmonise the conditions under which substances could be marketed and instead 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.

50. The scope of REACH goes far beyond Directive 76/769/EEC. 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 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.

51. The Authority notes that in its observations on the letter of formal notice, Norway seeks to rely on paragraphs 31-32 of the judgment in Toolex, which refer to Regulation 793/93. Regulation 793/93 introduced a consistent and coherent system for evaluating the risks related to chemical substances. However, it was clear from paragraph 31of the judgment of the CJEU 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, the Authority does not consider that the judgment in Toolex supports Norway's arguments as regards the scope of harmonisation under the latter Regulation.

4.2.1 Alternative – Notification of intention to submit Annex XV dossier as point of departure

52. In the alternative, even if Norway's position could be accepted, i.e. that there is no harmonisation under REACH until a final restriction decision has been taken, it is the Authority's view, as previously stated in the letter of formal notice, that once the process under Title VIII has been initiated (in the present case through the notification by Germany and Norway of an intention to submit an Annex XV dossier in respect of PFOA on 19 February 2014) this represents a point of departure for community action which implies that Norway is under a duty of close co-operation with the EEA States and Institutions in order to ensure the aims of REACH, in particular the effective functioning of the internal market, can be upheld.

53. Parallels with the case currently under consideration may be drawn from the case law of the CJEU, in particular its findings in Case C-246/07[35]. The Case was brought by the Commission to challenge Sweden's unilateral decision to propose

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[32] Directive 67/548/EEC.

[33] *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.

[34] *Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.*

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

the addition of the substance PFOS to the Stockholm Convention on Persistent Organic Pollutants[36]. 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 action[37].

54. While it is clear that the substance of Case C-246/07 does not concern the EEA Agreement, the Authority would argue that, by analogy, the initiation of the restriction process under Title VIII of REACH represents a point of departure for concerted EEA action which precludes unilateral action by States. In this regard, the Authority notes Norway's observations on the judgment as set out in its letter of 13 April 2015, in particular its reference to paragraph 102 of the judgment. In that paragraph, the CJEU considered it could not be bound by a national measure whereas it could be bound by an amendment to an Annex of an international agreement. The Authority does not see that this paragraph in any way questions its line of argument.

55. 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[38]. Having regard to Article 128(1) of REACH, the Authority considers that this, 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 both Norway and Germany has been finalised.

56. In its observations on the letter of formal notice, Norway states that it is in close co-operation with the other EEA States, referring to its work under REACH. The Authority does not question the work done by Norway under the auspices of REACH. However, this is not relevant to the legal question of the scope of the harmonising effect of Title VIII of REACH.

57. On page 5 of that letter, Norway states that the amendments to the Product Regulation were "*already in place and entered into force before the procedure under Title VIII even was initiated*" (sic). On this basis, Norway claims that repealing its national legislation "*would be difficult to reconcile with the objective of ensuring a high level of protection of human health and the environment*".

58. The Authority cannot share Norway's assertion regarding the timelines in this case. Norway and Germany notified their intention to submit an Annex XV dossier to ECHA on 19 February 2014. The amendments to the Norwegian Product Regulation which restricted PFOA entered into force on 1 June 2014, i.e. over 3 months after the Title VIII process had been initiated through the formal

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[36] 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.
[37] Case C-246/07, cited above, at paragraph 74.
[38] See, for example, Cases E-7/97 *EFTA Surveillance Authority v Norway* [1998] EFTA Court Report 62, at paragraphs 15-17 and E-5/01 *EFTA Surveillance Authority v Liechtenstein* [2000–2001] and joined cases E-5/05, E-6/05, E-7/05, E-8/05 and E-9/05 *EFTA Surveillance Authority v Liechtenstein* [2006] EFTA Court Report 142, at paragraph 18.

notification of the intention to submit an Annex XV dossier by Norway and Germany. As long as different rules relating to the manufacture, import, export and sale of PFOA remain in place across the EEA, the objective of REACH to ensure the free circulation of substances on the internal market cannot be met.

59. Moreover, the Authority notes that Commission Regulation 317/2014[39] has been identified as EEA relevant. The Regulation introduces a restriction on PFOA through entries 28-30 in Annex XVII to REACH at a limit value of 0.3% by weight. Once Regulation 317/2014 is incorporated into the EEA Agreement Norway will be obliged to respect this limit value and to make the necessary adjustments to the Norwegian Product Regulation.

4.2.2 Conclusion

60. The Authority takes the view that by 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 (as set out in more detail at section 2 above), Norway is in breach of its obligations under Article 128(1) of REACH.

4.3 Alternative – Breach of Article 11 of the EEA Agreement

61. It follows from the above that, as Title VIII of REACH has exhaustively harmonised the area of restrictions, recourse to primary law is no longer possible[40]. In the alternative however, if the Authority were to accept Norway's views of the limited scope of harmonisation under REACH and find that there had been no breach of that Regulation, the restrictions on PFOA as introduced by the Norwegian Product Regulation must be considered under the general rules on the free movement of goods as established by the EEA Agreement.

62. It is recalled that 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[41].

63. The Authority contends that the prohibition on PFOA introduced by the amendments to the Norwegian Product Regulation is sufficiently wide so as to be considered 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.

4.3.1 Justification under Article 13 of the EEA Agreement

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[39] Commission Regulation (EU) No 317/2014 *of 27 March 2014 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances).*

[40] See on this point the settled case law of the CJEU in, for example, Case C-52/92 *Commission v Portuguese Republic* [1993] ECR I-02961 at paragraph 17; Case C-1/96 *Compassion in World Farming Limited* [1998] ECR I-1251 at paragraph 47.

