



## JUDGMENT OF THE COURT

5 April 2001

*(Failure of a Contracting Party to fulfil its obligations – Fortification of foodstuffs with iron and vitamins – Protection of public health – Precautionary principle)*

In Case E-3/00,

**EFTA Surveillance Authority**, represented by Peter Dyrberg, Director, Legal & Executive Affairs, acting as Agent; assisted by Bjarnveig Eiríksdóttir, Senior Officer, Legal and Executive Affairs Department, 74 Rue de Trèves, Brussels, Belgium,

*applicant,*

v

**The Kingdom 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, Office of the Attorney General (Civil Affairs), P.O. Box 8012 Dep., 0030 Oslo, Norway,

*defendant,*

supported by 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,

*intervener,*

APPLICATION for 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.

#### THE COURT,

composed of: Thór Vilhjálmsson, President, Carl Baudenbacher (Judge-Rapporteur) and Per Tresselt, Judges,

Registrar: Gunnar Selvik,

having regard to the written pleadings of the parties and the intervener, the written observations of the Government of France, represented by Ms Kareen Rispal-Bellanger, acting as Agent, and Ms Régine Loosli-Surrans, acting as Co-agent, the written observations of the Government of the Netherlands, represented by Mr Ivo van der Steen, acting as Agent, and the written observations of the Commission of the European Communities, represented by Mr Michael Shotter, Member of its Legal Service, acting as Agent,

having regard to the Report for the Hearing,

after hearing oral argument from the applicant, represented by Peter Dyrberg, Agent for the EFTA Surveillance Authority, the defendant, represented by Fanny Platou Amble, Agent for the Norwegian Government, the intervener, represented by Jørgen Molde, Agent for the Government of Denmark and the Commission of the European Communities, represented by Michael Shotter, Agent for the Commission of the European Communities, at the hearing on 14 February 2001,

gives the following

## **Judgment**

### **Facts and procedure**

- 1 By an application lodged at the Court Registry on 10 April 2000, the EFTA Surveillance Authority submitted a request for a declaration that, by 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.
- 2 By a letter of 4 July 1997, the Norwegian Food Control Authority (*Statens Næringsmiddeltilsyn*) refused the application of Nordisk Kellogg's A/S (hereinafter "Kellogg's"), a company incorporated under Danish law, 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 in the Norwegian population. 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.
- 3 Kellogg's lodged an administrative complaint against the refusal. By letter of 6 February 1998, the Ministry of Health and Social Affairs dismissed the complaint. The Ministry stated that the starting point of the considerations had to be a global evaluation based on a total consumption of fortified products in a

situation of free fortification of foodstuffs. It 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 administrative law principle of non-discrimination would lead to a situation in which all applications for fortifications would have to be granted if fortification was allowed for one single product. The result of such a free fortification practice would be that an unknown number of fortified products were on the market and the recommended intake in the population could be exceeded. Another problem with free fortification, in the view of the Ministry, is the imbalance in the intake of nutrients when only some nutrients are added.

- 4 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. It contended that, in order to have the ban on imports of fortified corn flakes justified under Article 13 EEA, 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.
- 5 In answering the 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 fortification with these vitamins. Less restrictive measures, such as labelling, were not possible because, for them to work, the consumer would have to have knowledge of the nutritional content of all dietary sources in order to calculate the risk of an excessive and unbalanced intake of nutrients.
- 6 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.

- 7 The Government of Norway responded to the reasoned opinion on 14 January 2000, reiterating its position that the prohibition of fortified cornflakes for import and marketing in Norway was justified under Article 13 EEA, and declaring that the prohibition would be maintained. Furthermore, the Government of Norway 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 in Norway are 20 000 homozygous and between 500 000 and 600 000 heterozygous individuals with primary haemochromatosis, adult healthy men and postmenopausal women. The Government of Norway added that a precautionary attitude towards fortification was reasonable, because of the unknown causal relation between iron levels in the body and certain diseases.
- 8 Since measures had not been taken to comply with the reasoned opinion, the EFTA Surveillance Authority filed the application which has given rise to the present case.
- 9 By order of 7 September 2000, the Government of Denmark was given leave to intervene in support of the defendant.

