DECISIONS

COMMISSION DECISION

of 18 April 2012

extending the period referred to in Article 114(6) of the Treaty on the Functioning of the European Union in relation to national provisions concerning the maximum admissible content of cadmium in fertilisers notified by the Kingdom of Sweden pursuant to Article 114(5) of the TFEU

(notified under document C(2012) 2461)

(Only the Swedish text is authentic)

(Text with EEA relevance)

(2012/230/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(6) thereof,

Whereas:

I. FACTS

(1) On 17 October 2011, the Kingdom of Sweden notified the Commission, pursuant to Article 114(5) of the Treaty on the Functioning of the European Union (TFEU), of its intention to introduce national provisions to lower the content of cadmium allowed in phosphorous fertilisers to a maximum level of 46 grams of cadmium per tonne of phosphorous (equivalent to 20 mg Cd/kg P_2O_5). Those measures would derogate from Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers [1] and would lower the maximum level of 100 grams of cadmium per tonne of phosphorous (equivalent to 44 mg Cd/kg P_2O_5) for which a derogation has already been granted to the Kingdom of Sweden.

1. Article 114(5) and (6) TFEU

(2) Article 114, paragraphs (5) and (6) TFEU provide:

'5. … if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications … approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs … 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.'

2. EU legislation

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

(4) 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 fertiliser had to fulfil to be eligible for designation as 'EC fertiliser'. Type designations in this list were grouped into categories, depending on the content of the primary nutrients, i.e. the elements nitrogen, phosphorus and potassium.

(5) According to Article 7 of Directive 76/116/EEC [3], Member States were not permitted on grounds of composition, identification, labelling or packaging, to prohibit, restrict or hinder the marketing of fertilisers marked 'EC fertiliser' which complied with the provisions of the Directive.

[1] OJ L 304, 21.11.2003, p. 1.

[2] OJ L 24, 30.1.1976, p. 21, replaced by Regulation (EC) No 2003/2003.

[3] Replaced by Article 5 of Regulation (EC) No 2003/2003.

(6) 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 ([1]), granted a derogation from Directive 76/116/EEC, by approving the Swedish provisions which prohibited 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.

(7) Directive 76/116/EEC has been replaced by Regulation (EC) No 2003/2003 relating to fertilisers.

(8) 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 former Article 95(6) of the EC Treaty shall be construed as derogations from Article 5 of that Regulation and shall continue to produce their effects notwithstanding the entry into force of the Regulation.

(9) 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. The Commission has conducted extensive preparatory work but due to the complexity of the various factors to be taken into account has not yet adopted a proposal.

(10) Since the Swedish derogation was granted only until 31 December 2005, Sweden requested in June 2005 an extension of the existing derogation. Commission Decision 2006/347/EC 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 ([2]) allows the Swedish authorities to maintain the national measures until harmonised measures on cadmium in fertilisers are applied at EU level.

3. **National provisions**

(11) 'The Chemicals Products (Handling, Import and Export Prohibitions) Ordinance' (1998:944) ([3]) contains provisions relating, *inter alia*, to the maximum permissible cadmium content in fertilisers, including EC-designated fertilisers. Section 3, paragraph 1, 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.

(12) The envisaged national measure notified under Article 114(5) TFEU would lower the content of cadmium allowed in phosphorous fertilisers from the current maximum level of 100 grams of cadmium per tonne of phosphorus to a level of 46 grams of cadmium per tonne of phosphorus (46 mg Cd/kg P, equivalent to 20 mg Cd/kg P_2O_5).

II. **PROCEDURE**

(13) By letter of 17 May 2011 the Kingdom of Sweden notified the Commission that, pursuant to Article 114(5) TFEU, it requests approval to introduce national provisions to lower the content of cadmium allowed in phosphorous fertilisers to a maximum concentration of 46 grams per tonne of phosphorus. The Swedish authorities thus request to lower the cadmium content allowed by the derogation provided by Decision 2006/347/EC.

(14) By letter of 17 October 2011, the Swedish authorities sent additional information to the Commission to provide the text of the national legislation in force reflecting the amendments introduced by Ordinances 2008:255 and 2009:654 ([4]).

(15) By letter of 14 November 2011, the Commission informed the Swedish authorities that the six-month period for its examination according to Article 114(6) started on 18 October 2011.

(16) By letter of 17 October 2011, 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* ([5]) in order to inform other interested parties of the national measures that Sweden intends to introduce as well as the grounds invoked to that effect. In reaction, Latvia supported the Swedish request. No other comments were received by the Commission.

