II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 24 May 2002

on the national provisions notified by the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers

(notified under document number C(2002) 1931)

(Only the Finnish and the Swedish texts are authentic)

(Text with EEA relevance)

(2002/398/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, in particular Article 95(6) thereof,

Whereas:

I. **FACTS**

1. *COMMUNITY LEGISLATION*

(1) Council Directive 76/116/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to fertilisers [1], as last amended by Directive 98/97/EC [2], lays down the requirements that fertilisers must fulfil in order to be placed on the market with the designation 'EC fertilisers' [3].

(2) Annex I of the Directive 76/116/EEC sets out the type designation and the corresponding requirements, e.g. with respect to its composition, that each EC-designated fertiliser must fulfil. EC-designated fertilisers included in this list are grouped into categories, depending on the content of the primary nutrients, i.e. the elements nitrogen, phosphorus and potassium.

(3) Directive 76/116/EEC has been amended and adapted to technical progress several times in order, *inter alia*, to include new fertiliser-types in Annex I.

(4) The amendments to Directive 76/116/EEC have been introduced by the following Directives:

— Directive 88/183/EEC [4] has extended the scope of Directive 76/116/EEC to include in Annex I straight and compound fluids fertilisers,

— Directive 89/284/EEC [5] has extended the scope of Directive 76/116/EEC to include in Annex I fertilisers containing calcium, magnesium, sodium and sulphur;

[1] OJ L 24, 30.1.1976, p. 21.
[2] OJ L 18, 23.1.1999, p. 60.
[3] The term 'EEC fertilizer' provided for by Directive 76/116/EEC was replaced by the term 'EC fertiliser' by Directive 97/63/EC (OJ L 335, 6.12.1997, p. 15).
[4] OJ L 83, 29.3.1988, p. 33.
[5] OJ L 111, 22.4.1989, p. 34.

— Directive 89/530/EEC [6] has extended the scope of Directive 76/116/EEC to include in Annex I solid or liquid fertilisers:

  — containing one of the following trace elements: boron, cobalt, copper, iron, manganese, molybdenum and zinc,

  — mixtures of such fertilisers containing at least two of these trace elements,

  — a list of authorised organic chelating agents for trace elements.

(5) The adaptations to technical progress to Directive 76/116/EEC have been introduced by Directive 93/69/EEC [7], Directive 96/28/EC [8] and Directive 98/3/EC [9]. Under these Directives, new fertilisers are added to the Annexes of Directive 76/116/EEC.

(6) For the purposes of this Decision, the term Directive 76/116/EEC shall be construed as referring to that Directive as amended by the Directives mentioned in recitals 4 and 5.

(7) The rules governing the composition of fertilisers covered by Directive 76/116/EEC do not provide for a limit value for the cadmium content of EC-designated fertilisers.

(8) According to Article 7 of Directive 76/116/EEC, Member States may not on grounds of composition, identification, labelling or packaging, prohibit, restrict or hinder the marketing of fertilisers marked 'EC fertiliser' which comply with the provisions of this Directive and the Annexes thereto.

2. *THE ACCESSION OF FINLAND*

(9) Finland acceded to the European Union on 1 January 1995. The Act of Accession [10] lays down transitional provisions concerning the use and marketing of cadmium in that State. Article 84(1) provides that during a period of four years from the date of accession, the provisions referred to in Annex X of the Act shall, in accordance with that Annex and subject to the conditions set out therein, not apply to Finland. Article 84 and point 2 of Annex X of the Act of Accession provide that Article 7 of Directive 76/116/EEC, in so far as it concerns the cadmium content of fertilisers, shall not apply to Finland before 1 January 1999 and that the provisions of Directive 76/116/EEC will be reviewed in accordance with Community procedures by 31 December 1998.

(10) Article 2 of the Act of Accession provides that 'from the date of accession, the provisions of the original Treaties and the acts adopted by the institutions before accession shall be binding on the new Member States and shall apply in those States under the conditions laid down in those Treaties and in this Act'. Article 168 of the Act of Accession stipulates that 'the new Member States shall put into effect the measures necessary for them to comply, from the date of accession, with the provisions of directives and decisions within the meaning of Article 189 (now Article 249) of the EC Treaty […], unless a time-limit is provided for in the list of Annex XIX or in any other provisions of this Act'.

