REPORT FOR THE HEARING
in Case E-3/2000

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

EFTA Surveillance Authority

and

The Kingdom of Norway

supported by the **Government of Denmark**, as intervener,

seeking a declaration that, by applying its legislation so as to prohibit the import and marketing in Norway of corn flakes, fortified per 100 g with 1 mg thiamine, 1 mg riboflavin, 10 mg niacin and 7 mg iron, which have been lawfully manufactured and marketed in other EEA States, the Kingdom of Norway has failed to fulfil its obligations under Article 11 EEA.

I. Introduction

1. The case at hand concerns the cereal product corn flakes, fortified with certain vitamins and with the mineral iron. The product is manufactured in Germany by Kellogg's Europe for Nordisk Kellogg's A/S (hereinafter 'Kellogg's'), a company incorporated under Danish law. In April 1997, Kellogg's applied to the Norwegian Food Control Authority for authorisation to sell the fortified product in Norway. The Norwegian authorities oppose the import and the marketing on the grounds that there is no nutritional need in the Norwegian population for the fortification.

2. It is disputed between the parties whether the refusal to grant the selling authorisation can be justified under Article 13 of the Agreement on the European Economic Area (hereinafter variously 'EEA' and 'EEA Agreement'). It is not disputed that the product concerned is covered by the EEA Agreement and that the Norwegian measure to ban the marketing of the product in question constitutes a barrier to trade within the meaning of Article 11 EEA. It is, furthermore, not disputed that, in assessing a nutritional need, the Norwegian authorities must have regard to the Norwegian population, and that the EFTA States, in the absence of harmonisation of the fortification of foodstuffs, are entitled to take the measures they consider necessary to protect public health.

II. Legal background, pre-litigation procedure and procedure before the Court

Legal background

EEA law

3. The application is based on one plea in law, namely, that Norway has failed to comply with its obligations under Article 11 EEA by applying its legislation so as to prohibit the import and marketing of fortified corn flakes which have been lawfully manufactured and marketed in other EEA States, and that this prohibition is not justified under Article 13 EEA.

4. Article 11 EEA provides that quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties.

5. The dispute before the EFTA Court concerns the question of whether such a measure can be justified under Article 13 EEA. That Article provides *inter alia* that Article 11 EEA does not preclude prohibitions justified on grounds of protection of human health, as long as a given prohibition does not constitute a means of arbitrary discrimination or a disguised restriction on trade.

6. Since Articles 11 and 13 EEA are, in substance, the same as Articles 28 and 30 EC, they should be interpreted in a manner consistent with the relevant rulings of the Court of Justice of the European Communities, in accordance with Article 6 EEA and Article 3, paragraph 2 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice.

The contested national provisions

7. The Norwegian authorities' rejection of the application of Kellogg's was based on section 10(2) of Norwegian Regulation No. 1252 of 8 July 1983 concerning the production and supply of foodstuffs ('*Generell forskrift for*

produksjon og frambud m.v. av næringsmidler'), adopted pursuant to the Norwegian Food Act ('*Lov av 19 mai 1933 nr. 3 om tilsyn med næringsmidler*'). That provision forbids the fortification of foodstuffs in the absence of an authorisation granted by the Norwegian Food Control Authority. According to the Government of Norway, section 10(2) is administered in accordance with the Codex Alimentarius General Principles. This means that individual authorisations are granted where there is a need in a population group or in the population as a whole. The assessment of need is decided by the Norwegian National Council on Nutrition and Physical Activity ('*Statens råd for ernæring og fysisk aktivitet*') and the Norwegian Food Control Authority ('*Statens Næringsmiddeltilsyn'*).

Pre-litigation procedure

8. By a letter of 4 July 1997, the Norwegian Food Control Authority refused the application of Kellogg's for authorisation to sell fortified corn flakes in Norway, on the grounds that the addition of nutrients is only authorised if there is a nutritional need. Furthermore, the Norwegian Food Control Authority stated that extensive use of fortification would lead to an unbalanced addition of nutrients, with a high intake of substances added to many products. It would also be misleading for consumers if emphasis were to be placed on the nutrients instead of on the total nutritional quality of the product. Basic foodstuffs should be produced by raw materials of high nutritional value, which should not be lost during the manufacturing process, and nutrients should only be added when the authorities recommend that a product carry a nutrient for which a deficiency may arise in the population. Lastly, the Norwegian Food Control Authority noted that the addition of nutrients to breakfast cereals was not obligatory in any Nordic country and that, consequently, harmonised production could be attained by marketing the non-fortified variety of the cereal in all countries.

9. Kellogg's appealed against the refusal. By letter of 6 February 1998, the Ministry of Health and Social Affairs dismissed the appeal. The Ministry stated that the starting point of the considerations has to be a global evaluation based on a total consumption of fortified products in a situation of free fortification of foodstuffs. It was pointed out that the number of fortified products on the market would create a risk for public health. Therefore, it was not decisive that the fortification in question did not represent any risk to public health. Furthermore, the principle of administrative law on non-discrimination would lead to a situation that all applications for fortifications have to be granted if fortification was allowed for one single product. The result of such a free fortification practice is that an unknown number of fortified products are on the market and the recommended intake in the population could be exceeded. Another problem with free fortification is the imbalance in the intake of nutrients when only some nutrients are added.

10. Kellogg's then filed a complaint with the EFTA Surveillance Authority. Following contacts with the Norwegian authorities, the EFTA Surveillance Authority sent a letter of formal notice to the Government of Norway on 29 January 1999. The EFTA Surveillance Authority pointed out that, in order to get the ban on imports of fortified corn flakes justified under Article 13 EEA, the Government of Norway must demonstrate that the product constitutes a health risk. Since the Government of Norway had not submitted any evidence on this point, Norway had failed to fulfil its obligations under Article 11 EEA.

11. In answering this letter of formal notice, the Government of Norway argued that it would be sufficient to produce documentation that, according to the present state of scientific research, the fortification in question might be a health hazard when eaten in uncontrollable and unforeseen amounts. With regard to the fortification with iron, the Government of Norway referred to the risks associated with excessive iron intake, especially for adult men and postmenopausal women. Special precautions had to be taken for persons with hereditary iron overload (haemochromatosis). For the vitamins, there was no need in Norway, and large doses of niacin could cause adverse effects. Furthermore, the precautionary principle should be applied to the fortification with these vitamins. Less restrictive measures, such as labelling, were not possible because the consumer would have to have knowledge of the nutritional content of all dietary sources in order to calculate the risk of a too high and unbalanced intake of nutrients.

12. On 8 October 1999, the EFTA Surveillance Authority sent a reasoned opinion to the Government of Norway, maintaining its position as expressed in the letter of formal notice, and asking Norway to take the necessary measures to comply with the reasoned opinion within two months following notification thereof.

13. In its answer, the Government of Norway maintained its previous position and stated that it was not possible to prove that the fortified product alone gave rise to health hazards. However, there was sufficient evidence to support the view that some vitamins and minerals in larger doses, although not acutely toxic, could cause a health hazard, by themselves and through their interactive effects. Because the mineral iron carries a higher risk than the vitamins used, the risk evaluation was limited to that substance. According to the conclusions of the evaluation, the main hazard identified with iron fortification was increasing iron stores due to small needs and a limited ability to excrete iron. The main risk groups are 20 000 homozygous and between 500 000 and 600 000 heterozygous individuals with primary haemochromatosis, healthy adult men and postmenopausal women. A precautionary attitude towards fortification is reasonable because of the unknown causal relation between the iron level of the body and certain diseases.

Procedure before the Court

14. Since measures had not been taken to comply with the reasoned opinion, the EFTA Surveillance Authority filed the application in question here, which was registered at the Court Registry on 10 April 2000.

15. By order of 7 September 2000, the Government of Denmark was given leave to intervene in support of the defendant.

III. Forms of order sought by the parties

16. The EFTA Surveillance Authority claims that the Court should:

(i) declare that the Kingdom of Norway has failed to fulfil its obligations under Article 11 of the EEA Agreement, by applying its legislation so as to prohibit the import and marketing in Norway of corn flakes, fortified per 100 g with 1 mg thiamine, 1 mg riboflavin, 10 mg niacin and 7 mg iron, which are lawfully manufactured and marketed, in other EEA States;

(ii) order the Kingdom of Norway to pay the costs.

17. The Kingdom of Norway contends that the Court should:

(i) dismiss the application as unfounded;

(ii) order the EFTA Surveillance Authority to bear the costs.

18. The Government of Denmark, as intervener, contends that the Court should:

(i) dismiss the application.

IV. Written procedure

19. Written arguments have been received from the parties:

– the EFTA Surveillance Authority represented by Peter Dyrberg, Director, Legal and Executive Affairs, acting as Agent, assisted by Bjarnveig Eiríksdóttir, Senior Officer, Legal and Executive Affairs Department;
– the Government of Norway, represented by Fanny Platou Amble, Advocate, Office of the Attorney General (Civil Affairs), acting as Agent, and Beate Berglund Ekeberg, Assistant Director General, Ministry of Foreign Affairs, acting as Co-agent.

20. Pursuant to Article 89 of the Rules of Procedure of the EFTA Court, a statement in intervention has been received from:

– the Government of Denmark, represented by Jørgen Molde, Head of Department, Ministry of Foreign Affairs, acting as Agent, and Nina Holst Christensen, Head of Department, Ministry of Justice, assisted by Asger Kroll, Head of Section, Ministry of Foreign Affairs.

