# DECISIONS

# COMMISSION DECISION (EU) 2020/1205

of 6 August 2020

on the national provisions notified by the Slovak Republic pursuant to Article 114(4) of the Treaty on the Functioning of the European Union concerning the cadmium content in phosphate fertilisers

(notified under document C(2020) 5285)

(Only the Slovak text is authentic)

THE EUROPEAN COMMISSION,

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

Whereas:

# 1. FACTS AND PROCEDURE

(1) On 9 August 2019, the Slovak Republic notified the Commission, based on Article 114(4) of the Treaty on the Functioning of the European Union (TFEU), of its intention to maintain national provisions on cadmium content in phosphate fertilisers derogating from Regulation (EU) 2019/1009 of the European Parliament and of the Council (<sup>1</sup>).

#### 1.1. Union Legislation

1.1.1. Article 114(4) and (6) TFEU

(2) Article 114, paragraphs 4 and 6 TFEU provide:

<sup>4</sup>. 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 maintain national provisions on grounds of major needs referred to in Article 36, 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 notifications referred to in paragraphs 4 [...] 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 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.'

<sup>(&</sup>lt;sup>1</sup>) Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

# 1.2. Harmonisation rules in the field of fertilising products

#### 1.2.1. Regulation (EC) No 2003/2003

- (3) Regulation (EC) No 2003/2003 of the European Parliament and the Council (<sup>2</sup>) applies to products which are placed on the market as fertilisers designated 'EC fertilisers'. A fertiliser belonging to a type of fertilisers listed in Annex I to Regulation (EC) No 2003/2003 and complying with the conditions laid down in that Regulation may be designated 'EC fertiliser' and move freely in the internal market.
- (4) Annex I to Regulation (EC) No 2003/2003 sets an exhaustive list of types of fertilisers covered by the harmonisation rules. For each type of fertiliser there are specific requirements concerning, for instance, nutrient content, nutrient solubility or processing methods.
- (5) Regulation (EC) No 2003/2003 applies mainly to inorganic fertilisers. Some of the types of fertilisers covered have a phosphorus content of 5 % phosphorus pentoxide (P<sub>2</sub>O<sub>5</sub>)-equivalent or more by mass.
- (6) Article 5 of Regulation (EC) No 2003/2003 sets the principle of free circulation of EC fertilisers on the internal market, stating that Member States shall not, on grounds of composition, identification, labelling or packaging, and other provisions contained in that Regulation, prohibit, restrict or hinder the placing on the market of EC fertilisers which comply with that Regulation.
- (7) Regulation (EC) No 2003/2003 sets no limit values for contaminants in EC fertilisers. Therefore, with a few exceptions based on the Commission Decisions in application of the respective TFEU provisions (<sup>3</sup>), EC fertilisers with a phosphorus content of at least 5 %  $P_2O_5$  move freely in the internal market irrespective of their cadmium content.
- (8) Nevertheless, the Commission's intention to address the issue of unintentional cadmium content in mineral fertilisers was already announced in recital 15 of Regulation (EC) No 2003/2003. According to it 'Fertilisers can be contaminated by substances that can potentially pose a risk to human and animal health and the environment. Further to the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), the Commission intends to address the issue of unintentional cadmium content in mineral fertilisers and will, where appropriate, draw up a proposal for a Regulation, which it intends to present to the European Parliament and the Council. Where appropriate, a similar review will be undertaken for other contaminants'.

#### 1.2.2. Regulation (EU) 2019/1009

- (9) Regulation (EU) 2019/1009 sets harmonisation rules for 'EU fertilising products'. It repeals Regulation (EC) No 2003/2003 as of 16 July 2022.
- (10) EU fertilising products are fertilising products, which are CE marked when made available on the internal market. An EU fertilising product must meet the requirements set out in Regulation (EU) 2019/1009 for the relevant product function category ('PFC') and component material category or categories, and be labelled in accordance with the labelling requirements laid down therein. There are seven PFCs for EU fertilising products, one of which covers fertilisers.
- (11) Regulation (EU) 2019/1009 covers inorganic fertilisers in a more generic manner than Annex I to Regulation (EC) No 2003/2003, subject to some general requirements concerning their quality and safety. In addition, Regulation (EU) 2019/1009 applies to organic and organo-mineral fertilisers, which are outside the material scope of Regulation (EC) No 2003/2003.
- (12) Regulation (EU) 2019/1009 introduces at Union level the notion of 'phosphate fertilisers' for organo-mineral fertilisers or inorganic macronutrient fertilisers with a phosphorus content of at least 5 % P<sub>2</sub>O<sub>5</sub>.