(11) Directive 98/97/EC of the European Parliament and of the Council [11], subsequently amended Directive 76/116/EEC as regards the marketing in Austria, Finland and Sweden of fertilisers containing cadmium. Article 1 provides that, *inter alia*, Finland may prohibit the marketing on its territory of fertilisers containing cadmium at concentrations in excess of that which were fixed nationally at the date of accession and that this derogation applies for the period from 1 January 1999 until 31 December 2001.

3. *NATIONAL PROVISIONS*

(12) The Decision of Finland's Ministry of Agriculture and Forestry on fertilisers [12] No 45/1994 of 21 January 1994, *inter alia*, lays down a limit value for the cadmium content in fertilisers, including EC-designated fertilisers. According to Section 3, it is prohibited to place on the Finnish market phosphorus mineral fertilisers with a cadmium content exceeding 50 mg for each kilogram of phosphorus.

[6] OJ L 281, 30.9.1989, p. 116.
[7] OJ L 185, 28.7.1993, p. 30.
[8] OJ L 140, 13.6.1996, p. 30.
[9] OJ L 18, 23.1.1998, p. 25.
[10] OJ C 241, 29.8.1994, p. 37 and p. 308.
[11] OJ L 18, 23.1.1999, p. 60.
[12] Statutes of Finland No 45/1994 of 26 January 1994, p. 117.

II. **PROCEDURE**

(13) By letter of 7 December 2001, the Finnish authorities notified the Commission that Finland, in accordance with article 95(4) of the EC Treaty, intends to continue to apply from 1 January 2002 national provisions concerning the cadmium content in fertilisers.

(14) By letter of 8 January 2002, the Commission informed the Finnish authorities that it had received the notification under Article 95(4) and that the six months period for its examination according to Article 95(6) started on 8 December 2001, the day following the one when the notification was received.

(15) By letter of 23 January 2002, the Commission informed the other Member States about the request received from Finland. The Commission also published a notice regarding the request in the *Official Journal of the European Communities* ([13]) in order to inform other interested parties of the national measures that Finland intends to maintain.

III. **ASSESSMENT**

1. *CONSIDERATION OF ADMISSIBILITY*

(16) Article 95(4) of the Treaty provides that, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

(17) The notification submitted by the Finnish authorities on 7 December 2001 intends to obtain authorisation to maintain national provisions incompatible with those concerning the composition of EC-denominated fertilisers contained in Directive 76/116/EEC.

(18) As already indicated, Article 7 of Directive 76/116/EEC prevents Member States from restricting the marketing of EC-denominated fertilisers because of their composition, but the rules governing composition do not set any limit value for cadmium content. This means that pursuant to Article 7 of Directive 76/116/EEC, EC-denominated fertilisers complying with the requirements of that Directive can be placed on the market regardless of their cadmium content.

(19) In the light of the above mentioned, it is clear that the national provisions notified by Finland, in so far as they prohibit the placing on the market of EC-denominated phosphorus mineral fertilisers with a cadmium content exceeding 50 mg for each kilogram of phosphorus, are more restrictive than those contained in Directive 76/116/EEC.

(20) The national provisions notified by the Finnish authorities were adopted before Finland acceded to the European Union. As indicated above, the Act of Accession lays down transitional provisions allowing Finland to continue to apply its national provisions concerning the cadmium content of fertilisers to products covered by Directive 76/116/EEC for a period of four years. By Directive 98/97/EC Finland was authorised to continue to apply the above national provisions until 31 December 2001.

(21) As required by Article 95(4), as interpreted in the light of Articles 2 and 168 of the Act of Accession, Finland notified the Commission of the actual wording of the national provisions adopted before the accession to the European Union that it intends to maintain, accompanying the request by an explanation of the reasons which, in its opinion, justify the maintenance of those provisions.