### **Arguments of the parties**

- 10 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 the prohibition is not justified under Article 13 EEA.
- 11 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 an EEA State is entitled to maintain rules prohibiting, without prior authorisation, the marketing of fortified or enriched foodstuffs, if the conditions of Article 13 EEA are met. Moreover, it is not

disputed that, in assessing the issues at hand, the Norwegian authorities must have regard to the nutritional habits of the Norwegian population and the aggregate of the vitamins and minerals available to it through the general consumption of foodstuffs.

- 12 However, it is disputed between the parties whether the authorisation may be refused on the grounds of lack of nutritional need in the population, regardless of whether there is a real danger to public health.
- 13 The Government of Norway argues that it is for the national health authorities to decide what vitamins and minerals should be added to what foodstuffs and in what quantities. National authorities may refuse to grant an authorisation allowing fortified food to be marketed on grounds of lack of nutritional need in the population.
- 14 The Government of Denmark is of the view that, for practical reasons, the national authorities are only required to authorise the introduction of additives in a product if there is a need in the population for the additive in question. It would be too heavy a burden for the national administration to carry out a risk evaluation in each case.
- 15 In the view of the Commission of the European Communities and the EFTA Surveillance Authority, the relevant requirement for justification is that of public health. Nutritional need is not such a requirement in itself. Examination by the national authorities as to whether there is nutritional need may play an important role, but only because it may enable the applicant to establish that the product can be presumed safe.
- 16 The EFTA Surveillance Authority argues, in substance, that the fortification policy of the Norwegian authorities is inconsistent, since they have, for many years, allowed iron fortification of domestically-produced whey cheese and other whey products. Whey cheese is fortified with 10 mg iron per 100 g. Furthermore, Norway allows or imposes fortification of products with vitamins for which safety margins are lower than the one for iron.
- 17 Furthermore, it is disputed whether the refusal to grant the marketing authorisation may be justified under Article 13 EEA.
- 18 The Government of Norway has stated that the refusal to grant the marketing authorisation is justified under Article 13 EEA, in view of the health risk connected to the particular fortification in the case at hand.

- 19 The Government of France is of the view that, in a field of law which is not harmonised, it is sufficient 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.
- 20 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 scientific information, followed by a risk assessment.
- 21 The EFTA Surveillance Authority is of the view that a ban on the marketing of a product in order to protect the interests laid down in Article 13 EEA must be based on international scientific research and the prevailing eating habits in the importing State. A general reference to a potential health risk cannot justify a ban on a product.
- 22 The Commission of the European Communities states that it would not be justified under Article 13 EEA to base a rejection of an application for authorisation to market a fortified food product solely on the absence of nutritional need for the addition in question.

### **Findings of the Court**

- 23 The Court notes that, pursuant to Article 11 EEA, quantitative restrictions on imports and all measures having equivalent effect are prohibited between the Contracting Parties. Article 13 EEA states that Article 11 EEA does not preclude prohibitions justified on grounds of *inter alia* protection of human health, as long as a given prohibition does not constitute a means of arbitrary discrimination or a disguised restriction on trade.
- 24 With regard to Article 36 of the EC Treaty (now, after amendment, Article 30 EC), the Court of Justice of the European Communities has held that the power of a Member State to prohibit the import of goods lawfully produced in other Member States is limited to what is necessary for attaining the legitimate aim of protecting public health, and that it must authorise the marketing of fortified products when that is compatible with the need to protect health (Case 174/82 *Sandoz BV* [1983] ECR 2443, at paragraph 18, hereinafter “*Sandoz*”). That ruling is, pursuant to Article 6 EEA, relevant for the judgment of the EFTA Court in the case at hand.