21. Pursuant to Article 20 of the Statute of the EFTA Court, written observations have been received from:

– the Government of France, represented by Kareen Rispal-Bellanger and Régine Loosli-Surrans, Ministry of Foreign Affairs, acting as Agents;
– the Government of the Netherlands, represented by Ivo van der Steen, Legal Affairs Department, European Law Division, acting as Agent;
– the Commission of the European Communities, represented by Michael Shotter, Member of its Legal Service, acting as Agent.

V. Summary of the pleas in law and arguments

The EFTA Surveillance Authority

22. The EFTA Surveillance Authority seeks to demonstrate that the ban on imports of fortified products cannot be justified under Article 13 EEA, because the Government of Norway has not substantiated its claim that the fortification in question would constitute a danger to public health.

23. According to the EFTA Surveillance Authority, the Government of Norway seems to rely upon an incorrect interpretation of the judgment of the Court of Justice of the European Communities in the *Sandoz*[1] case, *viz.*, that the judgment would appear to legitimise any ban on foodstuffs fortified with vitamins, as long as there is no nutritional need for those substances in the importing State, regardless of whether the fortification may constitute a risk to public health.

24. To the EFTA Surveillance Authority, it seems that the Government of Denmark, in its intervention, seeks to turn the obligation (following from the *Sandoz* judgment) to grant the authorisation when there is a real need into a right in the sense that the authorisation may be refused on the grounds of lack of need, regardless of whether there really is a danger to public health, and no matter how remote or hypothetical such a danger may be.

25. However, a ban on a product in order to protect the interests laid down in Article 13 EEA must be based on international scientific research and the

[1] Case 174/82 *Sandoz BV* [1983] ECR 2445 (hereinafter '*Sandoz*').

prevailing eating habits in the importing State. A general reference to a potential health risk cannot justify a ban on a product.[2]

26. The EFTA Surveillance Authority submits that the concept of need must be assessed in the light of the raw materials used, bearing in mind the assessment made by the authorities of the Member States where the product is lawfully manufactured and marketed, implying that one could not require the foreign trader to change to another production method or another, less risky addition.[3]

27. The Government of Denmark's interpretation of need leads to a situation in which the dietary habits are crystallised because the government will always tend to ensure that the needs of the population are met. Thus, if the national authorities are successful, there will be no room for a new market entrant. These consequences have been rejected by the Court of Justice of the European Communities.[4]

28. With respect to the *Toolex Alpha* judgment,[5] referred to by the Government of Denmark, concerning the wide discretion of Member States when there is scientific uncertainty surrounding the establishment of a threshold above which the product in question constitutes a serious risk to human health, the EFTA Surveillance Authority points out that the substance trichloroethylene has been classified as dangerous at the Community level, and that there is hard evidence of its carcinogenic effects on humans.

29. With respect to the administrative law principle of non-discrimination, it follows from the case-law of the Court of Justice of the European Communities that the EEA States cannot justify breaches of their obligations under the EEA Agreement by referring to matters of their internal legal order.[6]

30. The EFTA Surveillance Authority states that it is not arguing in favour of free fortification. It refers to the situation in other EEA States, where the allowance of a number of vitamins in certain foodstuffs or categories of foodstuffs has not led to markets being flooded with fortified foods.

31. With respect to vitamins, the EFTA Surveillance Authority notes that the precautionary principle does not exempt authorities from having to base their policy on a risk assessment. A proper risk assessment would have to be made with regard to the nutrients at issue in the present case, based on the actual intake

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2 Case 178/84 *Commission* v *Germany* [1987] ECR 1227.

3 Joined Cases C-13/91 and C-113/91 *Debus* [1992] ECR I-3617; and Case 178/84 *Commission* v *Germany* [1987] ECR 1227.

4 *Ibid.*

5 Case C-473/98 *Kemikalieninspektionen* v *Toolex Alpha AB*, judgment of 11 July 2000, not yet reported.

6 Case 170/78 *Commission* v *United Kingdom* [1980] ECR 417; Case 280/83 *Commission* v *Italy* [1983] ECR 2361.

among the population. Furthermore, any measure based on the precautionary principle must be non-discriminatory, proportionate, and not aim at zero risk.[7]

32. Thiamine is commonly known as vitamin B1 and riboflavin as vitamin B2. There are two types of niacin: nicotinic acid[8] and nicotinamide. The latter is used in the fortification in question. The properties of these three vitamins and of iron are described in greater detail in the Reports of the Scientific Committee for Food – Nutrient and energy intakes for the European Community, published by the Commission of the European Communities in 1993.[9]

33. The nutritive value of a serving (30 g) of the fortified product is:

Energy	465 KJ (111 calories)
Proteins	2.1 g
Carbohydrates	24.6 g
Fat	0.30 g
Dietary fibres	0.75 g
Mineral sodium	0.36 g
Thiamine	0.3 mg
Riboflavin	0.3 mg
Niacin	3 mg
Iron	2.1 mg

34. The recommended daily intake (RDI)[10] of the vitamins in question is as follows:[11]

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7 See Communication from the Commission on the precautionary principle, of 2 February 2000, COM(2000)1.

8 According to the American report referred to by the Government of Denmark, the particular reason for reviewing the upper level of niacin is flushing, caused by nicotonic acid. Nicotinamide does not appear to be associated with these effects. The Scientific Committee for Food was aware of these facts when setting the upper level for niacin.

9 The report is attached as Annex 3 to the application of the EFTA Surveillance Authority.

10 This is a measure which indicates the daily intake needed for the proper maintenance of physical functions.

11 The values set out are the average ones indicated in the report attached as Annex 3 to the application of the EFTA Surveillance Authority. The lower values are the ones for men and the upper ones for women. In Annex 3, more detailed tables are found, broken down according to age group and gender.

Thiamine	0.9 – 1.1 mg (0.7 mg)[12]
Riboflavin	1.3 – 1.6 mg (1.0 mg)
Niacin	14 – 18 mg (11 mg)
Iron	9 – 20 mg (4 mg)

35. The upper daily intake level (UL)[13] is as follows:[14]

Thiamine	500 mg
Riboflavin	No maximum level set
Niacin	500 mg
Iron	30 – 100 mg

36. The EFTA Surveillance Authority also points out that, according to the above-mentioned Reports of the Scientific Committee for Food (SCF), there is 'no evidence of toxicity of thiamine taken by mouth, at intakes of up to 500 mg/day (for 1 month)'. As regards riboflavin, the Reports state that 'there is little or no accumulation or storage of the vitamin in the body, and there is no evidence of any toxicity of riboflavin taken by mouth'. As regards niacin, the Reports indicate that more than 500 mg/day of niacin may have harmful effects. A serving of the product in question has 3 mg. Therefore, it was not shown that the addition of these vitamins may put the Norwegian population's health at risk.

37. The EFTA Surveillance Authority observes that the Government of Denmark, which states that iron fortification is now being reviewed in Denmark in the light of new scientific knowledge, is not reviewing fortification with nicotinamide.

38. With respect to the mineral iron, the EFTA Surveillance Authority submits that there is a deficiency in the Norwegian population.[15] This is why iron fortification of domestically-produced whey cheese[16] and other whey products

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12 The amounts in brackets concern children (4 to 6 years of age), as presented in the defence of the Government of Norway.

13 This is a measure which indicates the maximum safe intake or the intake without adverse effects, if the nutrient is taken over a certain period of time

14 The definition and the amounts are questioned by the Government of the Netherlands because the SCF does not make any observations on the safety levels of intake of micro-nutrients.

15 Reference is made to the risk evaluation (Enclosure 3 to Annex 5 to the application) and to an article written by Lars Johansson, *Dietary habits among Norwegian men and woman*, Scandinavian Journal of Nutrition, 1997 (Enclosure 9 to Annex 5 to the application).

16 Whey cheese is fortified with 10 mg of iron per 100 g of cheese. According to the EFTA Surveillance Authority's information, the annual per capita consumption of whey cheese in

has been allowed for many years under the Norwegian fortification policy, as part of a 'targeted' addition of nutrients to foodstuffs, so as to reach those segments of the population who have low iron status or who wish to increase their iron intake.[17] Contrary to the view of the Government of Norway, the EFTA Surveillance Authority states that it is difficult to discern the 'targeted' aspect of adding iron to whey cheese. If whey cheese is part of the average household diet in Norway, it will also find its way to consumers who should not increase their iron intake. According to the risk evaluation conducted by the Norwegian authorities, hereditary iron overload cannot be prevented through dietary measures and is a task for the health care system.

39. The EFTA Surveillance Authority points out that a consumer who does not eat whey cheese should have the possibility of meeting his nutritional needs through, for example, fortified corn flakes.

40. The EFTA Surveillance Authority agrees with the finding of the Government of Norway to the effect that there are only small groups of the population that suffer from iron deficiency anaemia.[18]

41. With respect to the danger stemming from iron fortification ingested by people with iron overload, hereditary or otherwise, the EFTA Surveillance Authority points out that it did give sufficient attention to this problem. The report of the 'Nordic Nutritional Recommendations 1996' mentions haemochromatosis,[19] and a possible link between iron intake and cancer and cardiovascular diseases. However, newer studies have not been able to confirm the existence of such a relation.

42. The EFTA Surveillance Authority states that Norway allows for fortification of products with other vitamins for which the safety margin is lower than the one for iron. Fortification with vitamins A and D, for example, is allowed. Vitamin D fortification is allowed on the grounds that there is a deficiency in the elder part of the population and among immigrants and, consequently, margarine, edible oil, other edible fats, butter, and milk are all fortified with vitamin D. The Government of Norway has defended the vitamin D fortification by referring to the fact that an adult would have to drink more than 10 litres of milk per day to reach the upper limit of safe intake. The EFTA Surveillance Authority cannot see any justification for this different treatment of

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Norway is between 2 and 3 kg. The annual per capita consumption of corn flakes is approximately 300 g.