(22) The notification submitted by Finland on 7 December 2001 in order to obtain approval for maintaining national provisions derogating from the provisions of Directive 76/116/EEC is therefore to be considered admissible under Article 95(4) as interpreted in the light of Articles 2 and 168 of the Act of Accession.

([13]) OJ C 23, 25.1.2002, p. 5.

2. *ASSESSMENT OF MERITS*

(23) In accordance with Article 95 of the Treaty, the Commission has to ensure that all the conditions enabling a Member State to avail itself of the possibilities of derogation provided for in this article are fulfilled.

(24) In particular, the Commission has to assess whether the provisions notified by the Member State are justified on grounds of major needs referred to in Article 30 of the Treaty, or relating to the protection of the environment or the working environment.

(25) In addition, pursuant to Article 95(6) of the Treaty, where it considers that the national provisions are justified, the Commission must check whether or not those national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.

(26) Finland has based its request on the need of protection of human health and the environment. Cadmium in fertilisers is deemed to pose a threat to the environment and human health. In support of its request, Finland makes reference to the conclusions of a Finnish study published in April 2000 ([14]) which contains an assessment of the risks posed by cadmium-containing fertilisers.

2.1. JUSTIFICATION ON GROUNDS OF MAJOR NEEDS

2.1.1. ***General information on cadmium***

(27) Cadmium is a heavy metal naturally present in the environment, but most emissions of this metal are due to various human activities (production of non-ferrous metals, incineration of fossil fuels, application of fertiliser, etc.).

(28) A general risk assessment on cadmium metal and cadmium oxide is currently being carried out under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ([15]) with Belgium acting as rapporteur. This risk assessment will address all important uses and emissions of cadmium. At present only a partial draft report is available for discussions at the technical level.

(29) From the scientific data available up to now, it can be concluded that cadmium metal and cadmium oxide in general can be considered to pose serious risks to health. In particular, cadmium oxide has been classified as a carcinogen, mutagen or substance toxic for reproduction, category 2 ([16]). It is also generally agreed that cadmium in fertilisers is by far the most important source of cadmium input to soil and to the food chain.

2.1.2. ***Cadmium in fertilisers***

(30) Cadmium is present in the natural state in the phosphate mineral rocks which are mined for use as raw material to manufacture phosphatic mineral fertilisers. In the finished state, these fertilisers always contain certain amounts of cadmium, depending on the original content of the phosphate rocks.

(31) Cadmium is regarded as harmful both to the environment and to human health. Phosphate fertilisers have been identified as a major source of cadmium on arable land, where it tends to accumulate over time. Crops tend to absorb cadmium from the soil, and the cadmium content of food, which is the main source of human intake of cadmium, has become an issue of concern for human health. When ingested in food, cadmium tends to accumulate in the kidneys and may eventually lead to kidney dysfunction in vulnerable groups.

([14]) Finnish Ministry of Agriculture and Forestry, Cadmium in fertilisers, risks to human health and the environment, April 2000.
([15]) OJ L 84, 5.4.1993, p. 1.
([16]) See Annex I to Directive 67/548/EEC and Annex I to Directive 76/769/EEC as amended.

(32) The environmental concerns raised by cadmium in fertilisers were first raised at Community level during the negotiations for the Accession of Austria, Finland and Sweden to the European Union. As indicated above, those three Member States were granted temporary derogations from Community legislation on fertilisers in order to allow a careful evaluation of the risks from cadmium in fertilisers at Community level.

(33) In this context, the Commission first gathered all available data and information on the exposure situation in the European Community from cadmium in fertilisers. As not enough data were available in all Member States, the Commission mandated two studies to elaborate a methodology and procedures with a view to assessing the risks to health and the environment from cadmium in fertilisers ([17]). Member States were subsequently invited to carry out nation-wide risk assessments by making use of the above methodology and procedures.

(34) Nine Member States have completed risk assessments concerning cadmium in fertilisers. These risk assessments have been made available to the public since September 2001 on the Commission's web-site ([18]). In addition, a separate study which analyses these risk assessments has been published and various options for risk management of cadmium in fertilisers at a Community wide scale have been developed ([19]).

