

COMMISSION DECISION

of 17 October 2012

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

(notified under document C(2012) 7177)

(Only the Swedish text is authentic)

(Text with EEA relevance)

(2012/719/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 P₂O₅). 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 P₂O₅) 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 notification [...] 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.
- (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 ⁽⁴⁾, 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.

⁽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.

⁽⁴⁾ OJ L 138, 28.5.2002, p. 24.

⁽¹⁾ OJ L 304, 21.11.2003, p. 1.

- (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⁽¹⁾ 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)⁽²⁾ 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 P₂O₅).
- (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⁽³⁾.
- (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*⁽⁴⁾ 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.
- (17) In view of the complexity of the matter, 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.
- (18) SCHER adopted its opinion on 27 February 2012⁽⁵⁾. SCHER concluded that the risk assessment report prepared by the Swedish authorities was of good scientific quality and that in general the scenarios studied were appropriate and most parameter values used in the scenarios acceptable. However, SCHER considered that a number of statements in the report were not supported by sufficient evidence.
- (19) Due to the remaining uncertainties identified by the SCHER regarding key assumptions used by the Swedish authorities to conclude that there is a risk to aquatic organisms in small brooks in Sweden, which is the only environmental risk identified by the Swedish authorities, and in the absence of evidence highlighting a danger for human health linked to a prolongation of the period for assessment of the Swedish request, the Commission deemed justified to extend the period referred to in Article 114(6), first subparagraph.

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

⁽¹⁾ OJ L 129, 17.5.2006, p. 19.

⁽²⁾ Swedish Code of Statutes (SFS Svensk Författningssamling) of 14 July 1998.

⁽³⁾ Swedish Code of Statutes (SFS Svensk Författningssamling) of 4 June 2009.

⁽⁴⁾ OJ C 309, 21.10.2011, p. 8 and OJ C 339, 19.11.2011, p. 24.

⁽⁵⁾ http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_156.pdf

- (20) On 18 April 2012, the Commission notified the Kingdom of Sweden of its Decision⁽¹⁾, pursuant to Article 114(6), third subparagraph, TFEU, to extend the period of six months referred to in its first subparagraph to approve or reject the notified national provisions for a further period expiring on 18 October 2012.
- (21) By letter of 27 April 2012, the Commission informed the Swedish authorities about the uncertainties identified in the SCHER opinion and invited them to provide further clarifications that would allow the Commission to take a final position.
- (22) By letter of 2 July 2012, the Swedish authorities replied to the Commission without addressing the uncertainties identified by SCHER and, instead, argued that the notion of 'protection of the environment' under Article 114(5) TFEU covers health aspects. Therefore, an examination of the Swedish notification should include arguments in the notification relating to human health aspects.

III. ASSESSMENT

1. Consideration of admissibility

- (23) The Commission considered in Decision 2012/230/EU that the application submitted by the Kingdom of Sweden with a view to obtaining an authorisation to introduce stricter national measures concerning the maximum admissible content of cadmium in fertilisers is admissible.

2. Assessment of merits

- (24) In accordance with the provisions of Article 114 TFEU, the Commission has to assure that all conditions enabling a Member State to avail of the possibilities of derogation provided for in that Article are met.
- (25) Article 114(5) TFEU requires that when a Member State deems it necessary to introduce national provisions derogating from a harmonisation measure, those provisions have to be justified on the basis of 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.
- (26) In addition, pursuant to Article 114(6) TFEU, the Commission is either to approve or reject the draft national provisions in question after verifying 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.

- (27) Concerns regarding adverse effects of cadmium in fertilisers on the environment (and human health) were already extensively raised 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 Union legislation on fertilisers in order to allow a careful evaluation of the risks from cadmium in fertilisers at EU level.

- (28) In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) was asked by the Commission for its opinion⁽²⁾ on the likelihood for accumulation of cadmium in soils through the use of phosphate fertilisers. Based on risk assessment studies carried out by eight Member States and additional analysis, the SCTEE estimated that phosphate fertilisers containing 60 mg cadmium/kg P₂O₅ or more are expected to lead to cadmium accumulation in most EU soils whereas phosphate fertilisers containing 20 mg cadmium/kg P₂O₅ or less are not expected to cause long-term soil accumulation over 100 years, if other cadmium inputs are not considered.

- (29) In the framework of Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁽³⁾, cadmium and cadmium oxide were identified as priority substances for evaluation.

- (30) When Regulation (EC) No 2003/2003 was adopted, the Commission did not set a limit value for cadmium in fertilisers but recognised the need to address this specific concern once information from the EU risk assessment on cadmium and cadmium oxide would become available.