- 25 EEA law in this area may be summarised as follows. In the absence of harmonisation of rules, when there is uncertainty as to the current state of scientific research, it is for the Contracting Parties to decide what degree of protection of human health they intend to assure, having regard to the fundamental requirements of EEA law, notably, the free movement of goods within the European Economic Area. This means that a risk management decision rests with each Contracting Party. It is within the discretion of the Contracting Party to make a policy decision as to what level of risk it considers appropriate. Under those conditions, a Contracting Party may invoke the precautionary principle, according to which it is sufficient to show that there is relevant scientific uncertainty with regard to the risk in question. That measure of discretion must, however, be exercised subject to judicial review.
- 26 Measures taken by a Contracting Party must be based on scientific evidence; they must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken. With regard to the proportionality principle, the Court of Justice of the European Communities observed in *Sandoz* that, even in areas of foodstuff treatment in which there has been some degree of harmonisation within the Community (in that case referring specifically to colouring, preservatives and dietary food products), the Community legislature has shown considerable prudence regarding the potential harmfulness of additives, and, where uncertainty persists, a wide discretion has been left to the Member States.
- 27 The need to safeguard public health has been recognised as, and remains, a primary concern, and the level of protection chosen by the Contracting Parties should not be placed in question. However, the principle of proportionality must be respected.
- 28 In that process, the question of nutritional need with regard to additives to foodstuffs in any given population may have a proper place. Indeed, the most authoritative definition of “fortification and enrichment” is directly linked to this element (See Codex Alimentarius General Principles for The Addition of Essential Nutrients To Foods, doc. CAC/GL 09-1987 (amended 1989, 1991), Section 2). However, under the requirement of proportionality, the need to safeguard public health must be balanced against the principle of the free movement of goods. The mere finding by a national authority of the absence of a nutritional need will not justify an import ban, a most restrictive measure, on a product which is freely traded in other EEA States.

- 29 The national authority must address the issue of the protection of health and life of humans. A purely hypothetical or academic consideration will not suffice. It is not only the specific effects of the marketing of a single product with a set amount of additives that are relevant. It may be appropriate to take into account the aggregate effect of the presence in the market of a number of natural or artificial supply sources of a given nutrient, and of the possibility of future additional sources that can reasonably be foreseen.
- 30 In many cases, the assessment of such questions will show that there is a great measure of scientific and practical uncertainty linked to the issue under consideration. A proper application of the precautionary principle presupposes, firstly, an identification of potentially negative health consequences arising, in the present case, from a proposed fortification, and, secondly, a comprehensive evaluation of the risk to health based on the most recent scientific information.
- 31 When the insufficiency, or the inconclusiveness, or the imprecise nature of the conclusions to be drawn from those considerations make it impossible to determine with certainty the risk or hazard, but the likelihood of considerable harm still persists were the negative eventuality to occur, the precautionary principle would justify the taking of restrictive measures.
- 32 Such restrictive measures must be non-discriminatory and objective, and must be applied within the framework of a policy based on the best available scientific knowledge at any given time. The precautionary principle can never justify the adoption of arbitrary decisions, and the pursuit of the objective of “zero risk” only in the most exceptional circumstances.
- 33 On the basis of the information which has been made available to the Court during the course of the present proceedings, in particular the indication that a proposal is forthcoming for the rescission of the authorisation for the fortification of whey cheese with iron, it has not been shown that Norwegian authorities have exercised their authority in the matter of the application from Kellogg’s in a manner which would, at the time of giving judgment, constitute a material breach by Norway of its obligations under Article 11 EEA. There is, at this time, no indication of an inappropriate use of the precautionary principle as a disguised form of trade protectionism.
- 34 However, the Court has to consider whether the Government of Norway dealt with Kellogg’s application in an appropriate manner, when applying EEA law to the question of granting or denying an authorisation for enrichment of corn flakes.

