

Commission Decision of 24 May 2006 on the national provisions notified by the Czech Republic under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers (notified under document number C(2006) 2036) (Only the Czech version is authentic) (Text with EEA relevance) (2006/390/EC)

COMMISSION DECISION

of 24 May 2006

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

(notified under document number C(2006) 2036)

(Only the Czech version is authentic)

(Text with EEA relevance)

(2006/390/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

I. FACTS

(1) By letter of the Office of the Permanent Representation of the Czech Republic to the European Union of 1 December 2005, the Czech Government, referring to Article 95(4) of the Treaty, notified to the Commission its national provisions regarding the cadmium content in fertilisers that it deems necessary to maintain after the adoption of Regulation (EC) No 2003/2003 of the European Parliament and the Council of 13 October 2003 relating to fertilisers⁽¹⁾.

1. ARTICLE 95(4) AND (6) OF THE TREATY

(2) Article 95(4) and (6) of the Treaty provides:

4. 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.

(...)

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

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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.

In the absence of a Decision by the Commission within this period the national provisions referred to in paragraphs 4 (...) 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. COMMUNITY 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⁾, as last amended by Directive 98/97/EC⁽³⁾, laid down the requirements that fertilisers must fulfil in order to be placed on the market with the designation 'EC fertilisers'. Directive 76/116/EEC has been replaced by Regulation (EC) No 2003/2003.

(4) Annex I to Regulation (EC) No 2003/2003 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.

(5) The rules governing the composition of fertilisers covered by Regulation (EC) No 2003/2003 do not provide for a limit value for the cadmium content of EC-designated fertilisers.

(6) Article 5 stipulates that Member States are not permitted 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 Regulation.

(7) Recital 15 of the Regulation 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.

3. NATIONAL DEROGATIONS GRANTED TO AUSTRIA, FINLAND AND SWEDEN

(9) The environmental concerns caused by cadmium in fertilisers were raised at Community level during the negotiations for the Accession of Austria, Finland and Sweden to the European Union. In their Act of Accession these three countries 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.

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(10) On the basis of the conclusions of national risk assessments, the Commission renewed in 2002 the derogations to Austria⁽⁴⁾, Finland⁽⁵⁾ and Sweden⁽⁶⁾ until 31 December 2005. Due to delays in the adoption of Community legislation concerning the content of cadmium in phosphorous fertilisers, the derogations were once again extended in January 2006.

(11) The following provisions are currently in place:

- Article 1 to Commission Decision 2006/349/EC⁽⁷⁾ allows Austria to prohibit the placing on the national market of phosphorous mineral fertilisers with a cadmium content exceeding 75 mg/kg P₂O₅,
- Article 1 to Commission Decision 2006/348/EC⁽⁸⁾ allows Finland to prohibit the placing on the national market of phosphorous mineral fertilisers with a cadmium content exceeding 50 mg for each kilogram of phosphorus,
- Finally, Article 1 to Commission Decision 2006/347/EC⁽⁹⁾ allows Sweden to prohibit the placing on the national market of phosphorous mineral fertilisers with a cadmium content exceeding 100 grams per tonne of phosphorous.

(12) These derogations shall apply until harmonised measures on cadmium in fertilisers are adopted at EU level.

4. CZECH NATIONAL LEGISLATION

(13) The national provisions notified by the Czech Republic were introduced by the Fertilisers Act⁽¹⁰⁾. Article 3, paragraph 2, point (c) stipulates that it is prohibited to place on the national market a fertiliser with a higher content of hazardous substances than that specified in the Decree.

(14) Decree 474/2000 of 13 December 2000 laying down requirements for fertilisers⁽¹¹⁾, sets, *inter alia*, the limit value for cadmium in mineral fertilisers. According to Annex I, the cadmium content of phosphorous mineral fertilisers (with 5 % P₂O₅ or more) cannot exceed 50 mg/kg of P₂O₅.

(15) The Czech Republic acceded to the European Union on 1 May 2004. The Act of Accession does not contain transitional provisions concerning the use and marketing of cadmium in the national territory.

(16) Decree 209/2005 of 20 May 2005 amending Decree 474/2000 on establishing the requirements for fertilisers⁽¹²⁾, brings the national provisions in line with Regulation (EC) No 2003/2003. Article 1, paragraph 1 of the Decree, stipulates that the market restriction on cadmium in fertilisers is only applicable to national fertilisers. It does not apply to 'EC-type' fertilisers.

II. PROCEDURE

(17) By letter of 1 December 2005, the Czech authorities notified the Commission its national provisions on the cadmium content in fertilisers that it intends to maintain after the adoption of Regulation (EC) No 2003/2003.

