

## II

(Acts whose publication is not obligatory)

## COMMISSION

## COMMISSION DECISION

of 3 January 2006

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

(notified under document number C(2005) 5532)

(Only the Swedish text is authentic)

(Text with EEA relevance)

(2006/347/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

identification, labelling or packaging, to prohibit, restrict or hinder the marketing of fertilisers marked 'EC fertiliser' which comply with the provisions of this Directive.

## 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 <sup>(1)</sup>, laid down the requirements that fertilisers must fulfil in order to be placed on the market with the designation 'EC fertilisers'.
- (2) Annex I to Directive 76/116/EEC set 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) According to Article 7 of Directive 76/116/EEC, Member States were not permitted on grounds of composition,

- (4) Commission Decision 2002/399/EC of 24 May 2002 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers <sup>(2)</sup>, granted a derogation to Directive 76/116/EEC, by approving the Swedish provisions which prohibit the placing on the Swedish market of fertilisers containing in excess of 100 grams of cadmium per tonne of phosphorus. This derogation was applicable until 31 December 2005.
- (5) Directive 76/116/EEC, as amended, has been replaced by Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers <sup>(3)</sup>.
- (6) Article 35(2), of Regulation (EC) No 2003/2003 states that derogations from Article 7 of Directive 76/116/EEC that were granted by the Commission under Article 95(6) of the Treaty shall be construed as derogations from Article 5 of the present Regulation and shall continue to produce their effects notwithstanding the entry into force of this Regulation.

<sup>(1)</sup> OJ L 24, 30.1.1976, p. 21. Directive as last amended by the 2003 Act of Accession.

<sup>(2)</sup> OJ L 138, 28.5.2002, p. 24.

<sup>(3)</sup> OJ L 304, 21.11.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 2076/2004 (OJ L 359, 4.12.2004, p. 25).

- (7) Recital 15 of Regulation (EC) No 2003/2003 announces that the Commission will address the issue of unintentional cadmium content in mineral fertilisers and will, where appropriate, draw up a proposal for a Regulation and will present it to the European Parliament and the Council.
- (8) Work is in progress to prepare a Commission proposal on cadmium in fertilisers.

## 2. The accession of Sweden

- (9) Sweden acceded to the European Union on 1 January 1995. The Act of Accession <sup>(4)</sup> lays down transitional provisions concerning the use and marketing of cadmium in that State. Article 112(1) provides that during a period of four years from the date of accession, the provisions referred to in Annex XII of the Act shall, in accordance with that Annex and subject to the conditions set out therein, not apply to Sweden. Article 112 of and point 4 of Annex XII to 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 Sweden 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 <sup>(5)</sup> 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*, Sweden 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.

- (12) On 7 December 2001, the Kingdom of Sweden notified existing national legislation, deviating from the provisions of Directive 76/116/EEC on the approximation of the laws of the Member States relating to fertilisers. After careful consideration, Decision 2002/399/EC granted a prolongation of the derogation from Directive 76/116/EEC until 31 December 2005.

## 3. National provisions

- (13) 'The Chemicals Products (Handling, Import and Export Prohibitions) Ordinance' (1998:944) <sup>(6)</sup> contains provisions relating, *inter alia*, to the maximum permissible cadmium content in fertilisers, including EC-designated fertilisers. Section 3, paragraph 3, of the Ordinance, provides that fertilisers covered by customs tariffs numbers 25.10, 28.09, 28.35, 31.03 and 31.05 containing in excess of 100 grams of cadmium per tonne of phosphorous may not be offered for sale or transferred.
- (14) The provisions relating to the maximum permissible cadmium content in fertilisers have been in force since 1985 following the adoption of 'The Cadmium Ordinance' (1985:839). 'The Chemicals Products Ordinance' (1998:944) codifies different provisions relating to the protection of the environment, including those contained in 'The Cadmium Ordinance' (1985:839).

## II. PROCEDURE

- (15) By letter of 29 June 2005, the Kingdom of Sweden notified the Commission that, in accordance with article 95(4) of the EC Treaty, it intends to continue to apply from 1 January 2006 national provisions concerning the cadmium content in fertilisers. The Swedish authorities request an extension of the current derogation provided by Decision 2002/399/EC.
- (16) By letter of 29 July 2005, the Commission informed the Swedish authorities that it had received the notification under Article 95(4) and that the six-month period for its examination according to Article 95(6) started on 30 June 2005, the day following the one when the notification was received.