17 Since whey cheese does not contain iron prior to processing, one cannot speak of 'restoration'.

18 Regarding the differences between iron deficiency and iron deficiency anaemia, reference is made to an Article written by Prof. Leif Hallberg (Attached as Annex 8 to the Reply).

19 Regarding the different figure for persons with haemochromatosis, reference is made to Enclosure 8 to the reply to the letter of formal notice indicating that 0.3 – 0.5% of the Norwegian population (12 000 – 16 000 individuals) have homozygote haemochromatosis and approximately 10 % (400 000) have heterozygote haemochromatosis, and to Enclosure 3 to the answer to the reasoned opinion (20 000 – 500 000 – 600 000 individuals).

domestic and imported products. It follows from the case-law that national authorities may not seek to 'crystallise' given consumer habits.[20]

43. The Government of Norway has produced an undated risk evaluation of iron,[21] seemingly prepared solely for the purposes of the present case. The evaluation is based on the hypothesis that the granting of an authorisation for fortification to Kellogg's would entail the fortification of flour. The EFTA Surveillance Authority notes that the doubling of iron intake as a consequence of such a fortification would come mainly from the fortification of bread, which is not at issue. Furthermore, there are no reports of excessive intake from countries where the fortification of flour is permitted.

44. Furthermore, the evaluation is highly hypothetical, because of the assumption that, once corn flakes are fortified, flour will be fortified as well. Moreover, the evaluation does not reflect individual eating patterns.

45. In the view of the EFTA Surveillance Authority, a labelling requirement would be sufficient to meet concerns about health. Labelling requirements are required under the present Norwegian rules governing those fortifications currently allowed under Norwegian law. The EFTA Surveillance Authority concludes by noting the paradox between the view of the Government of Norway on the dangers of iron and the fact that iron supplements are on free sale in Norway.

The Government of Norway and the Government of Denmark

46. The Government of Norway, supported by the Government of Denmark as intervener, has put forward the following pleas in law and arguments.

47. Although the prohibition on the import and marketing of fortified corn flakes in Norway, pursuant to section 10(2) of Norwegian Regulation No. 1252 of 8 July 1983, constitutes a measure having an effect equivalent to a quantitative restriction and is prohibited under Article 11 EEA, the measure is justified under Article 13 EEA.

48. The rejection of Kellogg's application, on the basis that there is no nutritional need in the Norwegian population for the fortification in question, is in accordance with legally adopted and consistently applied Norwegian nutrition policy. This policy is based on scientifically founded and internationally adopted nutrition recommendations, applied not only in Norway, but also in other EEA States. Excessive consumption of vitamins and minerals may have harmful

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[20] Case 170/78 *Commission* v *United Kingdom* [1980] ECR 417, at paragraph 14; Case 178/84 *Commission* v *Germany* [1987] ECR 1227, at paragraph 32.

[21] Attached as Enclosure 3 to the answer to the reasoned opinion, as part of Annex 7 to the application. The EFTA Surveillance Authority alleges that this evaluation was made between the date of the reasoned opinion and the date of the Government of Norway's answer thereto.

effects. Scientific research is still not sufficiently advanced to be able to determine with certainty the upper levels of tolerable intake and the precise effects at different intake levels of the different vitamins and minerals. Thus, as long as there is no nutritional need for the vitamins and minerals, this may constitute a health risk. The Norwegian regulations are non-discriminatory and do not constitute a ban on nutrient fortification, and their sole purpose and aim is the protection of public health.

49. The fortification in question fails to satisfy a nutritional need in the Norwegian population. Further, it, and particularly the iron fortification, may actually constitute a health risk for large population groups. Thus, even if the Court should find that a prohibition based on lack of nutritional need due to the potential health risks inherent in any consumption of vitamins and minerals beyond nutritional need is not justified under Article 13 EEA, the prohibition on the fortification in question is, in any event, justified under that Article.

50. The Government of Norway argues that an overly simplified approach has been taken by the EFTA Surveillance Authority in its application with regard to the setting of tolerable, or safe, upper intake level values. The values are taken from an opinion from the Scientific Committee for Food, dated December 1992 (published 1993), and are not fully up to date.[22] Several scientific expert groups in Scandinavia, Europe, and the United States published upper levels for chronic intakes of selected nutrients in the 1990s. However, they have emphasised that the figures should be used with great caution, as they are based on insufficient data.

51. A generic model for risk assessment for biological and chemical agents was agreed upon at the FAO/WHO Expert consultation 'Application of risk analysis to food standards issues' in 1995, and this model is now the basis for discussions on risk assessment in the Codex Alimentarius Commission and the Commission of the European Communities.

52. In order to standardise procedures and establish more sound upper levels for nutrient intake, the US Food and Nutrition Board has recently developed a risk assessment model for establishing upper intake levels for nutrients.[23]

53. The Board defines the Tolerable Upper Intake Level (UL) as: the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As the intake increases above the UL, the risk of adverse effects increases. The UL applies to regular daily use. The Board emphasises that, for many nutrients, there are not sufficient data to

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22 Even though the NRN (Nordic Recommendations of Nutrients) upper level for iron is higher than that of the SCF, it is not tenable to conclude that there is a general scientific trend towards increasing levels for iron.

23 *Dietary reference intakes: A risk assessment model for establishing upper intake levels for nutrients*, Food and Nutrition Board, National Academy Press, Washington, D.C., 1998.

develop a UL. This does not mean that there is no potential for adverse effects resulting from high intake. When data about adverse effects are extremely limited, extra caution may be warranted.

54. The term ‘adverse effect’ is defined as: any significant alteration in the structure or function of the human organism, or any impairment of a physiologically important function. In the case of nutrients, it is important to consider the possibility that the intake of one nutrient may adversely affect the health benefits conferred by another nutrient.

55. Furthermore, it is pointed out that the US model for risk assessment gives considerably lower figures for tolerable upper levels than those published earlier by Nordic and European expert groups.

56. The Scientific Committee for Food is also currently developing guidelines for setting upper intake levels for vitamins and minerals. In several cases, upper intake levels which were once considered to be safe have had to be substantially lowered in the light of new research. Similar significant changes in upper intake levels have been indicated for some of the nutrients that are at issue in the present case.

57. As regards niacin, the upper daily intake level for adults was 500 mg/d, as defined by European experts in 1993 and Nordic experts in 1996. However, according to the US Food and Nutrition Board 1998, the tolerable upper intake level for niacin as a supplement in fortified foods or a combination of the two is 35 mg/d for adults and 10 mg/d for children aged 1-3 years. The average intake of niacin from food by Norwegian men and women is 26 and 18 mg/d, respectively. Thus, four servings of fortified corn flakes would give an intake of niacin above the UL for the age group 1-3 years.

58. As regards riboflavin, the 1993 EU report states that there is no evidence of any toxicity for riboflavin taken by mouth. The EFTA Surveillance Authority therefore assumes that no maximum level has been set. In contrast, the US Food and Nutrition Board stated in 1998: ‘No adverse effects have been associated with excess intake of riboflavin from food or supplements. This does not mean that there are no potential adverse effects resulting from high intakes. Because data on the adverse effects of riboflavin intake are limited, caution may be warranted’.

59. The US Food and Nutrition Board has not yet set a UL for iron because the lack of data makes it very difficult at present to specify a safe upper range for daily iron intake. Scientists therefore advise that, for the time being, dietary iron intake should not exceed recommended daily allowance (RDA) values. Thus, it may be argued that, for iron, the safe upper intake level is no higher than the

recommended daily intake.[24] Because of the health risks associated with excess iron, the safer upper level for iron should not exceed the recommended daily intake of this mineral, which implies that the safety margin for this mineral is, in fact, zero.[25]

60. It would not be appropriate for the Government of Norway to question the scientific or evidential weight of the documentation, on the grounds that these observations, comments and assessments have been prepared for the purpose of the case.

61. It follows from the *Sandoz* judgment of the Court of Justice of the European Communities that, when there is scientific uncertainty as to the critical quantities and the precise harmful effects of vitamins, and the harmful effects are dependent upon the quantities consumed as part of the general diet, which is impossible to monitor or foresee, a prohibition on the marketing of foodstuffs fortified with vitamins is justified on grounds of human health and in accordance with the principle of proportionality, provided that the marketing is authorised where the addition of vitamins to foodstuffs meets a real technical or nutritional need.

62. Consequently, it is not necessary to prove that each and every fortified product as such constitutes a risk to human health, as this would be impossible. This view is strongly supported by the Government of Denmark.

63. Furthermore, according to the Government of Denmark, it is sufficient to satisfy the principle of proportionality to establish that there is no nutritional need for the fortification in question.[26]

64. The Government of Denmark supports the view that it must be up to the Norwegian authorities to decide whether or not there is a need in the Norwegian population for the nutrients in question. Such an evaluation should only be questioned if the work of national experts is inconsistent.

65. The Government of Denmark does not agree with the interpretation made by the Commission of the European Communities of the *Sandoz* judgment, to the effect that the Court of Justice of the European Communities preferred to draw its conclusion based on the proportionality of the authorisation procedure as a whole, because the Court was faced with difficult technical questions. On the

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24 The uncertainties surrounding UL indicate that the levels that have been suggested up to now are not suitable as tools in the risk assessment of foods included in the everyday diet of the entire population.