- (31) The EU Risk Assessment Report on cadmium and cadmium oxide was issued in December 2007⁽⁴⁾. Based on its conclusions, the Risk Reduction Strategy for cadmium and cadmium oxide recommended concrete measures to reduce cadmium content in food-stuffs, tobacco blends and for phosphate fertilisers taking into account the variety of conditions throughout the Union⁽⁵⁾.

- (32) Work is ongoing at EU level to set appropriate limit values for cadmium in fertilisers taking into account a range of factors including also the variety of conditions throughout the EU, as well as the availability, geographic origin and composition of phosphates for the production of fertilisers. The Commission intends to include appropriate limits for contaminants in fertilising materials (including cadmium) in the proposal for the revision of the Fertilisers Regulation which is planned for 2013.

⁽¹⁾ Commission Decision 2012/230/EU 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 (OJ L 116, 28.4.2012, p. 29).

⁽²⁾ http://ec.europa.eu/health/ph_risk/committees/sct/documents/out162_en.pdf

⁽³⁾ OJ L 84, 5.4.1993, p. 1.

⁽⁴⁾ http://esis.jrc.ec.europa.eu/doc/risk_assessment/REPORT/cdoxidereport302.pdf

⁽⁵⁾ OJ C 149, 14.6.2008, p. 6.

- (33) To support their request for lowering the existing limit value in Sweden, the Swedish authorities have conducted a new risk assessment of cadmium in the Swedish environment, which was finalised in January 2011. It compares the predicted no effect concentrations (PNECs) for organisms representative for various environmental compartments with the cadmium concentrations in the Swedish environment taking on the basis of various scenarios for cadmium input from fertilisers and other sources. In the 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) TFEU (which were already taken into account to justify the current derogation allowing Sweden to maintain a maximum level of 100 grams of cadmium per tonne of phosphorous) and to the EU risk assessment on cadmium and cadmium oxide.
- (34) 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. It is, therefore, likely that aquatic organisms in Swedish waters are in general more sensitive to cadmium compared to waters in central and southern Europe.
- (35) 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.
- (36) 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 CaCO₃/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.
- (37) Due to the complexity of the relations between soil cadmium inputs via phosphate fertilisers, possible soil accumulation and risks to the environment, 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.
- (38) SCHER adopted its opinion on 27 February 2012 ⁽¹⁾. As already presented in Decision 2012/230/EU, 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 considered that a number of statements and/or assumptions in the report were not supported by sufficient evidence and that for some scenarios rather worst case conditions were used. SCHER considered that the assumptions proposed by the Swedish authorities to predict cadmium concentration in soft water could lead to an over-estimation of the risks and, consequently, did 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. Overall, SCHER did not consider the assumptions made in the Swedish report as appropriate for calculating risk in the Swedish environment.
- (39) None the less, SCHER recalled 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. Although not being new scientific evidence, SCHER confirmed that such estimate is still defensible including for Swedish agricultural soils and noted 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.
- (40) In their letter of 2 July 2012, the Swedish authorities have not provided further clarification that would address the weak points identified by SCHER with regard to the possible risks to the environment. Noting that the opinion of CSTEE in 2002 predates the adoption of Regulation (EC) No 2003/2003, the Commission, therefore, concludes that the Swedish authorities have not demonstrated that there is a risk to the environment based on new scientific evidence on grounds of a problem specific to Sweden arising after the adoption of Regulation (EC) No 2003/2003.
- (41) In their letter of 2 July 2012, the Swedish authorities argued that the notion of 'protection of the environment' in Article 114(5) TFEU covers health aspects and that an examination of the Swedish notification should, therefore, include arguments relating to the health aspects.