(35) The above risk assessments have also been submitted to the SCTEE (Scientific Committee for Toxicity, Ecotoxicity and the Environment) and are currently under evaluation. In particular, the SCTEE has been asked to indicate what is the highest cadmium concentration in fertilisers that can be tolerated in order to avoid a significant increase in the cadmium content of cultivated soil due to the application of phosphate fertilisers.

(36) The completion of the risk assessments took a relatively long time. Moreover, the SCTEE needs time in order to assess the scientific material thoroughly. It was therefore not possible to present a proposal for a Regulation on cadmium limits in fertilisers by 31 December 2001.

2.1.3. ***The risk assessment carried out by Finland***

(37) The risk assessment submitted by the Finnish authorities is part of the above process of information-gathering based on common methodology and procedures. The framework used by Finland for conducting its risk assessment is built around three modules:

2.1.3.1. **The accumulation module**

(38) According to this module, the net accumulation of cadmium in soil and soil solution (or pore water) ([20]), resulting from the application of fertiliser, is computed over time and at steady state. The accumulation module allows for a range of inputs, for example average and extreme rates of application. The Finnish risk assessment shows that with this module, the following parameters have been considered:

— the total cadmium content in agricultural soil (due to mineral fertilisers, but also to atmospheric deposition, agrochemicals and wastes);

— the cadmium uptake by plants as function of soil properties;

— for a one hundred year period an estimate has been made of:

  — cadmium concentration in pore water/leachate,

  — cadmium leaching rate,

([17]) ERM, Study on data requirements and programme for data production and gathering to support a future evaluation of the risks to health and the environment from cadmium in fertilisers, March 1999, and A study to establish a programme of detailed procedures for the assessment of risks to health and the environment from cadmium in fertilisers, February 2000. (ERM (Environmental Resources Management) is the consultant who developed the methodology for the risk assessments.)

([18]) http://europa.eu.int/comm/enterprise/chemicals/fertilizers/riskassest/reports.htm

([19]) ERM, Analysis and conclusions from Member States' assessment of the risk to health and the environment from cadmium in fertilisers, October 2001.

([20]) Pore water means that part of the water contained in the soil which is maintained by capillarity between the solid particles of the soil.

— cadmium content in soils,

— cadmium output via erosion,

— cadmium content of crops,

— cadmium uptake by plants.

2.1.3.2. **The exposure module**

(39) According to this module, the uptake of cadmium from soil into cultivated plants and the subsequent intake of cadmium by humans are computed, using exposure parameters characterizing both average and extreme exposure scenarios. Environmental exposure is also characterised for vulnerable environments and is taken to be the predicted cadmium concentration in a particular environmental compartment.

2.1.3.3. **The risk characterisation module**

(40) This module allows Finland to estimate the incidence and severity of the adverse effects likely to occur due to actual or predicted exposure to cadmium.

2.1.4. ***The results of the risk assessment***

(41) The application of the modules has produced the following results:

— concerning water, the Finnish risk assessment report states that 'risk characterisation reveals that there is risk for aquatic environment for all calculated scenarios, both at present time and in the future. In practice this means that no margin of safety can be established, and any increase to the natural background concentrations is likely to present a risk for the aquatic environment';

— concerning the soil, the Finnish risk assessment states that 'based on the available data, the current cadmium concentrations in Finnish agricultural soils present a risk for the soil environment. This conclusion can be reached both by using mean extractable cadmium concentrations ([21]) and 90 percentile values in the five Finnish cultivation zones for the year 1987. Only in the most northern zone the PEC/PNEC ratio ([22]) using the mean concentration is below 1. Risk ratios for the different cultivation zones vary from 1,2 to 2,8';

— concerning human health, the Finnish risk assessment report states that 'in Finland, there is no margin of safety for the risk group (worst cases) between the estimated urinary levels and the critical levels that have been associated with adverse health effects caused by cadmium'. The Finnish risk assessment report also states that 'if phosphorus fertilisers containing average Community level of cadmium were to be used in Finland the dietary intake of cadmium would increase by more than 40 % over one hundred years, based on model calculations'.