25 See Schümann, Klaus, *Safety aspects of iron in food* (to be published 2001), attached as Annex 3 to the rejoinder.

26 The judgment of the Court of Justice of the European Communities in *Sandoz* only concerned vitamins. Minerals do, however, have the same general characteristics as vitamins in terms of the possibility of harmful effects due to excessive consumption, and they are treated in the same manner as vitamins in the EC directives concerning foodstuffs for special nutritional purposes.

contrary, the conclusion of the Court in that case is evidently based on the very clear assumption that intake of excessive amounts of vitamins may cause health risks and, that, as intake cannot be controlled, it may exceed safe levels if additions to various foodstuffs are permitted without a prior authorisation procedure. This fact justifies that a State may maintain an authorisation procedure for the addition of vitamins in which decisions are made on a case-by-case-basis. This conclusion cannot be changed by reasoning that it would imply the legitimacy of a ban on other foodstuffs which do not really have a nutritional value. The comparison is not valid, because there is no reason to ban such products insofar as they do not contain toxic or other substances adverse to human health.

66. The Government of Norway adds that scientific uncertainty about the upper levels and the effects of excessive intake calls for an approach in accordance with the precautionary principle, as developed and applied internationally and within the Community. In cases of scientific uncertainty and in the absence of harmonisation, it is up to the national authorities to establish the level of exposure to risk they wish to allow. Excessive intake of iron over a long period of time carries a risk to human health. The needs in different groups of the population vary, and call for caution as to the allowance of fortification of foodstuffs with iron.

67. The Government of Norway goes on to state that the measures are proportionate and necessary to achieve the level of protection Norway wishes to provide against the risks in question. Other measures, such as the introduction of upper levels for the addition of these vitamins to foodstuffs and/or labelling requirements, would not effectively protect the health of the population against the risks.

68. Norwegian policy regarding the fortification of foods has formed an important part of Norway’s health policy since the 1950s. For many years, the purposeful and targeted addition of nutrients to foods to prevent deficiencies in Norwegians, based on surveys and studies of the diet and health in the population, has been regarded as an important instrument for enhancing public health and avoiding health risks.

69. As the need for vitamins and minerals is fairly well documented, and has been for many years, the government has long acknowledged the usefulness of targeted fortification in order to improve public health. However, the health authorities have been aware that scientific knowledge of tolerable upper intake levels is still limited, and poorly documented, for many vitamins and minerals. New research underlines the uncertainty inherent in the upper levels, which have previously been considered tolerable upper levels. Similarly, the scientific knowledge of the health consequences of interaction between various nutrients is so far limited, and little studied. What is known, however, is that there is extensive interaction between nutrients at levels much lower than the tolerable

upper intake level for the individual nutrient.[27] Consequently, as long as there is no nutritional need for the fortification of foodstuffs with vitamins and minerals, fortification may constitute a health risk for large population groups.

70. The case at hand is about a situation where there, admittedly, does exist a nutritional need for iron in certain population groups, albeit small. There are, however, other population groups which are at risk of iron overload, population groups that are substantial in number and for whom the inherent health risks are of a serious nature. The passage from *Sandoz* referred to earlier does not address a situation where the addition of vitamins simultaneously meets a need and represents a health risk. Thus, it cannot be construed so as to oblige national authorities to always give preference to a nutritional need over health risk, regardless of the number of people in need and at risk, respectively, and the consequences of putting need before risk in each case.

71. As a result of this, a precautionary approach has been chosen, and the government has aimed at limiting fortification and ensuring that the system is transparent, so as to minimise the risks of adverse effects from excessive intake of vitamins and minerals. In its *Sandoz* judgment,[28] the Court of Justice of the European Communities also took a precautionary approach.

72. Reference is made to the Communication from the Commission on the precautionary principle.[29] The EC Treaty prescribes the application of that principle only in relation to the environment[30] but, in practice, its scope is much wider, particularly where preliminary objective scientific assessment indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, or on human, animal or plant health, may be inconsistent with the high level of protection chosen for the Community.

73. The importance of a precautionary attitude towards the fortification of foodstuffs with vitamins and minerals was also emphasised at the Kellogg's Satellite Symposium in Lillehammer in 1999.[31]

74. Nutrients should only be added to foods for health reasons, in order to counteract deficiencies in the population or in large population groups. The food in question must, moreover, be a suitable carrier of the nutrient to the sections of the population where there is a need.

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27 For example, iron in the diet may affect the uptake and/or transport of manganese, zinc and copper, and vitamin C may alter the excretion rate of copper and other minerals. Furthermore, there is extensive interaction between nutrients and *inter alia* toxic metals, see *Goyer* 1997 and *Peraza et al* 1998, cf. the reference list in Enclosure 2 to Annex 7 to the application.

28 Paragraphs 11 and 18.

29 Communication from the Commission on the precautionary principle, of 2 February 2000, COM(2000)1.

30 Article 130 R of the EC Treaty (now Article 174 EC).

31 Published in Scandinavian Journal of Nutrition, Annex 2 to the application.

75. Historically, vitamin and mineral deficiencies were relatively common, but they are now considered to be minor problems in the Norwegian population. The competent government body, the National Council on Nutrition and Physical Activity, keeps the need to add nutrients to foods under continuous review on the basis of updated documentation. It presented a comprehensive report on fortification of foods in 1994. Based on relevant research and survey material, the Council then found that the Norwegian diet provides sufficient amounts of most nutrients.

76. In accordance with the current recommendations of the National Council on Nutrition and Physical Activity, general permission to fortify foodstuffs pursuant to section 10(2) of Norwegian Regulation No. 1252 of 8 July 1983 is, on the basis of the above-mentioned principles, presently limited to four food groups (edible fats, low-fat milk, brown cheese/whey products and salt) and four nutrients (vitamins A and D, and iron and iodine).[32]

77. Permission to add iron to brown whey cheese was first given almost 30 years ago. The Government of Norway stresses that this must be seen in its proper historical context.

78. The problems concerning iron deficiency anaemia among children and women were the subject of much discussion in the 1960s. Different measures to prevent anaemia were debated, such as adding iron into infant foods, whey cheese and flour, or having a high extraction rate of flour, in order to preserve more of the vitamin and mineral content of the grain.

79. Around the same time, Norwegian paediatricians showed that iron fortification of infant foods was effective in lowering the risk of anaemia among children. Permission to add iron to selected infant foods was, therefore, given.

80. As brown whey cheese was and still is a popular sandwich spread among children, it was decided in 1972 to permit restoration of the iron content in whey cheese of up to 10 mg of iron per 100 g of cheese. The bioavailability of the added iron is good. The addition of iron to whey cheese has been considered an effective and targeted measure for those segments of the population who may have low iron status or wish to increase their iron intake from foods.

81. General fortification of flour with iron was debated, but rejected. Instead, a high extraction rate was recommended for Norwegian flour. The other Nordic countries chose to fortify flour with iron, but that was later found to be undesirable and was abolished in Denmark in 1987, in Finland in 1994, and in Sweden in 1995.

82. Since the 1960s, the iron status of the population in Norway has improved. Today in Norway, only small groups of the population have iron deficiency

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[32] Annex 5 to the application.

anaemia.[33] The proportion of women of childbearing age with iron deficiency anaemia has decreased from 10-12% in the 1960s to 4% in the 1990s. Furthermore, a large proportion of Norwegian men have high iron stores. In addition, genotyping (method available in 1996) has revealed that as many as 15% of the population may have heterozygous haemochromatosis, and thus problems related to excessive iron intakes. Consequently, the government's evaluation of the iron status of the population and the need for fortification is quite different today from what it was 30 years ago.

83. More recently, the Norwegian health authorities have advised against the general addition of iron to foodstuffs because they fear that it might be injurious to the health of certain segments of the population. Considering the improved iron status in the Norwegian population, the increased prevalence of iron overload, the difficulty of setting an upper safe level for iron intake, and the fact that an iron intake exceeding the recommended daily intake does not offer any health benefits but, on the contrary, may entail health risks, it is not advisable to increase the addition of iron to foods intended for the Norwegian market.

84. Furthermore, the National Council on Nutrition and Physical Activity established a working group with a mandate to re-evaluate the existing permission for restoration of whey cheese products with iron, in the light of new knowledge about the adverse effects of iron overload and the new data about the high prevalence of haemochromatosis in the Norwegian population.

85. The National Council on Nutrition and Physical Activity has, by a decision of 21 December 2000,[34] recommended that the present permission to fortify whey cheese be withdrawn. The summary of the working group, which is confirmed by the Council, states the following:

> ***'Evaluation and recommendation of the working group***[35]
>
> *Permission to add iron to brown cheese and whey products was given in the early 1970s with the purpose of preventing iron deficiency in segments of the population. Recent research indicates that the basis for this decision has changed significantly.*
>
> *Since then, several studies indicate that the prevalence of iron deficiency anaemia has decreased. This is probably related to changes in the composition*

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33 The Government of Norway does not agree with Prof. Hallberg's definition of iron deficiency to which the EFTA Surveillance Authority referred, because it is commonly acknowledged that iron deficiency must imply that, in addition to a serum ferritin value of 15 µg/L, other iron status indicators are abnormal.

34 Supplementary information submitted by the Government of the Kingdom of Norway. The information presented herein is in addition to the submission already put forth in the written procedure.

35 Working group appointed by the National Council on Nutrition and Physical Activity.

of the diet over the past few decades, i.e. with higher consumption of fruit, vegetables and meat.

On the other hand, recent surveys have shown that the prevalence of high iron stores is greater than previously assumed. Only since 1996 we have been aware that as many as 0.5% of the population are homozygous and 15% heterozygous for primary haemochromatosis.