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

- (42) Without prejudice to the correct legal interpretation of Article 114(5), the Commission extended its analysis to the assessment of possible risks posed by cadmium in fertilisers to the Swedish population via the environment, i.e. notably through dietary intake.
- (43) In their justification, the Swedish authorities identify health-related grounds for further reducing cadmium exposure amongst the population in Sweden, such as a high frequency of osteoporosis, increased cases of brittle bones and bone fractures, impacts on the functioning of kidneys in parts of the population where cadmium content exceed 1 mg/g creatinine, as well as risks for sensitive groups of the population (diabetics and people suffering from iron deficiency, both groups being of high proportion in Sweden). According to the Swedish authorities, the lower pH level in Swedish soils may lead to higher uptake of cadmium in crops, which in turn can lead to higher exposure of the population, as exposure depends to a great extent on the intake of cadmium through food, above all food of plant origin.
- (44) The Commission requested a further opinion of SCHER on whether the risks to human health identified by the Swedish authorities are specific to Sweden and have arisen after the adoption of Regulation (EC) No 2003/2003⁽¹⁾.
- (45) With regard to the question whether the situation in Sweden is different compared to other parts of Europe, SCHER agreed that soil pH is on average lower in Sweden than in other parts of Europe. However, as cadmium removal from the soil by leaching is also increasing with lower soil pH value, the net cadmium soil accumulation is lower in Sweden than in most parts of Europe at comparable cadmium concentration and fertiliser application rates. SCHER notes that the Swedish report itself (summary of Annex IV) supports SCHER's conclusion as it states: 'It was difficult to unambiguously show whether there are specific conditions in Sweden that make Swedish soils more vulnerable to Cd input than those in central Europe. However, pH is a major factor that regulates the uptake of cadmium from soils to crops and pH in Swedish soil appears to be around one pH unit lower than the general average for Europe. This is probably related to the scarcity of lime-bearing bedrock in Sweden. Swedish wheat also contains cadmium in levels that are comparable to those in many other European countries, in spite of the fact that cadmium concentrations in Swedish soils are relatively low'. SCHER comments that while input data on atmospheric deposition have been updated in the Swedish report, the scenarios for mass balance calculation were already included in the scenarios considered in the opinion of the CSTE of 2002, and there is no new information suggesting that these would not be applicable anymore.
- (46) SCHER agrees that the lower pH increases cadmium bioavailability and uptake by crops, hence that the soil cadmium availability to wheat is somewhat larger than in most European countries. However, SCHER notes that if that low pH is maintained, the future trends in crop cadmium concentrations are smaller (lower increase) in Sweden compared to most other trends in Europe because soil cadmium increases at a lower rate at equal input.
- (47) With regard to dietary exposure to cadmium, SCHER concludes that the Swedish report does not provide data suggesting that dietary cadmium exposure is larger in Sweden than in the rest of Europe neither at the mean nor at the upper percentiles of exposure. Recent trends do not suggest an increasing trend in dietary exposure, including body burden cadmium in the general population. Lastly, SCHER notes that the Swedish report provides evidence that effects of cadmium on human health in Sweden can be noted at a body burden of cadmium that is lower than that reported before, however it does not provide evidence that the Swedish population is more sensitive or became more sensitive to cadmium than those in other European countries.
- (48) Overall, SCHER concludes that the Swedish report contains a detailed and updated assessment of long-term effects of cadmium from fertilisers on human health via the food chain. SCHER notes that the report does not provide convincing arguments to show that the Swedish case is a unique one or that data which appeared after the adoption of Regulation (EC) No 2003/2003 suggest specific reasons for additional concern.
- (49) In conclusion, the Commission considers that the Kingdom of Sweden has not provided justification for the intended national measure with regard to the maximum content of cadmium in fertilisers on the basis of new scientific evidence relating to the protection of the environment on grounds of a specific problem in Sweden having arisen after the adoption of Regulation (EC) No 2003/2003.
- (50) The Commission notes that the Swedish notification does not refer to the protection of the working environment as a ground for introducing the notified measure.

IV. CONCLUSION

- (51) Article 114(5) TFEU requires that, if a Member State deems it necessary to introduce national provisions in derogation from Union harmonisation measures, the national provisions must be justified by new scientific evidence relating to the protection of the environment or the working environment, there must be a problem specific to the State making the request, and the problem must have arisen after the adoption of the harmonisation measure.

⁽¹⁾ Opinions of SCHER are available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/index_en.htm#id5

- (52) In this case, after having examined the Swedish request, the Commission considers that the Kingdom of Sweden has not provided new scientific evidence relating to the protection of the environment or working environment demonstrating that there is a specific problem within its territory which arose following the adoption of Regulation (EC) No 2003/2003 relating to fertilisers, and which makes it necessary to introduce the notified national measures.
- (53) Consequently, the request from the Kingdom of Sweden for introducing national measures to lower the content of cadmium allowed in phosphorous fertilisers to a maximum level of 46 grams of cadmium per tonne of phosphorous does not fulfil the conditions set out in Article 114(5).
- (54) Under Article 114(6) of the EC Treaty, the Commission is either to approve or reject the draft national provisions in question after verifying whether or not they are a means of arbitrary discrimination or a disguised restriction to trade between Member States, and whether or not they shall constitute an obstacle to the functioning of the internal market.
- (55) Since the request made by the Kingdom of Sweden does not fulfil the basic conditions set out in Article 114(5), there is no need for the Commission to verify the conditions in Article 114(6).
- (56) 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 but does not fulfil the conditions set out in Article 114(5) TFEU, as Sweden did not provide new scientific evidence relating to the protection of the environment on grounds of a problem specific to their territory arising after the adoption of Regulation (EC) No 2003/2003.

- (57) The Commission therefore considers that the notified national provisions cannot be approved in accordance with Article 114(6) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The envisaged national provisions intended to 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, which the Kingdom of Sweden notified to the Commission on 17 October 2011, are rejected.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 17 October 2012.

For the Commission
Antonio TAJANI
Vice-President