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(18) By letter of 13 December 2005, the Commission informed the Czech Government that it had received the notification under Article 95(4) of the Treaty and that the six-month period for its examination under Article 95(6) started on 6 December 2005, the day following the day on which the notification was received.

(19) By letter of 2 February 2006, the Commission informed the other Member States of the notification received from the Czech Republic. The Commission also published a notice regarding the notification in the *Official Journal of the European Union*⁽¹³⁾ in order to inform other interested parties of the national provisions that the Czech Republic intends to maintain as well as the grounds invoked to that effect.

III. ASSESSMENT

1. CONSIDERATION OF ADMISSIBILITY

(20) 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.

(21) The notification submitted by the Czech authorities on 1 December 2005 intends to obtain authorisation to maintain the application of national provisions incompatible with those concerning the composition of EC-denominated fertilisers contained in Regulation (EC) No 2003/2003.

(22) 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, EC-denominated fertilisers complying with the requirements of that Regulation can be placed on the market regardless of their cadmium content.

(23) In the light of the above mentioned, it is clear that the national provisions notified by the Czech Republic, in so far as they prohibit the placing on the market of EC-denominated phosphorus mineral fertilisers with a cadmium content exceeding 50 mg/kg P₂O₅, are more restrictive than those contained in Regulation (EC) No 2003/2003.

(24) As indicated above, the Commission has already granted derogations to maintain the national legislation to Austria, Finland and Sweden. Although their Act of Accession already included transitional provisions, the derogations were renewed on the basis of the conclusions of risks assessments provided by the national authorities following a common methodology agreed by the European Commission.

(25) Article 95(4) requires that the notification of the national provisions be accompanied by a description of the grounds relating to one or more of the major needs referred to in Article 30 or to the protection of the environment or the working environment. The application submitted by the Czech Republic contains the actual

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wording of the national provisions, together with a study⁽¹⁴⁾ to assess risks resulting from the use of phosphate fertilisers containing cadmium which, in the opinion of the Czech authorities, justify the maintenance of its national provisions. The national risk assessment follows the methodology agreed by the European Commission.

- (26) In the light of the foregoing, the Commission is of the opinion that the notification submitted by the Czech Republic 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) of the EC Treaty.

2. ASSESSMENT OF MERITS

- (27) 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.

- (28) In particular, the Commission has to assess whether the provisions notified by the Member States 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.

- (29) 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.

- (30) The Czech Republic 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, the Czech Republic makes reference to the conclusions of a national study, which contains an assessment of the risks posed by cadmium-containing fertilisers.

2.1. JUSTIFICATION ON GROUNDS OF MAJOR NEEDS REFERRED TO IN ARTICLE 30 OR RELATING TO THE PROTECTION OF THE ENVIRONMENT OR WORKING ENVIRONMENT

2.1.1. General information on cadmium

- (31) 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, combustion of fossil fuels, application of fertiliser, etc.).

- (32) 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 draft report is available for discussions at the technical level.

- (33) 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 human

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health, in particular to kidneys and bones. Furthermore, cadmium oxide has been classified as a carcinogen, 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. The draft general risk assessment calls for caution as risk to human health can not be excluded for local and regional situations, and that even risk factors that are below 1.0 may not be protective enough for all sections of the general population because of the large variability in food cadmium concentrations, dietary habits and nutritional status.

2.1.2. Cadmium in fertilisers

(34) 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.

(35) 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.

(36) 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.

(37) 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⁽¹⁶⁾. Member States were subsequently invited to carry out nation-wide risk assessments by making use of the above methodology and procedures.

(38) 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⁽¹⁷⁾. 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⁽¹⁸⁾.

(39) The above national risk assessments were submitted to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)⁽¹⁹⁾ for evaluation. In particular, the CSTEE was 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

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content of cultivated soil. The CSTEE concluded that the content of cadmium in fertilisers does need to be limited to prevent accumulation of cadmium in the soil. Accumulation can occur in some soils even when fertilisers containing very low cadmium concentrations and will not be observed in some soils even when using fertilisers with high cadmium levels. However, fertilisers containing less than 20 mg Cd/kg P₂O₅ would, in most soils, not expect to result in long-term soil accumulation, if other Cd inputs are not considered, while fertilisers containing more than 60 mg Cd/kg P₂O₅ would, in most soils, expect to result in long-term soil accumulation. Therefore, a limit for cadmium in phosphate fertilisers should be derived based on a risk assessment approach and taking all cadmium sources into account⁽²⁰⁾.

(40) The completion of the general risk assessment on cadmium and cadmium oxide has taken a relatively long time, and there is at present no final EU-wide assessment of risks from cadmium. The final draft of the general risk assessment, dated March 2005, endorses the opinion of the CSTEE concerning the accumulation of cadmium 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.

(41) 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.