<sup>(4)</sup> OJ C 241, 29.8.1994, p. 41 and p. 316.

<sup>(5)</sup> OJ L 18, 23.1.1999, p. 60.

<sup>(6)</sup> Swedish Code of Statutes (SFS Svensk Författningssamling) of 14 July 1998.

- (17) By letter of 10 August 2005, the Commission informed the other Member States about the request received from Sweden. The Commission also published a notice regarding the request in the *Official Journal of the European Union* <sup>(7)</sup> in order to inform other interested parties of the national measures that Sweden intends to maintain.

the European Union. As indicated above, the Act of Accession lays down transitional provisions allowing Sweden 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 Sweden was authorised to continue to apply the above national provisions until 31 December 2001. Decision 2002/399/EC extended the derogation until December 2005.

### III. ASSESSMENT

#### 1. Consideration of admissibility

- (18) 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.

- (23) As required by Article 95(4), as interpreted in the light of Articles 2 and 168 of the Act of Accession, Sweden 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.

- (19) The notification submitted by the Swedish authorities on 29 June 2005 intends to obtain authorisation to extend, beyond 31 December 2005, the current derogation provided in Decision 2002/399/EC. This Decision allows Sweden to maintain the application of national provisions incompatible with those concerning the composition of EC-denominated fertilisers contained in Regulation (EC) No 2003/2003.

- (24) The reasons provided by the Swedish authorities are those already submitted in the past and that lead the Commission, in Decision 2002/399/EC, to grant a derogation until 31 December 2005. This period was granted on the assumption that harmonised legislation would be in place by end 2005. Although work is in progress, legislation would not be adopted at Community level before the end of the year.

- (20) As already indicated, Article 5 of Regulation (EC) No 2003/2003 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 5 of Regulation (EC) No 2003/2003, EC-denominated fertilisers complying with the requirements of that Regulation can be placed on the market regardless of their cadmium content.

- (25) The notification submitted by Sweden on 29 June 2005 in order to obtain approval for maintaining national provisions derogating from the provisions of Regulation (EC) No 2003/2003 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.

#### 2. Assessment of merits

- (21) In the light of the abovementioned, it is clear that the national provisions notified by Sweden, in so far as they prohibit the placing on the market of EC-denominated fertilisers with a cadmium content exceeding 100 grams per tonne of phosphorus, are more restrictive than those contained in Regulation (EC) No 2003/2003.

- (26) 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.

- (22) The national provisions notified by the Swedish authorities were adopted in 1985 before Sweden acceded to

- (27) 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.

<sup>(7)</sup> OJ C 197, 12.8.2005, p. 6.

(28) 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.

(29) Sweden 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, Sweden makes reference to the conclusions of a Swedish study published in October 2000 <sup>(8)</sup> which contains an assessment of the risks posed by cadmium-containing fertilisers.

#### 2.1. Justification on grounds of major needs

(30) As regards the general information on cadmium, 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. 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.

(31) As regards cadmium in fertilisers, the most relevant information of the risk assessment carried out by Sweden can be summarised as follows:

— concerning surface water, the Swedish risk assessment report states that 'the chosen PNEC <sup>(9)</sup> value implies that in most rivers in southern Sweden, certain biota would already be affected by cadmium i.e. risk characterisation ratios <sup>(10)</sup> are larger than one <sup>(11)</sup>. If higher cadmium content in fertilisers would be allowed, a further increase in the exposure of and the concern for effects in the aquatic environment is expected to occur',

— concerning the soil, the Swedish risk assessment report states that 'by using the Swedish fertiliser for 100 years on common Swedish soils (PNEC 0,25 mg/kg), no concern for ecological effects is predicted when potatoes or wheat are grown. A concern is predicted when carrots are grown, but

this concern is also present at time zero. With the EC fertiliser, a concern is predicted in all cases. In acid, sandy soils that are poor in clay and organic matter (PNEC 0,06 mg/kg), a risk is predicted even if the cadmium content in fertilisers is zero'.

(32) It is clear that these conclusions refer to the specific situation of the Swedish soil as well as the climatic conditions prevailing in Sweden.