III. **ASSESSMENT**

1. **Consideration of admissibility**

(17) Article 114(5) TFEU concerns cases in which national provisions are notified in relation to an EU harmonisation measure, where the national measures are to be introduced after the harmonisation measure has been adopted and enforced and where the new national measure would be incompatible with the EU harmonisation measure. The national provisions were notified in relation to Regulation (EC) No 2003/2003, which was adopted on the basis of former Article 95 of the EC Treaty, and which sets harmonised rules regarding the composition, identification, labelling and packaging of EC fertilisers. According to Article 5 of that Regulation, Member States are not allowed to introduce obstacles to the free movement of fertilisers based on any of those grounds.

([1]) OJ L 138, 28.5.2002, p. 24.
([2]) OJ L 129, 17.5.2006, p. 19.
([3]) Swedish Code of Statutes (SFS Svensk Författningssamling) of 14 July 1998.
([4]) Swedish Code of Statutes (SFS Svensk Författningssamling) of 4 June 2009.
([5]) OJ C 309, 21.10.2011, p. 8 and OJ C 339, 19.11.2011, p. 24.

(18) Furthermore, Article 114(5) TFEU requires that the notification of the intended national measures must be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to the notifying Member State arising after the adoption of the harmonisation measure and must be accompanied by a description of the grounds for introducing the intended national measures.

(19) In support of the request for a lower limit on cadmium in phosphate fertilisers the Swedish authorities have submitted a national risk assessment and some studies. This assessment takes into account the general EU risk assessment of cadmium and cadmium oxide produced in 2007 in accordance with Council Regulation (EEC) No 793/93 [1], a scientific opinion from the European Food Safety Authority on cadmium in food [2], as well as old and new data relating to the assessment of the risks to human health and the environment from cadmium in fertilisers in Sweden. The Swedish risk assessment is published on the internet [3].

(20) According to the Swedish authorities, the new risk assessment shows the need to reduce exposure to cadmium to protect the health of the Swedish population in the long term. Exposure depends on the intake of cadmium via food, mainly from plants and therefore it is necessary to reduce the risk of high levels of cadmium in crops. Arable soils are in general more acidic in Sweden than in Central Europe and this specific situation makes cadmium more readily available for plants.

(21) Furthermore, lowering the national limit of 100 grams of cadmium per tonne phosphorous to 46 grams of cadmium per tonne phosphorous is a measure intended to reduce the accumulation of cadmium in soils and also risks to aquatic organisms living in extreme soft waters as occur in Sweden.

(22) In the light of the foregoing, the Commission considers that the application submitted by the Kingdom of Sweden with a view to obtaining approval to lower the content of cadmium in fertilisers to a maximum level of 46 grams of cadmium per tonne of phosphorus is admissible.

[1] EU RAR, ECB 2007: European Union Risk Assessment Report cadmium oxide and cadmium metal, Volume 72 European Commission, Joint Research Centre, Institute of Health and Consumer Protection.

[2] EFSA 2009: Scientific Opinion of the Panel on contaminants in the Food Chain on a request from the European Commission on cadmium in food. The EFSA Journal (2009) 980, 1-139.

[3] Available at: http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/fertilisers/cadmium/risk-assessment_en.htm

2. **Recourse to Article 114(6), third subparagraph TFEU**

2.1. *Justification based on the complexity of the matter*

(23) To support its request, Sweden has conducted a new risk assessment which was finalised in January 2011, in which it compares the predicted no effect concentrations (PNECs) for organisms representative for various environmental compartments with the cadmium concentrations in the Swedish environment. In their notification, reference is also made to certain studies made available in the framework of the previous requests submitted to the Commission in accordance with Article 114(4) of the Treaty and to the EU risk assessment on cadmium and cadmium oxide.

(24) The PNEC for fresh water is dependent on hardness. Since Sweden has very soft fresh waters, toxicity for aquatic organisms is expected to occur at lower cadmium concentration compared to other parts of Europe. The Swedish authorities, therefore, consider that it is likely that aquatic organisms in Swedish waters are in general more sensitive to additional cadmium compared to waters in Central and Southern Europe.

(25) Results of monitoring programmes in Swedish surface waters in 2006 and 2009 show that about 1 % of the lakes and 7 % of the coastal waters show higher cadmium concentrations than the PNEC values. A review conducted in 2008 concluded that emission reduction measures have for most metals led to significant decreased concentrations in aquatic organisms, but for cadmium the situation is less clear. A tendency of increasing effects on the immune system in fish (eelpout) during the last years seems to correlate with increasing concentrations of cadmium in fish. A further report has been produced in 2011 with the aim to describe future trends of cadmium in arable soils and crops to estimate concentrations in 100 years and results have been used in a worst case modelling to estimate the risk to aquatic organisms inhabiting waters close to fields fertilised during 100 years ahead.