2.1.3. The risk assessment carried out by the Czech Republic

(42) In support of the request for a limit on cadmium in phosphate fertilisers the Czech authorities have submitted a national risk assessment. The framework used for conducting its risk assessment is built around three modules:

2.1.3.1. The accumulation module

(43) According to this module, the net accumulation of cadmium in soil and soil solution (or pore water)⁽²¹⁾, resulting from the application of fertilisers, is computed over time at steady state. The accumulation module allows for a range of inputs, for example average and extreme rates of application. The Czech risk assessment shows that with this module the following parameters have been considered:

- the present day cadmium concentration in soil,
- the cadmium input rate (due to mineral fertilisers but also to atmospheric deposition, soil conditioning preparations, sewage sludge and weathering of parent rock),
- the cadmium up-take rate concerning plants,
- the cadmium leaching rate, depending on the annual precipitation excess and the concentration of cadmium in the pore water leachate,
- the concentration of cadmium in the soil and leaching rates at present and after one hundred years for three scenarios: current conditions, conditions

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of increased fertiliser application rates and conditions of increased fertiliser cadmium content.

2.1.3.2. The exposure module

(44) 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 characterising both current and extreme exposure scenarios.

2.1.3.3. The risk characterisation module

(45) This module allows the Czech Republic to estimate the incidence and severity of the adverse effects likely to occur due to actual or predicted exposure to cadmium. Calculations are performed for three scenarios and four PNEC⁽²²⁾ values.

2.1.4. The results of the risk assessment

(46) The application of the modules has produced hazard indices (PEC/PNEC ratios)⁽²³⁾ in the range of 0,1-1,19, with a realistic worse-case value of 0,93 highlighted as justification for national restrictions, provided that the cadmium content in phosphorous mineral fertilisers does not exceed 50 mg/kg P₂O₅.

2.1.5. Evaluation of the position of the Czech Republic

(47) The risk-assessment submitted by the Czech 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.

(48) Given that the value proposed by the Czech Republic to justify the maintenance of national measures is to a PEC/PNEC ratio close to 1, it was deemed appropriate to submit the risk-assessment to the Commission's Scientific Committee on Health and Environmental Risks (SCHER) for a careful evaluation.

(49) In particular, the SCHER has been requested to:

- Assess the overall scientific quality of the Czech report and identify any major deficiencies.
- Comment on the appropriateness of the scenarios studied and on the conclusions concerning the accumulation of cadmium in the soil.
- Comment on whether the reported PEC/PNEC ratio of 0,93 is the most appropriate value to describe the risk to human health and the environment.

(50) The evaluation of the position of the Czech Republic is therefore deferred until the Commission receives the opinion of the scientific committee.

2.2. RECOURSE TO ARTICLE 95(6), THIRD SUBPARAGRAPH, OF THE TREATY

(51) After a careful examination of these data, the Commission considers that the conditions laid down in Article 95(6), third subparagraph, are met in order for it to

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have recourse to the possibility of extending the six-month period within which it has to approve or reject the national provisions provided for by that Article.

2.2.1. Justification based on the complexity of the matter

(52) In view of the study submitted by the Czech authorities, which concludes that the PEC/PNEC ratio is very close to 1, an examination by the SCHER is necessary in order to clarify whether there is indeed a risk to the environment and human health. The Commission's scientific committee was consulted in the past when Austria, Finland and Sweden submitted similar studies in support of their request for a national derogation. The Commission Decision under Article 95(6), first subparagraph, should therefore await the outcome of this review. In these circumstances, the Commission considers that it is justified to extend the six-month period within which it has to approve or reject the national provisions for a further period in order to allow for a careful evaluation and opinion by the scientific committee and for corresponding conclusions to be drawn as regards the national provisions. To this end, a period expiring on 6 December 2006 is necessary.

2.2.2. Absence of danger to human health

(53) On the basis of the assumptions and scenarios used, the Czech report concludes that there is currently no risk to human health resulting from the use of cadmium in fertilisers.

(54) The permitted tolerable weekly intake (PTWI) of cadmium set by the WHO (World Health Organisation) is of 7 µg/kg/week. This limit is equivalent to 60 µg/day for an individual with an average weight of 60 kg. In the Czech Republic, the average daily cadmium intake by an adult was estimated at 12-27 µg/day in 2000, depending on the scenario envisaged, which amounts to approximately 19 %-45 % of the WHO limit.

(55) In the human risk characterisation module provided by the Czech authorities, the intakes of cadmium identified in different scenarios were compared with the limit values recommended by the WHO. The result is the so-called margin of safety (MOS). When the margin of safety exceeds 1, the examined situation can be considered as a source of potential health risk for an exposed person. Under the assumptions and with the methodology used in the Czech report, which is being scrutinised by the Scientific Committee, the limit MOS ratio of 1 was not exceeded in any of the exposure scenarios, including the upper-bound scenario studied, i.e. assuming that 100 % of supplied food originates from fertiliser-applied areas and that the cadmium content is at the level of 90 mg/kg P₂O₅.