(33) In conclusion, the risk assessment carried out by Sweden shows that if fertilisers with a higher cadmium content than currently permitted would be allowed, this would lead to:

— a substantial increase in the cadmium concentrations of soils, which in turn would lead to toxic effects on soil organisms. Unacceptable concentrations could also appear in watercourses in agricultural regions,

— a substantial increase in the dietary intake of cadmium. The safety margin between current exposure and the World Health Organisation provisional tolerable weekly intake level is extremely small. For some high-risk groups, such as women with low body iron stores, there are no safety margins at all. A high dietary intake of cadmium could therefore lead to a larger number of people becoming subject to reduced kidney function and increased osteoporosis.

(34) The risk assessment submitted by the Swedish 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.

(35) The Commission already examined the information contained in the risk assessment in the context of Decision 2002/399/EC which allowed Sweden to maintain their national provisions until 31 December 2005.

(36) No other scientific and technical data was provided by Sweden in 2005. The accumulation process is a slow one which is not significantly modified on a three-year period. Therefore, it could be considered that the situation is similar as in 2002.

<sup>(8)</sup> Swedish National Chemical Inspectorate, Assessment of risks to health and the environment in Sweden from cadmium in fertilisers, 4 October 2000.

<sup>(9)</sup> PNEC: predicted no effect concentration.

<sup>(10)</sup> These ratios are PEC/PNEC where PEC is the predicted environmental concentration.

<sup>(11)</sup> A PEC/PNEC ratio greater than 1 indicates that there will be adverse effects.

- (37) The validity of the data provided by Sweden is confirmed by the following scientific basis used to support the preparation of the Commission proposal on cadmium in fertilisers:

- the opinion delivered on 24 September 2002 by the SCTEE<sup>(12)</sup> (now renamed SCHER<sup>(13)</sup>) concerning cadmium accumulation in agricultural soils due to fertiliser application. This opinion was based on risk assessment reports of nine Member States which address only the accumulation and not the possible risks to health and environment; the conclusion of the SCTEE was that the content of cadmium in fertilisers does need to be limited to prevent accumulation of cadmium in the soil,
- the final draft of the general risk assessment of cadmium and cadmium oxide, dated September 2004 produced in accordance with Council Regulation (EEC) No 793/93<sup>(14)</sup> and which considers all sources of cadmium. The draft endorses the opinion of the SCTEE concerning the accumulation in soil. Although it states that the contribution from cadmium in fertilisers may not, by itself, be sufficient to cause a severe and immediate risk to human health or to the environment, caution is needed, as the risk to human health cannot be excluded for all local and regional situations because of the large variability in food cadmium concentrations, dietary habits and nutritional status.

Pending finalisation of the general risk assessment on cadmium and cadmium oxide as well as the potential follow-up work on risk reduction measures, the Commission proposal on cadmium in fertilisers has been subject to some delays.

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

## 2.2. *Absence of arbitrary discrimination*

- (39) 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.

- (40) 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*

- (41) 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 Article 95(6) 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.

- (42) 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*

- (43) 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.

<sup>(12)</sup> Scientific Committee on Toxicity, Ecotoxicity and the Environment.

<sup>(13)</sup> Scientific Committee on Health and Environmental Risks.

<sup>(14)</sup> OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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

- as indicated above, the Act of Accession and Directive 98/97/EC allowed Sweden 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
- Decision 2002/399/EC allowed Sweden to maintain their national provisions until 31 December 2005 based on the risk assessment provided by the Swedish authorities, and
- ongoing work within the Commission for an approximation of Community limit values for the cadmium content in fertilisers does not lead to believe that a less restrictive measure would provide sufficient protection of health and environment in Sweden. The risk assessment shows that the specific soil and climatic condition of Sweden require national provision for the protection of the environment because some areas are more vulnerable to cadmium inputs due in particular to the acidic pH of their soil. Under acidic conditions, the solubility of cadmium increases and therefore could be more easily taken up by the crops.

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

(45) 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 legislation concerning cadmium in fertilisers at Community level. In order to avoid the implications of possible delays during the interinstitutional debate, the provisions of the current Decision should therefore be valid until the harmonised measure is applicable at EU level.

#### IV. CONCLUSION

- (46) In the light of the foregoing, it can be concluded that the request by the Kingdom of Sweden 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 29 June 2005, is admissible.
- (47) 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 Regulation (EC) No 2003/2003, the Swedish provisions which prohibit the placing on the Swedish market of fertilisers containing in excess of 100 grams of cadmium per tonne of phosphorous are approved.

The derogation shall apply until harmonised measures on cadmium in fertilisers are applied at Community level.

#### Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 3 January 2006.

For the Commission  
Günter VERHEUGEN  
Vice-President