Furthermore, since the 1970s, a new method for determining the size of the iron stores in the body has been introduced, i.e. analyses of serum ferritin, which makes it possible to assess more precisely an individual's iron status.

Today the vast majority of the population has a satisfactory iron status. Therefore there is no basis for a general iron enrichment of foods.

However, depleted iron stores and iron deficiency anaemia are still not uncommon among children and women of child-bearing age. Thus, measures to improve the iron status of these groups are considered advisable. These may include the targeted use of iron supplements or by addition of iron to selected foods, or by a combination of the two. It is recommended to continue fortification of flour used for baby cereals with iron, and that this iron has a high level of bioavailability.

One cannot preclude that a high intake of iron and large iron stores may have adverse effects on health. Accordingly, it is not desirable to increase the iron intake by adding iron to foods intended for the general population.

The working group recommends that the general permission to add iron to brown cheese and whey products should be withdrawn. However, it should be permitted to add iron to brown cheese and whey products that are marketed specifically for groups which need extra iron, particularly children and young women, on condition that information on the iron additive and the target groups is stated on the product packaging.

This type of iron additive would seem expedient since we know that the bioavailability of the iron added to brown cheese is high compared with other types of iron used to enrich foods. This is true despite the fact that brown cheese has a high calcium content, and that calcium has been shown to inhibit the bioavailability of iron in the diet. Moreover, brown cheese is a food which has traditionally been an important source of iron in the Norwegian diet, and one which is perceived as a source of iron by large segments of the population.'

86. According to the information supplied by the Government of Norway, the Norwegian Food Control Authority is the appropriate governmental body to revoke existing permissions to add iron to whey cheese products. Moreover, in the light of the status of the Council and previous governmental practice, it is highly unlikely that the Norwegian Food Control Authority will refrain from taking action in accordance with the Council's recommendation.

87. The implication of this supplementary information is that any submissions regarding allegedly different treatment between domestic and imported products must be dismissed as unfounded. Furthermore, the re-evaluation and withdrawal confirms that the government continuously evaluates its fortification practice to accommodate changes in nutritional need and new scientific research.

88. In this context, the Government of Norway points out that the new scientific knowledge concerning the problem of iron overload has also prompted other authorities to review their iron fortification practice. The Government of Norway refers to the situation in Denmark, where iron fortification of *inter alia* corn flakes is allowed. However, this practice is now under re-evaluation.

89. The Government of Denmark points out that the Danish Veterinary and Food Administration has established a working group with the mandate to review the actual iron intake with respect to iron deficiency and iron overload.

90. With respect to new research published after the date of a decision challenged under Article 11 EEA, the Government of Norway refers to the *Toolex Alpha* case.[36] That judgment shows that the Court of Justice of the European Communities is not only prepared, but has an obligation, to take into consideration new research published after the time of the decision. Another approach would be highly unsatisfactory for the parties to the case at hand, because the Norwegian health authorities would take an identical decision on the scientific basis currently available. The main point is that the issue in question is not the refusal as such, but rather the validity of section 10(2) of Norwegian Regulation No. 1252 of 8 July 1983.

91. The judgment by the Court of Justice of the European Communities in *Sandoz* means that, where the addition of vitamins to foodstuffs meets a real nutritional need in a Member State, the marketing of such fortified foodstuffs must be authorised under Community law.[37] The government has considered whether there is a need in the Norwegian population for the fortification which is the subject of the application by Kellogg's, but has found that this is not the case. For thiamine, riboflavin, and niacin, dietary surveys clearly indicate that the Norwegian population, in fact, consumes in excess of the recommended daily intakes of those vitamins.[38] The assessment is more complex for iron. In the opinion of the Government of Norway, however, it cannot be concluded that there is a need for general fortification of foods with iron in the Norwegian population as such.

92. The Codex Alimentarius General Principles state that fortification should be the responsibility of national authorities. Currently, the regulation of food

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36 Case C-473/98 *Kemikalieninspektionen* v *Toolex Alpha AB*, judgment of 11 July 2000, not yet reported.

37 Paragraph 20 of the judgment.

38 The 1997 Norwegian dietary survey, Enclosure 9 to Annex 5 to the application, page 67, table 6.

fortification, as well as basic policy attitudes towards fortification, varies greatly from one EEA State to the next.[39] Steps have been taken within the Community to initiate harmonisation of national fortification policies. Reference is made to the Commission White Paper on Food Safety from January 2000. The White Paper addresses *inter alia* the fortification of food with vitamins and minerals. As part of this effort, scientific committees in the United States and the European Union have developed standardised risk assessment models for establishing upper intake levels for nutrients, and are in the process of reviewing various aspects of health risks related to high nutrient intakes, such as the hitherto-established tolerable upper intake levels for vitamins and minerals.

93. There are several aspects to consider and several possible models for harmonisation in this area.[40] Reference is made to a Preliminary Draft Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the addition of nutrients to foods.

94. Present knowledge of optimal doses of vitamins and minerals is minimal, but there is even less knowledge about the interaction and optimal ratios between them and their interaction with other environmental factors. A precautionary approach is highly relevant in an area in which there is so much uncertainty, where no health benefits from a proposed fortification can be demonstrated and where there is considerable scientific evidence to support the hypothesis that random fortification that is not based on the health authorities' advice, may represent a health hazard to the population. It is, therefore, the view of the Government of Norway that the fortification policy is justified under Article 13 EEA. Furthermore, the Government of Norway is of the view that the legislation regarding fortification with nutrients, as applied in this case, fully meets the principles as established by the Court of Justice of the European Communities: (1) that the sole purpose of the legislation is to protect public health; (2) that the legislation in question does not impose a total ban on import and marketing of fortified nutrients; (3) that prohibition, when fortification does not meet a nutritional need and thus represents a potential danger to public health, is proportionate.

95. In conclusion, the rejection of Kellogg's application on the grounds that there is no nutritional need in the Norwegian population for the fortifications in question is in accordance with legally adopted and consistently applied Norwegian nutrition policy.

96. The Government of Norway is of the view that the rejection of the fortification in question, being in full compliance with long-standing Norwegian

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39 Cloutier and Baffigo, *Addition of vitamins and minerals to foods: Review of regulations in EU Member States*, Annex 2 to the application, pages 119S-121S.

40 Paul Gray, *Perspectives on European (EU) legislation on fortified food*, Annex 2 to the application, pages 97S-100S.

and international nutrition policy based on health need and health risk considerations, in light of the precautionary principle, is justified under Article 13 EEA.

97. The Government of Denmark states that, in a situation where scientific uncertainty exists, national rules prohibiting the marketing of foodstuffs with added nutrients are justified, provided that authorisation to market is granted when they are compatible with the need to protect health. Reference is made to recent case-law of the Court of Justice of the European Communities, which confirms that Member States have wide discretion when there is scientific uncertainty regarding the establishment of the threshold above which the product in question constitutes a serious risk to human health.[41]

98. However, the proposed fortification, particularly with iron, if allowed, would constitute a health hazard to the Norwegian population, and prohibition is therefore, in any event, justified under Article 13 EEA.

99. Norway has accepted that even excess intake of fortified corn flakes in and of itself does not constitute a health risk to the population in general. However, the Government of Norway is of the opinion that this is not the relevant test under the judgment by the Court of Justice of the European Communities in *Sandoz*. The Court found that a risk could not be excluded in so far as the consumer absorbs additional quantities of vitamins from other foods and these are impossible to monitor or foresee.[42] Thus, it is not necessary to demonstrate that the quantities of B vitamins and iron Kellogg's has chosen as the appropriate quantities to be added to corn flakes are, in themselves, so large as to represent a risk to public health. It is sufficient to establish that excessive consumption of those vitamins and iron may have harmful effects, that scientific research is unable to determine with certainty the critical quantities and the precise effects, and that a risk to public health cannot, therefore, be excluded in so far as the consumer absorbs further quantities of those vitamins and iron in other foods, which is impossible to monitor or foresee.

100. With respect to the need for iron, the EFTA Surveillance Authority states that it is recognised that there is an iron deficiency in the Norwegian population. The Government of Norway does not agree with this assertion.

101. The mean iron intake among Norwegian men aged 16-30 years exceeds the recommended daily intake by as much as 60%,[43] whereas the mean iron intake among women is lower than the recommended daily intake, particularly among women of childbearing age. However, despite low intake, several studies

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41 Case C-473/98 *Kemikalieninspektionen* v *Toolex Alpha AB*, judgment of 11 July 2000, not yet reported, paragraph 45.

42 Paragraph 12 of the judgment in *Sandoz*.

43 Enclosure 9 to Annex 5 to the application, Lars Johansson et al., *Dietary habits among Norwegian men and women 1997*, page 67, table 6.

over the last 15 years have shown that iron deficiency anaemia is a minor problem among women of childbearing age in Norway today. It should be noted that, since the 1960s, the proportion of women of childbearing age suffering from iron deficiency anaemia has, in fact, decreased substantially: from 10-12%[44] to 4% in the 1990s. The low incidence of iron deficiency anaemia today is substantiated in the expert witness statement from Professor Berit Borch-Iohnsen, University of Oslo, with references.[45] Borch-Iohnsen also offers explanations for these findings, including changes in dietary habits, increased bioavailability of iron, and reduced menstrual losses due to new contraceptive devices.

102. Children have traditionally been considered a risk group for iron deficiency anaemia, because of the increased need for iron for growth. Children are not covered by the 1993-94 national dietary survey, but the issue of iron deficiency among children (beyond infancy) is discussed in Borch-Iohnsen's expert witness statement. There are no studies available indicating that iron deficiency is a problem among children, and the incidence among adolescents aged 13-15 years is only 3%.[46]

103. The judgments of the Court of Justice of the European Communities in cases concerning German beer[47] and British wine duties[48] are not relevant to the case at hand, because the Norwegian health authorities, in accepting whey cheese but not corn flakes as a suitable vehicle for iron fortification, are not seeking to promote whey cheese to the detriment of corn flakes. Furthermore, whey cheese and corn flakes are not substitute products.