[41] See Case C-147/04 *De Groot en Slot Allium and Bejo Zaden* [2007] ECR I-245, paragraph 70 concerning the equivalent Article 34 TFEU.

64. The Authority notes that Article 13 of the EEA Agreement provides for certain exceptions to the general ban on quantitative import restrictions in Article 11 EEA. The Authority notes furthermore that 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.

65. 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 achieved[42]. However, since the notion of public health provides for an exemption from the fundamental principle, it must be interpreted strictly[43]. Any national rule likely to have a restrictive effect on imports can only be accepted if it is proportionate, meaning that health and life may not be protected just as effectively by measures that are less restrictive of trade within the EEA.[44]

66. 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. In order to rely on Article 13 of the EEA Agreement, Norway must demonstrate that the alleged risk for public health appears sufficiently established on the basis of the latest scientific data available at the date of adoption of the measure[45]. In addition, it is incumbent on Norway to provide a risk assessment, based on scientific and technical evidence that demonstrates the necessity and proportionality of the restrictive provisions[46]. In order to show the necessity and 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.

67. In its response to the pre-31 letter, Norway was very clear that "*PFOA is widely recognised as a substance harmful to health and the environment*". In its observations on the letter of formal notice, Norway states that, in relation to PFOA "*[t]he occurrence in the environment, in the food chain, blood, breast milk and umbilical cord blood therefore constitute a potential risk to human health and the environment*". Norway then goes on to state that the regulation is 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.

68. The Authority maintains its position, as set out in the letter of formal notice, that Norway's reference to such broad policy objectives are not sufficient to fulfil the burden of proof under Article 13. Norway's identification of PFOA as a hazard does not take into account the likelihood of exposure to a substance, and what

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[42] Case E-4/04 *Pedicel AS* v *Sosial- og helsedirektoratet,* cited above, paragraph 55. See also Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103.
[43] Case E-1/94 *Ravintoloitsjain Liiton Kustannus Oy Restamark,* cited above, paragraph 56. Case E-5/96, *Ullensaker Kommune* v *Nille AS*, Efta Ct. Rep [1997] p. 30, paragraph 33.
[44] Case C-322/01 *Deutscher Apothekerverband,* cited above, paragraph 104.
[45] Case C-41/02 *Commission v the Netherlands* [2004] ECR I-11375, paragraphs 47-49.
[46] Case C-41/02 *Commission v the Netherlands*, cited above, and Case C-192/01 *Commission v Denmark* [2003] ECR I-9693.

concentrations of that substances consumers are likely to encounter in practice. Merely referring to the inherent properties of PFOA cannot be considered sufficient to meet the obligation under Article 13 of the EEA Agreement. The Authority has not received any risk assessment or other scientific or technical evidence from Norway which would demonstrate the necessity or proportionality of this prohibition on PFOA that is now in force.

69. Moreover, 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.

70. While it is correct that in its 2010 DTR notification of proposed measures, Norway included an Impact Assessment of regulating PFOA in consumer products[47], this is the only document submitted to the Authority which discussed the risks presented by PFOA, as well as the alternatives currently available to replace the substance. As the Authority noted in its comments to that notification, even taking account of that impact assessment, Norway had failed to address the issues of substantiated justification, necessity and proportionality which had originally been made in the Authority's comments on the 2007 notification. The Commission too, in its comments on the 2010 notification, called upon Norway to "*provide the evidence that it has collected to establish the limits proposed in the notified drafts*".

71. In its observations on the letter of formal notice, Norway writes that the 0.001 weight percent concentration for PFOA was based on the concentration limit for PFOS in Regulation (EC) No 850/2004. This was chosen "*[s]ince PFOA and PFOS are similar compounds with similar chemical properties and hazards*". This is the only explanation provided by Norway for the chosen concentration limit. The Authority does not consider this sufficient to satisfy the proportionality test required by Article 13.

4.3.2 Conclusion

72. The Authority takes the view 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, the Authority considers that the Norwegian restriction on PFOA breaches Article 11 of the EEA Agreement.

FOR THESE REASONS,

THE EFTA SURVEILLANCE AUTHORITY,

pursuant to the first paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, and after having given Norway the opportunity of submitting its observations,

HEREBY DELIVERS THE FOLLOWING REASONED OPINION

[47] The Impact Assessment was included in the DTR Notification 2010/9019/N and can be found in Event No. 581403.

that by

i) Maintaining in force section 2 paragraph 32 of the Norwegian Product Regulation which bans the manufacture, import, export and sale of consumer products containing 0.001% or more by weight of perfluorooctanoic acid, Norway has breached its obligation arising from the Act referred to at point 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 9l/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended,* in particular Article 128 thereof, as adapted to the EEA Agreement by Protocol 1 thereto; or

ii) In the alternative, maintaining section 2 paragraph 32 of the Norwegian Product Regulation in force once the restriction process under Title VIII of 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 9l/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended* has been initiated, Norway is in breach of its obligations arising from Article 3 of the Agreement on the European Economic Area read together with Article 128(1) of REACH; or

iii) In the alternative, maintaining in force section 2 paragraph 32 of the Norwegian Product Regulation which bans the manufacture, import, export and sale of consumer products containing 0.001% or more by weight of perfluorooctanoic acid, Norway has failed to fulfil its obligation arising from Article 11 of the Agreement on the European Economic Area.

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, the EFTA Surveillance Authority requires Norway to take the measures necessary to comply with this reasoned opinion within *two months* following notification thereof.

Done at Brussels, 8 July 2015

For the EFTA Surveillance Authority

Helga Jónsdóttir
College Member

Markus Schneider
Acting Director