- 35 The initial refusal by the Norwegian Food Control Authority to grant authorisation was based chiefly on the grounds that no nutritional need was present in the Norwegian population. The accompanying comments did not address the essential element under Article 13 EEA, namely whether a concrete assessment of all relevant circumstances showed that the fortification in question would present any danger to public health (see Case 304/84 *Ministère public v Muller* ECR [1986] 1521, at paragraph 23).
- 36 In dismissing the appeal by Kellogg's, the Ministry of Health and Social Affairs did address the public health issue, but not by demonstrating that a comprehensive risk assessment had been made. Instead, the decision rested chiefly on the assumption that if the enrichment of corn flakes were authorised, the authorities would in the future be constrained, under a principle of equality of treatment, to grant all applications for the introduction of similar additives to foodstuffs, and that this would have deleterious effects on public health.
- 37 The Court views this assumption as mistaken, in that the authorities would at any subsequent time be in a position to assess new applications on their merits, and have regard to a broad evaluation of all additives present in the Norwegian dietary spectrum at that time. This mistaken assumption must also be regarded as constituting a projection which is too hypothetical and conjectural to form the basis of a weighing of the concerns for the protection of public health under Article 13 EEA against the requirements of the principle of the free movement of goods under Article 11 EEA.
- 38 This administrative procedure did not correctly address the question of risk assessment in the manner required by EEA law. The defects were not, in the Court's view, materially remedied by the broader documentation that was submitted by the Government of Norway to the EFTA Surveillance Authority in its reply to the reasoned opinion. A scientific paper entitled "Risk Evaluation of Iron" was annexed to the reply. The Ministry of Health and Social Affairs simply stated that the prohibition of the marketing of fortified corn flakes was justified, and that the competent body kept the need to add nutrients to foods under continuous review, and would evaluate the authorisation to fortify whey cheese with iron. Thus, there had not, by the expiry of the time-limit set in the reasoned opinion, as extended, that is, 14 January 2000, been a concrete assessment of all relevant circumstances in the matter of Kellogg's application, which showed that the fortification in question would present a danger to public health.

- 39 The question of whether a State has failed to fulfil its obligations must be determined by reference to the situation obtaining at the end of the time-limit for responding to the reasoned opinion, and the Court is precluded from taking into account any subsequent changes in that situation (most recently confirmed in Case C-355/98 *Commission v Belgium*, judgment of 9 March 2000, not yet reported, at paragraph 22).
- 40 The Court must draw its conclusions in the light of this procedural background. The Court takes into consideration that the fortification policy of the Norwegian authorities, as presented at the relevant time, did not fulfil the requirements of EEA law.
- 41 Firstly, it was inconsistent in that, on the one hand, authorisation to market fortified cornflakes had been refused because of a lack of need, while on the other hand, Norway maintained as a matter of policy fortification of brown whey cheese with up to 10 mg of iron per 100 of cheese to be freely sold in the country.
- 42 Secondly, it had not been demonstrated that a comprehensive risk assessment had been carried out by the Norwegian authorities in response to Kellogg's submission of its application for authorisation. A comprehensive risk assessment was only carried out in the course of the proceedings before the Court.
- 43 It must therefore be held that the Kingdom of Norway, 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 had, at the relevant time, i.e. 14 January 2000, failed to fulfil its obligations under Article 11 EEA.

### **Costs**

- 44 Under Article 66(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. The EFTA Surveillance Authority has asked for the Kingdom of Norway to be ordered to pay the costs. Since the latter has been unsuccessful in its defence, it must be ordered to pay the costs. The costs incurred by the Government of Denmark, the Government of France, the Government of the

Netherlands and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable.

On those grounds,

THE COURT

hereby:

- 1. Declares 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 had, at the relevant time, i.e. 14 January 2000, failed to fulfil its obligations under Article 11 EEA.**
- 2. Orders the Kingdom of Norway to pay the costs of the proceedings.**

Thór Vilhjálmsson

Carl Baudenbacher

Per Tresselt

Delivered in open court in Luxembourg on 5 April 2001.

Gunnar Selvik  
Registrar

Thór Vilhjálmsson  
President