IV. CONCLUSION

(56) In the light of the foregoing, the Commission concludes that the application that the Czech Republic notified to it on 1 December 2005 with a view to obtaining approval of its national provisions on the limit of the cadmium content in fertilisers is admissible.

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- (57) However, in view of the complexity of the matter and of the absence of evidence highlighting a danger for human health, the Commission considers it justified to extend the period referred to in Article 95(6), first subparagraph, for a further period expiring on 6 December 2006,

HAS ADOPTED THIS DECISION:

Article 1

Pursuant Article 95(6), third subparagraph, of the Treaty, the period referred to in the first subparagraph of the said Article to approve or reject the national provisions on cadmium in fertilisers notified by the Czech Republic on 1 December 2005 pursuant to Article 95(4) is extended until 6 December 2006.

Article 2

This Decision is addressed to the Czech Republic.

Done at Brussels, 24 May 2006.

For the Commission
Günter VERHEUGEN
Vice-President

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- (1) [OJ L 304, 21.11.2003, p. 1.](#)
- (2) [OJ L 24, 30.1.1976, p. 21.](#)
- (3) [OJ L 18, 23.1.1999, p. 60.](#)
- (4) Commission Decision 2002/366/EC of 15 May 2002 on the national provisions notified by the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers ([OJ L 132, 17.5.2002, p. 65](#)).
- (5) Commission Decision 2002/398/EC 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 ([OJ L 138, 28.5.2002, p. 15](#)).
- (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 ([OJ L 138, 28.5.2002, p. 24](#)).
- (7) [OJ L 129, 17.5.2006, p. 31.](#)
- (8) [OJ L 129, 17.5.2006, p. 25.](#)
- (9) [OJ L 129, 17.5.2006, p. 19.](#)
- (10) Act 156/1998 of 12 June 1998 on fertilisers, supplementary soil substances, supplementary plant preparations and substrates and on agrochemical testing of agricultural land (Sbírka zákonů České Republiky No 54, 13.7.1998, p. 6709).
- (11) Sbírka zákonů České Republiky No 137, 20.12.2000, p. 7404.
- (12) Sbírka zákonů České Republiky No 75, 20.5.2005, p. 3928.
- (13) [OJ C 29, 4.2.2006, p. 8.](#)
- (14) Čupr, P., Sářka, M., Holoubek, I.: Study to assess risks to the environment and health resulting from the use of phosphate fertilisers containing cadmium, November 2005; RECETOX Research Centre for Environmental Chemistry and Ecotoxicology, Masaryk University; TOCOEN REPORT No 285. <http://europa.eu.int/comm/enterprise/chemicals/legislation/fertilizers/cadmium/sctee.pdf>
- (15) [OJ L 84, 5.4.1993, p. 1.](#)
- (16) 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 for cadmium in fertilisers, March 1999; See also ERM, study to establish a programme of detailed procedures for the assessment of risks to health and the environment from cadmium in fertilisers, February 2000.
- (17) http://europa.eu.int/comm/enterprise/chemicals/legislation/fertilizers/cadmium/reports_en.htm
- (18) ERM, analysis and conclusions from Member States' assessment of the risk to health and the environment from Cadmium in fertilisers, October 2001.
- (19) Renamed SCHER (Scientific Committee on Health and Environmental Risks).
- (20) CSTEE's opinion on Member State assessments of the risk to health and the environment from cadmium in fertilisers. Opinion expressed at the 33rd CSTEE Plenary meeting, Brussels, 24 September 2002. <http://europa.eu.int/comm/enterprise/chemicals/legislation/fertilizers/cadmium/sctee.pdf>
- (21) Pore water means that part of the water contained in the soil which is maintained by capillarity between the solid particles of the soil.
- (22) PNEC: Predictable No-Effect Concentration.
- (23) The risk-assessment methodology, outlined in Commission Regulation (EC) No 1488/94 and further detailed in the Technical Guidance Document on risk assessment for new and existing substances, consists in calculating the ratios between the Predicted Environmental Concentration (PEC) of a given substance and the Predicted No-Effect Concentration (PNEC) of that substance in any specific environmental compartment. Risk is quantified by the PEC/PNEC ratio, a quantity referred to in the Czech report as the hazard index. A PEC/PNEC ratio below 1 indicates no risk to the environment, whereas a ratio of 1 or greater indicates a situation of real or potential risk; the larger the value, the greater the magnitude of the effect. Proportionate risk management measures are indicated in cases where the PEC/PNEC ratio is greater than 1.

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