(26) The Swedish authorities conclude in their assessment that there might be an increased risk for aquatic organisms living in extremely soft waters (below hardness 5 mg $CaCO_3$/l) in the longer term. But this is only likely in small brooks with low dilution of the drainage water from the agricultural soil. No other risk to the environment resulting from the use of cadmium in fertilisers has been identified by the Swedish authorities.

(27) In the light of the complexity of the relations of cadmium input via phosphate fertilisers, possible accumulation and risks to the environment, as already

demonstrated during the evaluation of similar requests for derogation from Austria, Finland, and the Czech Republic, as well as the earlier requests from Sweden, the Commission requested the Scientific Committee on Health and Environmental Risks (SCHER) for an opinion on the overall quality of the Swedish risk assessment, any significant deficiencies, the appropriateness of the scenarios studied and the assumptions made, as well as the reliability and validity of the conclusions concerning the identified risks for the environment.

(28) The SCHER adopted its opinion on 27 February 2012 ([1]). SCHER concluded that the risk assessment report prepared by the Swedish authorities is of good scientific quality and that in general the scenarios studied are appropriate and most parameter values used in the scenarios are acceptable. However, SCHER considers that a number of statements and/or assumptions in the report are not supported by sufficient evidence. For example, the observations given in the fish monitoring studies assume a cause-effect relationship which is not proven. Another example is the important (central to the risk assessment) assumption of a 1/2 dilution factor used to calculate the cadmium concentration in the surface waters of brooks. No scientific evidence or justification is given to support this factor. SCHER also notes that for some scenarios rather worst-case conditions were used. For example, the calculations for phosphate applications on agricultural soils use application rates that are actually valid for less than 25 % of Swedish soils. The calculations of the water surface concentrations in the brooks after drainage seem problematic and the proposed levels do not correspond with the measured concentrations given elsewhere in the report. The PNECs used in the Swedish risk assessment are those suggested in the EU RAR on cadmium and as such can be supported by SCHER. The presented risk characterisation ratios (RCR) are thus solely dependent on the exposure assessment, i.e. the predicted cadmium concentrations in Swedish surface waters. The latter are dependent on the – unsubstantiated – soil/brook dilution factor. SCHER does not agree either with the assumption that there is no adsorption of cadmium in the soil. This will occur only if the soil is already heavily contaminated and no net adsorption occurs at steady state, which is not the situation in Sweden. The Swedish report also assumes that there is no cadmium adsorption in soil occurring deeper than 30 cm, which is also not the case. Consequently, SCHER does not support the results presented by the Swedish authorities for brooks, which is the only environmental compartment for which the Swedish authorities had identified risks.

(29) Nonetheless, SCHER recalls the earlier assessment of CSTEE in 2002, which estimated that cadmium concentrations in soil are expected not to increase in most European soils at a limit of 46 mg Cd/kg P. SCHER confirms that such estimate is still defendable including for Swedish agricultural soils and notes that the derivation was based on a 'stand-still principle', not on a risk assessment as performed by the Swedish authorities in their current justification.

(30) Although, in its opinion of 27 February 2012, SCHER considers that the risk assessment report prepared by the Swedish authorities is of good scientific quality and contains new and relevant data, some uncertainties remain regarding certain key assumptions used by the Swedish authorities to conclude that there is a risk to aquatic organisms in small brooks in Sweden. This will need further clarification from the Swedish authorities to allow the Commission to take a final position.

2.2. *Absence of danger to human health*

(31) In their justification, the Swedish authorities identify risks for sensitive groups of the population (diabetics, people suffering from osteoporosis or iron deficiency). These risks are caused by long-term exposure to cadmium through the diet. Therefore, there is no danger to human health linked to a decision to extend the assessment of the Swedish situation for an additional period of six months. This additional period will allow the Commission to take into account further clarifications to be provided by the Swedish authorities in order to take a final decision.

(32) Based on the above, the Commission considers that the conditions laid down in Article 114(6), third subparagraph, are met in order for it to have recourse to the possibility of extending the six-month period within which it has to approve or reject the national provisions notified by Sweden.

IV. **CONCLUSION**

(33) In the light of the foregoing, it can be concluded that the request of the Kingdom of Sweden for introducing national provisions derogating from Regulation (EC) No 2003/2003 is admissible.

(34) However, in view of the complexity of the matter and of the absence of danger for human health by adopting the present Decision, the Commission considers it justified to extend the period referred to in Article 114(6), first paragraph, TFEU for a further period expiring on 18 October 2012,

([1]) http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_156.pdf

HAS ADOPTED THIS DECISION:

Article 1

Pursuant to Article 114(6), third paragraph, TFEU, the period to approve or reject the envisaged national provisions on cadmium in fertilisers notified by the Kingdom of Sweden on 17 October 2011 pursuant to Article 114(5) TFEU is extended until 18 October 2012.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 18 April 2012.

For the Commission
Antonio TAJANI
Vice-President