104. The Government of Norway strongly objects to the allegation that the rejection of Kellogg's application had a discriminatory purpose. Reference is made to the EFTA Court's judgment in the *Wilhelmsen* case.[49]

105. In the application, the EFTA Surveillance Authority based its argument with respect to iron fortification on the presumption that there exists an iron deficiency in the Norwegian population. The Government of Norway contests the validity of this presumption. In any case, the EFTA Surveillance Authority fails to address the issue of iron overload in the Norwegian population.

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44 Natvig H, Vellar OD, Andersen J, *Hemoglobin, hematocrit and MCHC values among boys and girls aged 6-20 years in elementary and grammar schools*, Acta Med Scand 1967:182, pages 182-191; and Natvig H, Vellar OD., *Hemoglobin, hematocrit and MCHC values among adult men and women*, Acta Med Scand 1967:182, pages 193-205.

45 Enclosure 3 to Annex 7 to the application, page 8.

46 *Ibid.* page 8-9.

47 Case 178/84 *Commission* v *Germany* [1987] ECR 1227.

48 Case 170/78 *Commission* v *United Kingdom* [1980] ECR 417.

49 Case E-6/96 *Tore Wilhelmsen AS* v *Oslo Kommune* [1997] EFTA Court Report 53.

106. The main scientific support for the EFTA Surveillance Authority's allegations in the application relating to iron is the 1993 report from the Scientific Committee for Food.[50] The section of that document dealing with iron discusses only very briefly the health hazards related to iron overload, other than from acute iron intoxication. Haemochromatosis is mentioned, but not addressed. This can most likely be attributed to the date of the report, which precedes the significant publications on this issue. The finding of the hereditary haemochromatosis gene was published in 1996.

107. Reference is made to the studies of Professor Borch-Iohnsen of the University of Oslo, who has described the negative health effects that may result from excess iron in the human body, and has identified the population groups at risk of iron overload.[51] Furthermore, a Dutch report on iron deficiency and overload in relation to nutrition has recently been presented.[52] The report concludes that 'fortification of iron in functional foods should be avoided and discouraged until the risks of iron overload has been more clearly determined', because of the low prevalence of iron deficiency and the association between iron intake and several chronic diseases.

108. In the discussion of the risks of excess iron in the context of fortification, the margin of safety between RDI and tolerable upper intake level (UL) is of major importance. It is an established fact that this margin is relatively narrow for iron, compared to the safety margin for most other vitamins and minerals.[53] The EFTA Surveillance Authority does not contest this fact, but merely points out that Norway 'allows for fortification of products with other vitamins for which the safety margin is lower than the one for iron'.[54] In the opinion of the Government of Norway, a comparison cannot be made between fortification with iron and vitamin D, although the safety margin of both is at least narrow, because there are no indications of too high vitamin D status in the Norwegian population.[55] The health risk related to fortification with vitamin D in Norway is, therefore, theoretical.

109. The reliability of the assessment of the safety margin for iron is contingent upon the reliability of the RDI and UL values presently accepted by the scientific community. The Government of Norway questions the reliability of existing

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50 Annex 3 to the application.

51 Enclosure 8 to Annex 5, and as further elaborated in Enclosure 3 to Annex 7 to the application.

52 Jansen and Spanjersberg, RIVM report 650250 004, *Iron deficiency and overload in relation to nutrition*, August 2000.

53 *Van den Berg*, Responding to consumer needs: Risk-benefit analysis of fortification (1999), Annex 3 to the application, page 114S.

54 Application, at paragraph 39 *in fine*.

55 Calculations show that if vitamin D had not been added to margarine, butter and milk, the average intake of vitamin D from foods would have been only approximately half of the recommended intake among adult Norwegians, and only one-third of the recommended intake among those over 60 years of age.

upper safe level values for iron, on the basis of recent research. It should also be borne in mind that the upper intake levels employed must be reduced if children constitute a significant proportion of the relevant consumers, as is the case for corn flakes.

110. Iron metabolism in the human body is complex and not yet fully understood.[56] However, one major problem is that iron is a 'one-way nutrient'.[57] The body has a large capacity to re-utilise iron, and very little iron is lost from the body. Once the body has accumulated a surplus of iron, it is very difficult to get rid of it, except by systematic bleeding. The body tries to maintain its iron balance by controlling the absorption of dietary iron, but this control mechanism is not perfect.

111. The 1993 report from the Scientific Committee for Food makes contradictory statements regarding this important issue. It first states: 'The body tries to maintain iron balance not by regulating the losses of iron but by controlling the absorption of dietary iron. This control is not perfect but still of great importance for the prevention of iron deficiency and excess.'[58] However, further on, it is claimed that '[t]he very effective regulation of iron absorption prevents overload of the tissues by iron from a normal diet, except in individuals with genetic defects as in idiopathic haemochromatosis'.[59]

112. It should be noted that the terms 'dietary iron' and 'normal diet' are used. If a healthy person, in addition to the usual diet, takes supplements or eats foods fortified with iron, the iron intake may be so high that the body cannot prevent excessive iron absorption and accumulation of iron in the body. For people suffering from haemochromatosis, any extra iron is a problem.

113. Since the method of genotyping became available in 1996, there has been increasing awareness of the large size of the iron-sensitive subpopulation suffering from homo- or heterozygote primary haemochromatosis. In subjects with haemochromatosis, iron absorption is two to three times more efficient than in normal subjects, and they must avoid extra iron intake.

114. The theory according to which excess iron stores may have serious adverse health effects has gained support during recent years.

115. The iron status of the population in Norway is improving. Similar trends are found in other countries, such as Denmark and the United States. Data from the Third National Health and Nutrition Examination Survey demonstrate that the prevalence of iron deficiency anaemia in the United States is now very low.

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56 Scientific Committee for Food, 1993 report, Annex 3 to the application, pages 177, 182-183.

57 Borch-Iohnsen, in Enclosure 3 to Annex 7 to the application, page 2.

58 Annex 3 to the application, page 177.

59 *Ibid*, page 179.

116. In the opinion of the Government of Norway, attention should be drawn to an article by Lynch and Baynes.[60] In their conclusion it is stated: 'Nonetheless, because there is no known benefit of high iron storage status, it seems prudent to avoid further increases in and possibly to reduce the dietary iron intake of men and postmenopausal women […] The complexity of the Western diet and an incomplete understanding of all of the factors affecting serum ferritin concentrations make it very difficult to specify a safe upper range for daily iron intake at the present time'.

117. The Government of Norway emphasises that it must be accepted that it is difficult to set a definite upper safe level for iron intake, because of insufficient data. Based on this, there is reason to conclude that the safety margin for iron is, at best, narrow, and possibly non-existent.

118. As mentioned, the human body has a very limited ability to get rid of excess iron. Animal experiments and *in vitro* studies have shown that iron catalyses the formation of toxic oxygen radicals which may cause cell damage. This will happen in the event of iron overload when 'free iron' is released. Many diseases also produce toxic oxygen radicals with iron as a catalyst. Such pathological conditions include artherosclerosis, rheumatoid arthritis, and colon cancer. There is growing epidemiological indication of the association between iron and lipid peroxidation in cardiovascular disease, and recent studies have shown that excessive iron, i.e. unabsorbed iron, produces free radicals in the colon and may increase the risk of colorectal cancer.[61]

119. Excess iron may contribute to the development of serious diseases that affect a large number of people in western populations. The EFTA Surveillance Authority notes that there are no reports of excessive intake of iron from countries where fortification of flour – which affects the population to a greater extent than fortification of breakfast cereals – is permitted.[62] However, given that the end point of iron overload might be illnesses such as cardiovascular disease, colon cancer and arthritis, which take a long time to develop and may have multiple causes, the Government of Norway cannot accept that any present absence of reports should be considered evidence of lack of connection to disease.

120. Chronic iron overload is divided into primary and secondary iron overload or haemochromatosis. Primary haemochromatosis is a hereditary condition characterised by over-absorption of iron, which leads to iron overload. In addition to the potential diseases, primary haemochromatosis leads to several other ailments and diseases and may lead to premature death. Secondary

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60 Lynch SR, Baynes RD, *Deliberations and evaluations of the approaches, endpoints and paradigms for iron dietary recommendations*. J Nutr 1996 Sep;126 (9 Suppl.): 2404-2409.

61 For further details and references, see Professor Borch-Iohnsen's expert witness statement, Enclosure 3 to Annex 7 to the application, particularly pages 4-5.

62 Application at paragraph 40, *in fine*.

haemochromatosis has many causes, e.g. long-term abuse of iron supplements and increased iron stores with age.

121. An extensive Norwegian health study in 1997 revealed that primary haemochromatosis occurs much more frequently than previously believed. The prevalence in Norway, based on this study, is estimated to be 0.5%, or 20 000, homozygous, and close to 15%, or 500 000 – 600 000, heterozygous individuals in the Norwegian population of 4.2 million. Prevalence varies from one country to another, and Norway is one of those where it is highest. In addition to the fact that it affects a substantial proportion of the Norwegian population, primary haemochromatosis is a problem because the condition is considerably under-diagnosed, both in Norway and elsewhere. In the 1997 health study, only 3.3% of the homozygotes were aware of their diagnosis.