(42) It is clear that these conclusions refer to the specific situation of the Finnish soil as well as the climatic conditions prevailing in Finland.

(43) In conclusion, the risk assessment carried out by Finland shows that present cadmium concentrations in Finnish agricultural soil pose a risk for soil organisms and that the leaching of cadmium from the agricultural soil is causing a risk for the aquatic environment. Finland maintains that the risk assessment concludes also that there is a risk of adverse health effects as a result of the present total cadmium exposure in the Finnish population. While the average cadmium intake from food alone does not pose a risk in Finland, some sectors of the population are at risk because of high dietary intake, increased absorption and/or smoking.

([21]) The concentration of cadmium that is available for uptake by plants.
([22]) PEC = predicted environmental concentration, PNEC = predicted no effect concentration. A PEC/PNEC ratio greater than one indicates that there will be adverse effects.

2.1.5. ***Evaluation of the position of Finland***

(44) The risk assessment submitted by the Finnish authorities has been carried out according to the procedures and the methodology established at Community level, which are considered to ensure a high degree of reliability of the information obtained.

(45) The Commission already examined the information contained in this risk assessment in the context of the preparatory work of the proposal for a new Regulation relating to fertilisers ([23]). At that time, the Commission considered that the information available provided sufficient indication of a risk for the environment and human health arising from the application to the Finnish soil of cadmium-containing fertilisers. The Commission therefore proposed in Article 33 of its proposal an extension of the derogation already granted to Austria, Finland and Sweden in the Accession Treaty. As the proposed Regulation could not be adopted in time, Finland has applied for an individual Decision under Article 95(6).

(46) After having re-examined the scientific evidence in the light of the Finnish request, the Commission considers that the Finnish authorities have shown that cadmium-containing fertilisers pose environmental and human health risks, and that the national provisions notified by the Finnish authorities aiming to limit to the minimum the exposure of the Finnish environment to cadmium-containing fertilisers are justified.

2.2. ABSENCE OF ARBITRARY DISCRIMINATION

(47) Article 95(6) obliges the Commission to verify that the envisaged measures are not a means of arbitrary discrimination. According to the ruling of the Court of Justice, the absence of discrimination means that national restrictions on trade cannot be used in such a way as to create discrimination in respect of goods originating in other Member States.

(48) The envisaged national provisions are general and apply to national and imported phosphorous-based EC-designated fertilisers alike. As a result, there is no evidence that they can be used as a means of arbitrary discrimination between economic operators in the Community.

2.3. ABSENCE OF A DISGUISED RESTRICTION ON TRADE

(49) More restrictive national measures governing the composition of EC-designated fertilisers that derogate from the provisions of a Community Directive normally constitute a barrier to trade. Products that can be legally placed on the market in the rest of the Community cannot be placed on the market in the Member State concerned. The concept enshrined in paragraph 6 of Article 95 is intended to prevent the national provisions based on the criteria set out in paragraphs 4 and 5 being applied for inappropriate reasons, and in reality constituting economic measures to be introduced to impede the import of products from other Member States in order to indirectly protect national production.

(50) As already established, there is concern with regard to the protection of the environment and human health due to the application on soil of cadmium-containing fertilisers. Therefore, the protection of the environment and human health appears to be the goal of maintaining the national provisions and not the creation of disguised barriers to trade.

2.4. ABSENCE OF OBSTACLES TO THE FUNCTIONING OF THE INTERNAL MARKET

(51) This condition cannot be interpreted in such a way that it prohibits the approval of any national measure likely to affect the establishment of the Internal Market. In fact, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the Internal Market, constitutes in substance a measure that is likely to affect the Internal Market. Consequently, to preserve the useful character of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of the Article 95(6), the concept of obstacle to the functioning of the Internal Market has to be understood as a disproportionate effect in relation to the pursued objective.

([23]) Commission proposal for a European Parliament and Council Regulation relating to fertilizers (COM(2001)508 final, 14.9.2001).