<sup>(&</sup>lt;sup>2</sup>) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, OJ L 304, 21.11.2003, p. 1.

<sup>(&</sup>lt;sup>3</sup>) See Commission Decisions of 3 January 2006: 2006/347/EC 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 129, 17.5.2006, p. 19), 2006/348/EC 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 129, 17.5.2006, p. 25) and 2006/349/EC 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 129, 17.5.2006, p. 31).

- (13) Regulation (EU) 2019/1009 sets, for the first time at Union level, limit values for contaminants in EU fertilising products. Based on point 3(a)(ii) in PFC 1(B), Organo-mineral fertiliser, and point 2(a)(ii) in PFC 1(C)(I), Inorganic macronutrient fertiliser, of Annex I to that Regulation, the cadmium content in phosphate fertilisers must not exceed the limit value of 60 mg/kg P<sub>2</sub>O<sub>5</sub>.
- (14) The principle of free movement is enshrined in Article 3(1) of Regulation (EU) 2019/1009, according to which Member States shall not impede, for reasons relating to composition, labelling or other aspects covered by that Regulation, the making available on the market of EU fertilising products which comply with that Regulation. However, in accordance with Article 3(2) of Regulation (EU) 2019/1009, a Member State which, on 14 July 2019, benefits from a derogation from Regulation (EC) No 2003/2003 in relation to cadmium content in fertilisers granted in accordance with Article 114(4) TFEU may continue to apply the national limit values for cadmium content in phosphate fertilisers until such time as harmonised limit values for cadmium content in phosphate fertilisers which are equal to or lower than the national limit value are applicable at Union level.
- (15) In addition, by 16 July 2026, the Commission has an obligation to review the limit values for cadmium content in phosphate fertilisers, with a view to assess the feasibility of reducing these limit values to a lower appropriate level. The Commission has to take into account environmental factors, in particular in the context of soil and climatic conditions, health factors, as well as socioeconomic factors, including considerations of security of supply.

#### 1.2.3. Optional regime

- (16) The EU market for fertilising products is only partly harmonised.
- (17) Regulation (EC) No 2003/2003 aims to ensure the free circulation on the internal market of EC fertilisers. However, it does not affect 'the national fertilisers' placed on the market of the Member States in accordance with their respective national legislation. Manufacturers can choose to market fertiliser either as 'EC fertiliser' or as 'national fertiliser'.
- (18) Regulation (EU) 2019/1009 maintains intact the optional regime. Thus, it ensures the free movement on the internal market of EU fertilising products and continues to allow the placing on the market of national fertilising products. The choice remains with the manufacturer.
- (19) Based on both Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009, Member States must not impede the making available on the market of compliant EC fertilisers and, respectively, EU fertilising products, for reasons relating to, inter alia, cadmium content.
- (20) However, Member States may maintain or introduce any limit values deemed appropriate for contaminants in national fertilising products. Every Member State is concerned to a greater or lesser extent by the threat that accumulation of cadmium poses to the long-term sustainability of crop production. The majority of Member States have already introduced rules limiting the cadmium content in national fertilising products with the objective of reducing emissions of cadmium in the environment and thereby the exposure of humans to cadmium. This Decision does not refer to this type of rules.
- (21) Thus, Union harmonisation rules coexist with the national provisions applicable to fertilising products.

# 1.3. National provisions notified

- (22) The national provisions notified by the Slovak Republic as regards cadmium limit values for phosphate fertilisers ('the notified national provisions') are contained in the Slovak Ministry of Agriculture Decree No 577/2005 laying down the types of fertilisers, the composition, packaging and labelling of fertilisers, analytical methods for testing fertilisers, risk elements and their limit values for individual groups of fertilisers, permitted deviations and limits for agricultural fertilisers for the purposes of Act No 136/2000 on fertilisers and Act No 220/2004 on the protection and use of agricultural land.
- (23) Point 1 of Annex 3 to Decree No 577/2005 sets a limit value of 20 mg/kg  $P_2O_5$  for cadmium. This limit value applies to three categories of fertilisers: phosphorous fertilisers, compound fertilisers and fertilisers containing also trace elements irrespective of their content of  $P_2O_5$ . The limit value is not applicable to EC fertilisers under Regulation (EC) No 2003/2003.

- (24) The Slovak Republic has made clear in its notification and the additional information submitted to the Commission that its notification covers only phosphate fertilisers covered by Regulation (EU) 2019/1009 and made available on the market in Slovakia. Such fertilisers are referred to in point 3(a)(ii) PFC 1(B) and point 2(a)(ii) PFC 1(C)(I) of Annex I of Part II to that Regulation, which apply to inorganic and organo-mineral fertilisers with a total phosphorus content that is equal or more than 5 % phosphorus pentoxide ( $P_2O_5$ ) equivalent by mass.
- (25) Additionally, the Slovak Republic has confirmed that it does not apply for any other derogations with regard to the placing on the market of fertilising products within the meaning of Regulation (EU) 2019/1009.