122. In homozygous individuals, iron absorption is two to three times higher than in normal individuals. A person who absorbs 1 to 3 mg of iron from the diet in excess of their needs may accumulate 20-40 g of iron in the body over a period of 40 to 50 years, whereas the normal range is 2 g to 6 g of iron. Accumulation occurs especially in the liver and may, if undetected and untreated, cause severe injuries and premature death. In heterozygous individuals, a normal diet without extra iron will not or only to a moderate degree lead to pathological iron overload in the liver. However, recent studies have revealed biochemical and possibly clinical abnormalities and increased risk of cardiovascular disease in heterozygotes.

123. It must, therefore, be concluded that a diet rich in iron is likely to increase iron accumulation and associated diseases in individuals with undiagnosed primary haemochromatosis. This group constitutes a substantial proportion of the Norwegian population, and general preventive measures are needed to protect them, as their condition is not reliably detected by the health system. Dietary fortification with iron would increase the risk of disease.

124. It is not a legal condition for applying restrictive measures pursuant to Article 13 EEA, according either to the *Sandoz* judgment or to other case-law of the Court of Justice of the European Communities, that such measures are justified only where the majority of the population is exposed to health risks due to fortification.

125. As has been demonstrated, approximately 15% of Norwegians have a hereditary disorder involving increased iron absorption that makes them vulnerable to extra iron in their diets. The overwhelming majority of these individuals are unaware of their disorder and are, therefore, not able to protect themselves by avoiding foodstuffs rich in iron, either naturally-occurring iron or iron from fortification. This group is, therefore, particularly exposed to the serious diseases that may result from excess iron in the body.

126. On the other hand, the Government of Norway cannot reasonably deny that there are individuals in the Norwegian population who may benefit from iron fortification of corn flakes, namely, those who suffer from iron deficiency anaemia. However, only small groups of the population suffer from iron deficiency anaemia in Norway today. It cannot reasonably be claimed, on the basis of known dietary habits, that iron fortified corn flakes are a suitable vehicle for satisfying the needs of these sub-groups. For individuals with specific iron requirements, special measures must be taken to satisfy their needs, such as iron supplements for sub-groups of pregnant women and women with heavy menstrual bleeding, and iron fortification of infant formula and cereal-based baby food.[63]

127. In addition to the fact that the segment of the population at risk of iron overload is much larger than the segment of the population at risk of iron deficiency, it should also be pointed out that iron deficiency is not a condition with a lethal outcome, in contrast to progressive hereditary and secondary haemochromatosis, and some diseases that may be associated with iron catalysed oxygen radical damage.

128. If the application by Kellogg's is granted, other applications for fortification of foodstuffs with B vitamins and iron will have to be granted as well. This follows not only from Norwegian national law, but also from the EC law principle of non-discrimination, the case-law of the Court of Justice of the European Communities,[64] and the Commission Communication on free movement of foodstuffs within the Community.[65] It is, therefore, a reasonable factual and legal presupposition in fortification risk assessment that other brands of breakfast cereals will be similarly fortified, and perhaps also other breakfast products such as bread. In the assessment of the extent to which the marketing of Kellogg's fortified corn flakes creates a risk for the health of Norwegians, the frame of reference is what is otherwise consumed through the Norwegian diet. Referring to the judgment of the Court of Justice of the European Communities in *Sandoz*, the Government of Norway states that iron consumption through the intake of foodstuffs other than Kellogg's corn flakes cannot be disregarded in risk assessment.[66] The risk assessment was made in a proper and acceptable way and reflects the variation in dietary habits within the population.[67] In summary, the calculations show that if 7.5 mg and 10 mg of iron per 100 g of product were added to breakfast products, bread and brown whey cheese, respectively, the average intake of iron among Norwegian men would increase from 12 to 23 mg/d. Among the one-tenth of the men with the highest intake of breakfast

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63 Borch-Iohnsen, Enclosure 3 to Annex 7 to the application, page 9.

64 Case 176/84 *Commission* v *Greece* ECR [1987] 1213; and Case 178/84 *Commission* v *Germany* [1987] 1227.

65 OJ No. C 271, 24 October 1989, p. 3, paragraphs 36 and 37.

66 At paragraph 17 of the judgment.

67 Annex 1 to Enclosure 3 to Annex 7 to the Application.

products, the same amounts of added iron would increase the average iron in this group of men from 16 to 32 mg/d.

129. Among men with average intakes of these foods, the addition of iron thus would result in intakes that are twice as high as the recommended daily intakes (10 mg/d). Among the one-tenth of men with high intakes of breakfast products, iron enrichment at these levels would result in intakes that are over three times higher than the recommended level, or, above the upper daily intake level of 30 mg/d as mentioned by the EFTA Surveillance Authority in its application of 7 April 2000.

130. Article 13 EEA leaves considerable discretion to the Member States in the non-harmonised area of food fortification as regards striking a balance between conflicting health needs and health risks in the population. The Government of Norway has carefully considered and weighed the benefits and disadvantages of Kellogg's proposed fortification in relation to health needs and health risks for various population groups. Given the number of people affected, the severity of adverse health effects, and, not least, the current uncertainties in scientific knowledge, the Government of Norway has decided that such fortification should not be allowed. The fact that the existing practice of fortifying brown whey cheese with iron is being re-evaluated demonstrates the Government of Norway's concern about the serious health risk posed by excess iron in the Norwegian diet.

131. In conclusion, the fortification in question may constitute a health risk to large population groups, in particular with respect to fortification with iron. Thus, even if the Court should find that the prohibition based on lack of nutritional need because of the potential health risks inherent in any consumption of vitamins and minerals beyond nutritional need is not justified under Article 13 EEA, the prohibition of the fortification in question is, in any event, justified under that Article.

132. Concerning alternative measures, such as labelling requirements and/or maximum limits, the Government of Norway states that it follows from Article 13 EEA and the case-law of the European Court of Justice that the least restrictive measure necessary to protect public health should be chosen.

133. In the opinion of the Government of Norway and the Government of Denmark, labelling requirements[68] would not be sufficient, as the labelling itself could mislead the consumer to believe that the product is beneficial to health. Vitamins and minerals are both necessary and potentially dangerous, and the needs of different sexes and age groups differ. It would be almost impossible to label fortified products in a way which takes account of these differing and, in some cases, contradictory needs, without at the same time confusing the customer. As regards iron, labelling requirements are of no use to persons with

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[68] All food labelling requirements laid down in regulations presently in force in Norway are based on EC directives on labelling, including nutritional labelling.

haemochromatosis, as the majority of them have no knowledge of their condition.

134. Reference is made to a recent judgment of the Court of Justice of the European Communities,[69] in which that Court held that the numerical labelling requirement at issue '(…) is not capable of enabling them to decide whether or not they should consume the product, if they do consume it, in what quantities (...)'. Following this conclusion, labelling will not be sufficient to protect health, because the information provided thereby cannot enable consumers to decide whether or not they should eat fortified corn flakes and, if so, in what quantities.

135. In considering whether labelling requirements would be adequate, the Government of Norway refers to Annex 2 to the application of the EFTA Surveillance Authority, which contains two articles concerning studies of the awareness and attitudes to food fortification of European/Nordic consumers.[70] According to those studies, a large majority of European/Nordic consumers (77%/74%) believe that their habitual diet provides them with the vitamins and minerals they need. Despite this, between 23% and 50 % take vitamin pills or vitamin or mineral supplements, and 68 % of the European consumers agree that 'a little extra vitamins and minerals cannot do any harm'. In addition, 13 % of the European and 15%-26 % of the Nordic consumers 'don't know' whether or not they consume fortified foods. Up to one-third of the consumers are indifferent about the contents of added nutrients.

136. Accordingly, it must be concluded that labelling requirements are not sufficient to protect public health against the potential harmful effects of vitamins and minerals.

137. The possibility of introducing upper limits for fortification with vitamin B and iron is not mentioned in the application of the EFTA Surveillance Authority. It was, however, claimed in the *Sandoz* judgment, as with labelling without success, that maximum limits for fortification with vitamins could effectively meet public health concerns raised.

138. As the Court of Justice of the European Communities held in *Sandoz*, it is not possible to foresee or monitor the quantities of vitamins or minerals consumed as part of general nutrition. It would be impossible for the authorities to set upper levels which would exclude excessive intake in the different groups of the population with different needs, as mentioned above.

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69 Case C-217/99 *Commission* v *Belgium*, judgment of 16 November 2000, not yet reported.

70 *Fortification and the European consumer: Consumer awareness and attitudes to food fortification*, by Anne-Laure Gassin of Kellogg's Europe, and *Nordic legislative practices and consumer attitudes towards the addition of nutrients to foods*, by *Mette Peetz-Schou* of Nordisk Kellogg's AS.

139. With respect to the fact that iron supplements can be obtained without prescription in Norway, the Government of Norway emphasises that there are important distinctions between vitamin or mineral supplements and fortified food. Fortified food is intended for everyday diet, and adequate consumer consciousness of the need to regulate intake of regular foods due to high levels of vitamins or minerals cannot be expected. Supplements are taken in addition to ordinary foods, and reflect a specific choice made by the consumer.

140. It follows from what has been said that the position of the Government of Norway is that Norway has not failed to fulfil its obligations under Article 11 EEA by applying its legislation so as to prohibit the import and marketing in Norway of corn flakes fortified per 100 g with 1 mg of thiamine, 1 mg of riboflavin, 10 mg of niacin and 7 mg of iron, since the prohibition is justified under Article 13 EEA.

The Government of France

141. The Government of France refers to the partial and incomplete Community regulation in the field of nutrients added to foodstuffs and to a proposed directive. With respect to food products which are not designed for a particular nutritional use, there is thus far no Community legislation.