(52) In view of the risks for both the environment and human health resulting from the application of cadmium-containing fertilisers to the Finnish soil and taking into account that:

— as indicated above, the Act of Accession and Directive 98/97/EC allowed Finland to continue to apply its national provisions concerning the cadmium content in fertilisers awaiting the completion of the review of Directive 76/116/EEC as regards the issue of the cadmium content in fertilisers and;

— the opinion of the SCTEE was not available in time to be considered for this Decision in order to provide a sufficient scientific basis for the Commission to propose an approximation of Community limit values for the cadmium content in fertilisers, or to determine whether there would be a less restrictive measure,

the Commission considers that, at this stage of the review, there is no evidence indicating that the national provisions do constitute a disproportionate obstacle to the functioning of the internal market in relation to the pursued objectives.

2.5. LIMITATION IN TIME

(53) Finland asked the Commission to take a decision under Article 95(6) of the Treaty before 31 December 2001. Should the Commission approve the request for a derogation, Finland asked that the Decision shall take effect from 1 January 2002.

(54) It should first be noted that given the procedural framework established in Article 95 of the Treaty and in particular the six-month deadline for a Decision to be adopted, it is incumbent on Member States to submit a notification to the Commission in time so that the Commission is able to adopt a decision on the notification before the relevant Community harmonisation measure becomes enforceable ([24]).

(55) It should be recalled that the principle of legal certainty, which is a general principle of Community law, excludes, for the most part, retroactive application of Community legislation, except where the objective to be achieved requires it and then only on condition that the legitimate expectations of the parties concerned are respected ([25]).

(56) In the light of the foregoing, the Commission does not consider that in the present case the conditions exist for giving a retroactive effect to the Decision approving the national provisions. In fact, although there is a need to protect human health and the environment from the risks posed by cadmium in fertilisers, to render the more stringent national measures applicable retroactively would, in effect, be tantamount to undermining the legitimate expectations of those economic operators who acted in the belief that the rules in force after 31 December 2001 were the more liberal ones deriving from Directive 76/116/EEC.

(57) The period for which the derogation is granted should allow sufficient time for the Commission to propose and for the Council and the European Parliament to adopt a legislation concerning cadmium in fertilisers at Community level. It is estimated that such a Legislation could enter into force in 2005. The derogation of Finland should therefore expire on 31 December 2005.

IV. **CONCLUSION**

(58) In the light of the foregoing, it can be concluded that the request by Finland for maintaining national provisions that are more restrictive than the provisions of Directive 76/116/EEC with regard to the cadmium content of fertilisers, as submitted on 7 December 2001, is admissible.

([24]) In this connection, it is pointed out that the European Court of Justice, in paragraph 35 of its judgement of 1 June 1999 delivered in case C-319/97, states that 'it is incumbent on Member States under Article 10 EC (ex Article 5) to notify as soon as possible the provisions of national law which are incompatible with a harmonisation measure and which they intend to maintain in force'.

([25]) European Court of Justice's judgement of 25 January 1979 delivered in case C-98/78 Racke [1979] ECR 69, paragraph 20. See also the judgements delivered in the following cases: C-110/97 the Netherlands v Council, [2001] ECR 000, paragraph 151; C-99/78 Decker [1979] ECR 101, paragraph 8; C-258/80 Rummy v Commission [1982] ECR 487, paragraph 11; and C-337/88 SAFA [1990] ECR I-1, paragraph 13.

Moreover, the Commission finds that the national provisions:
— meet needs on grounds of the protection of human health and the environment,
— are proportionate to the objectives pursued,
— are not a means of arbitrary discrimination, and
— do not constitute a disguised restriction on trade between Member States.

The Commission therefore considers that they can be approved,

HAS ADOPTED THIS DECISION:

Article 1

In derogation from Directive 76/116/EEC, the Finnish provisions which prohibit the placing on the Finnish market of phosphorous mineral fertilisers with a cadmium content exceeding 50 mg for each kilogram of phosphorus are approved.

The derogation shall apply until 31 December 2005.

Article 2

This Decision is addressed to the Republic of Finland.

Done at Brussels, 24 May 2002.

For the Commission
Erkki LIIKANEN
Member of the Commission