# 1.4. Procedure

- (26) At the time of the adoption of Regulation (EU) 2019/1009, the Slovak Republic along with Hungary and the Czech Republic signed a political declaration expressing their regret as regards the low ambition of the final compromise on the cadmium limit value in phosphate fertilisers, and already indicating their support for national derogations from it based on Article 114(4) TFEU.
- (27) By letter of 9 August 2019, the Slovak Republic notified the Commission of its intention to maintain national provisions on cadmium content in phosphate fertilisers derogating from Regulation (EU) 2019/1009. According to Article 114(4) TFEU read in conjunction with Article 36 TFEU, the Slovak Republic's justification is based on grounds of major needs relating to the protection of human health and the protection of the environment.
- (28) By letter of 29 August 2019, the Commission acknowledged receipt of the notification and informed the Slovak authorities that the six-month period for its examination according to Article 114(6) TFEU ends on 10 February 2020.
- (29) In support of their notification based on Article 114(4) TFEU, the Slovak authorities sent by letter of 27 September 2019 additional information to the Commission. That information provides some clarifications as regards the material scope of the notified national provisions that the Slovak Republic seeks to maintain, as well as detailed data on the Slovak fertilisers market.
- (30) On top of this additional information, the Slovak Republic sent by letter of 8 November 2019 a study conducted by the French Agency ANSES concerning cadmium exposure and proposing ingestion Toxicity Reference Values (TRV), benchmark sanitary values in the body (for example in the blood and urine) and limit values for cadmium in fertilising products as well as crop supports in order to control the pollution of agricultural soils and the contamination of crop production (<sup>4</sup>).
- (31) Further, the Commission published a notice regarding the notification in the *Official Journal of the European Union* (<sup>5</sup>) in order to inform interested parties of the Slovak Republic's intention to maintain its national provisions, as well as the grounds invoked to support the request. By letter of 19 November 2019, the Commission also informed the other Member States on the notification and gave them the opportunity to submit comments thereon within 30 days.
- (32) The Commission received comments within this deadline from two Member States, namely the Czech Republic and the Kingdom of Belgium. Both Member States mentioned that they did not have any comments as regards the notification. No comments were received following the publication of the notice in the Official Journal.
- (33) In its Decision notified on 29 January 2020 (<sup>6</sup>), pursuant to the third subparagraph of Article 114(6) TFEU, in view of the complexity of the matter and the absence of danger for human health caused by the extension as such, the Commission considered it justified to extend the period referred to in the first subparagraph of Article 114(6) TFEU for a further period of six months expiring on 10 August 2020. Since the complexity of the matter was related to the conditions of admissibility, the Commission reserved the ruling on the admissibility of the notification to this decision.

<sup>(\*)</sup> Avis de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif a l'Exposition au cadmium (CAS n°7440-43-9), – Propositions de valeurs toxicologiques de référence (VTR) par ingestion, de valeurs sanitaires repères dans les milieux biologiques (sang, urine, ...) et de niveaux en cadmium dans les matières fertilisantes et supports de culture permettant de maîtriser la pollution des sols agricoles et la contamination des productions végétales: https://www.anses.fr/fr/system/files/ VSR2015SA0140.pdf

<sup>(&</sup>lt;sup>5</sup>) OJ C 394, 21.11.2019, p. 2.

<sup>(\*)</sup> Commission Decision 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 Slovak Republic pursuant to Article 114(4) of the Treaty (C(2020) 376 final).