142. With respect to public health, the Government of France refers to the recitals and provisions in Council Directive 89/398/EEC,[71] which, together with the White Paper on Food Safety and further plans in this field of law, show that this objective is at stake.

143. Furthermore, the Government of France points out that there is no discrimination between cereals of the corn flakes type imported by Kellogg's and locally manufactured cereals.

144. Reference is made to the food habits and food needs which vary from one area to another, taking into account other criteria, such as the climate of a given country, and the activities and traditions of its population. In a field of law which is not harmonised, it is enough that a government justifies its data with the work of national experts, provided that the work is not totally inconsistent with findings made by experts in other Member States, or that it is not in contradiction with international standards, such as the ones issued by the Codex Alimentarius. The Court of Justice of the European Communities has confirmed this approach.[72]

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[71] Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of Member States relating to foodstuffs intended for particular nutritional uses, OJ No L 186, 30.6.1989, p. 27.

[72] Case C-400/96 *Jean Harpegnies* [1998] I-5121; and Case C-100/96 *The Queen* v *Ministry of Agriculture, Fisheries and Food*, ex parte: *British Agrochemicals Association Ltd*. [1999] ECR I-1499.

145. The Government of France is of the opinion that the mere fact that Norway refers to data supplied by national experts in the area of fortification of breakfast cereals does not, by itself, make its national measures disproportionate, taking particularly into account the fact that the manufacturing and marketing rules of these products have not to date been harmonised.

The Government of the Netherlands

146. The Government of the Netherlands refers to a White Paper on Food Safety, in which the Commission of the European Communities indicates that it will present a proposal for a directive concerning fortified foodstuffs. Furthermore, reference is made to the *Sandoz* case, and to a judgment in which the Court of Justice of the European Communities ruled that, in so far as there are uncertainties at the present state of scientific research, it is for the Member States, in the absence of harmonisation, to decide what degree of protection of the health and life of humans they intend to ensure.[73]

147. In its interpretation of the *Sandoz* judgment, the Government of the Netherlands points to the following criteria which should be applied to the case at hand: (1) with regard to the present state of science, vitamins must be considered as potentially harmful substances; (2) the question of whether the addition as such is safe has to be answered on a case-by-case assessment, taking into account the total foodstuff-package and the eating habits in the State concerned; (3) the third point concerns the question of whether the addition meets a real nutritional need. The EFTA Surveillance Authority did not answer this question.

148. An assessment of the real nutritional need has to take account exclusively of the situation in the State of consumption.

149. Furthermore, the Government of the Netherlands observes that nothing in the application leads to the conclusion that fortified products are systematically banned in Norway.

150. The facts of the case concerning German beer have to be distinguished from the ones in the case at hand, because the micro-nutrients are not allowed in general in other categories of products in Norway and the protection of human health is not put forward as a general justification. The Government of Norway is only concerned about the protection against overly high intakes of the micro-nutrients in question.

151. Regarding alternative production methods, the Government of the Netherlands refers to the case-law of the Court of Justice of the European Communities. Following this, the line of reasoning regarding alternative production methods is linked to the concept of additives with a technological

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73 Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten BV* [1981] ECR 3277.

need (preservation), not to additions as micro-nutrients. It follows from the application that the Government of Norway refers only to requirements as to the composition of the product, and not to production methods.

152. Reference is made to the Communication from the Commission on the precautionary principle, in which guidelines are given. Following this, a careful risk assessment is an important element in applying the principle, but the Commission recognises that the decision to act or not to act is of 'an eminently political nature'.

153. With respect to the findings of the Scientific Committee for Food, it must be observed that the report does not make any observations on the safety levels of intake of micro-nutrients. Therefore, the Government of the Netherlands questions the reference of the EFTA Surveillance Authority to the upper intake level as 'a measure which indicates the maximum safe intake'. The only conclusion that can be drawn from the amounts quoted in the application is that the addition of thiamine and riboflavin causes less harm to human health than niacin and iron. It is not possible to consider the amounts quoted in the application as safe levels of intake.

154. Although, in a certain case, a product category, which is domestically produced in Norway, is taken into account, the EFTA Surveillance Authority has not indicated or proven that the Government of Norway aims to exclude the import of products in these categories from the Norwegian market.

155. The Government of the Netherlands observes that a recent report from the Dutch Health Council on the early tracing of hereditary iron overload indicates that 0.5% of the Dutch population suffers from this disease, and that 10% of the Dutch population carries the gene. As was indicated by the Government of Norway, only a small number of people of this group are aware of that fact.

156. The Government of the Netherlands submits that the question of whether the addition of vitamins and minerals is safe must be answered according to the most recent state of science, followed by a risk assessment. The national authorities have the responsibility to judge the safety of fortified foodstuffs. It is in line with the case-law of the Court of Justice of the European Communities and with the Communication from the Commission on the precautionary principle, that the national authorities have a reasonable margin of appreciation in deciding on the measures necessary to protect the health and life of citizens.

157. The Government of the Netherlands concludes that the Government of Norway was entitled to prohibit the import of fortified cornflakes and that the referral to Article 13 EEA is correct. Therefore, the application of the EFTA Surveillance Authority should be dismissed.

The Commission of the European Communities

158. The Commission of the European Communities refers to the judgment of the Court of Justice of the European Communities in *Sandoz*, other decisions relied upon,[74] and Annex II to Directive 89/107/EEC.[75] With regard to legislation concerning the addition of nutrients to foods in general, reference is made to the Commission's White Paper on Food Safety of 12 January 2000, and to the announced intention to make a proposal for a directive concerning fortified foods in the near future.

159. In the *Sandoz* case, the Court of Justice of the European Communities was faced with a difficult technical issue – namely, the toxicity of various vitamins – on which it put questions to the parties, but to which it received different answers. This could be the reason why the Court referred to uncertainties inherent in the scientific assessment and the potentially harmful effect. Because of these facts, that Court decided that a prior authorisation procedure would, in principle, be justified under Article 30 EC. Therefore, it is understandable that the Court of Justice of the European Communities chose to approach the question from the perspective of the proportionality of the authorisation procedure taken as a whole.

160. From a proper reading of the *Sandoz* judgment, it follows that it would be disproportionate to prohibit the marketing of a food, where the addition of the nutrient meets a nutritional need. In such a case, it can be presumed that there is no danger to health, but a health benefit.

161. However, it does not necessarily follow that where there is no nutritional need for the addition of nutrients, there is a danger to public health. Moreover, the Commission of the European Communities considers it not being appropriate elevating the concept of nutritional need from its proper role in assessing the proportionality of a measure taken to protect the public from potentially toxic products to that of a self-standing imperative requirement. Such an approach would crystallise existing consumer habits and place in question the marketing of numerous products having no nutritional interest whatsoever. Reference is made to the opinion of Advocate General Mancini in the *Sandoz* case.

162. The Commission of the European Communities concludes this argument by stating that it would not be justified under Article 13 EEA to base a rejection of an application for authorisation of a fortified food solely on the absence of any nutritional need for the addition in question. Where the concept of nutritional need is relevant is in cases where product safety is at issue. When a nutritional need is established for the addition of the nutrients, a rejection of the product cannot be justified on the grounds of food safety as a proportionate measure.

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74 Case C-227/82 *Van Bennekom* [1983] ECR 3883, Case 247/84 *Motte* [1985] ECR 3887; Case 304/84 *Müller and Others* [1986] ECR 1511; Case 178/84 *Commission* v *Germany* [1987] ECR 1227.

75 OJ No L 40, 11.2.1989, p. 27.

163. The Commission of the European Communities agrees with the approach of the Norwegian authorities, *viz.*, to take into account the total diet of the population when evaluating the health hazard. Furthermore, it is accepted that the health authorities have a large measure of discretion in their assessment of whether the addition of nutrients to foodstuffs constitutes an acceptable risk to public health or not.[76] However, the discretion should not constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties, and the national authorities should demonstrate that it has a sound scientific basis.[77] The mere reference to potential health risks is not sufficient.[78]

164. In the case at hand, it seems to the Commission of the European Communities that Norway does not rely on the Codex General Principles for the Addition of Nutrients as constituting a specific scientific basis for the rejection of the application. Throughout the procedure, Norway has referred to scientific research in support of its position.

165. However, it does not appear that this demonstration of a scientific basis to the refusal issued by the Control Authority was available to the applicant at the time the refusal was made. Following the case-law,[79] it is for the national authorities to demonstrate to an applicant in each case that their rules are necessary to give effective protection to the interests referred to in Article 13 EEA.

166. Concerning the risk assessment made by the Norwegian authorities, the Commission of the European Communities states that it is relevant to take into account all possible food sources of the nutrients from all products presently on the market. It is not appropriate to take into account future hypothetical eventualities, which presume a commercial decision on the part of other producers to fortify their products. In this limited respect, the scientific basis of the Norwegian authorities is questioned.

167. Furthermore, the fact that iron may be added to a typically Norwegian product but not to a breakfast cereal imported from other EEA States, without any objectively apparent reason for distinguishing between the products, suggests that the refusal to authorise the Kellogg's product could be considered as arbitrary discrimination or a disguised restriction on trade.

Carl Baudenbacher
Judge-Rapporteur

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76 Case C-227/82 *Van Bennekom* [1983] ECR 3883; *Sandoz*.

77 Case 178/84 *Commission* v *Germany* [1987] ECR 1227.

78 Case C-17/93 *Van der Veldt* [1994] ECR I-3537.

79 Case 304/84 *Müller and Others* [1986] ECR 1511.