# 2. ASSESSMENT

#### 2.1. Admissibility

- (34) Pursuant to Article 114(4) and (6) TFEU, a Member State may, after the adoption of a harmonisation measure, maintain its more stringent national provisions on grounds of major needs referred to in Article 36 TFEU, or relating to the protection of the environment or the working environment, provided that it notifies those national provisions to the Commission and the Commission approves them.
- (35) The Slovak Republic is asking the Commission to grant a derogation allowing the placing on the Slovak market of only those phosphate fertilisers with a phosphorus pentoxide (P<sub>2</sub>O<sub>5</sub>) content of at least 5 % P<sub>2</sub>O<sub>5</sub> which contain no more than 20 mg cadmium/kg P<sub>2</sub>O<sub>5</sub>. In its letter of 27 September 2019, the Slovak Republic clarifies that their intention is to maintain a derogation from the limit value set for cadmium in phosphate fertilisers, both inorganic macronutrient fertilisers and organo-mineral fertilisers.
- (36) To ascertain the admissibility of the notification, the Commission has to assess if the notified national provisions concerned are a pre-existent measure derogating from the newly introduced harmonisation rule and if they are more protective.
  - 2.1.1. On the pre-existence of the notified national provisions
- (37) For the purpose of this assessment, it is important to take note of the particular complexity of the situation at hand.
- (38) First, the exhaustive list of narrowly defined EC fertiliser types laid down in Regulation (EC) No 2003/2003 will be replaced by an entirely different regulatory regime. Regulation (EU) 2019/1009 will thus replace those fertiliser types by much more generic fertiliser categories, and extend the scope of harmonisation to product categories other than fertilisers. In other words, while Regulation (EU) 2019/1009 will cover all products previously harmonised under Regulation (EC) No 2003/2003, it will constitute the first EU harmonisation measure for certain fertiliser categories falling under its extended scope.
- (39) Second, while Regulation (EC) No 2003/2003 harmonises EC fertilisers, it does not impose a harmonised limit value for cadmium. In other words, while some of the fertilisers targeted by the notified national provisions have, as such, already been subject to harmonisation measures, those harmonisation measures have so far not targeted the risk that the notified national provisions seek to address.
- (40) Third, the Slovak Republic did not apply for a derogation from Regulation (EC) No 2003/2003 and currently does not apply any cadmium limit for the EC fertilisers.
- (41) These complexities raise the question whether the notified national provisions could be considered as maintained in force and notifiable to the Commission in accordance with Article 114(4) TFEU with respect to Regulation (EU) 2019/1009 while having regard to the harmonisation established by Regulation (EC) No 2003/2003.
- (42) On the one hand, Article 3(2) of Regulation (EU) 2019/1009 extends past derogations from Article 5 of Regulation (EC) No 2003/2003 to Article 3(1) of Regulation (EU) 2019/1009, thus allowing existing national measures lawfully applying, on the basis of notifications under Article 114(4) TFEU and Commission decisions under Article 114(6) TFEU, to fertilisers covered by the scope of harmonisation provided for by Regulation (EC) No 2003/2003 to also apply to EU fertilising products which will fall within the newly extended scope of harmonisation for the first time by virtue of Regulation (EU) 2019/1009. That also confirms that Regulation (EU) 2019/1009 is a continuation of the harmonisation stemming from Regulation (EC) No 2003/2003.
- (43) On the other hand, Recital 11 of Regulation (EU) 2019/1009 confirms that the legislator, by paraphrasing Article 114(4) TFEU, regarded that Regulation (EU) 2019/1009 should be considered for the purpose of assessments under Article 114(4) TFEU:

'Several Member States have in place national provisions limiting cadmium content in phosphate fertilisers on grounds relating to the protection of human health and of the environment. Should a Member State deem it necessary to maintain such national provisions after the adoption of harmonised limit values under this Regulation, and until those harmonised limit values are equal to or lower than the national limit values already in place, it should notify them to the Commission in accordance with Article 114(4) TFEU. Furthermore, in accordance with Article 114(5) TFEU, if a Member State deems it necessary to introduce new national provisions, such as provisions

limiting cadmium content in phosphate fertilisers, 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 this Regulation, it should notify the Commission of the envisaged provisions as well as the grounds for introducing them. [...]'.

- (44) This interpretation is further supported by the difference in the material scope of Regulation (EC) No 2003/2003 and Regulation (EU) 2019/1009, where Regulation (EU) 2019/1009 replaces Regulation (EC) No 2003/2003 not only with an extended scope but also with an entirely different regulatory regime.
- (45) It can also be noted that in past cases where a new harmonisation measure had replaced an existing one, the Court of Justice of the European Union ('Court'), has referred only to the newly adopted harmonisation measure as the one that should be considered for the purpose of assessments under Article 114(4) TFEU (').
- (46) In conclusion, since Regulation (EU) 2019/1009 is the harmonisation measure that should be considered for the purpose of the notified national provisions under Article 114(4) TFEU, it is for the Commission to ascertain whether the notified national provisions were pre-existing, in accordance with the requirement of Article 114(4) TFEU.
- (47) Fourth, both Regulation (EU) 2019/1009 and Regulation (EC) No 2003/2003 operate with optional regime as described above, which implies that national rules may co-exist with the EU harmonisation rules, within the same material scope as the harmonisation rules, but only to products that are not placed on the market based on the harmonisation rules. The notified national provisions have so far applied only to the latter products i.e. to fertilisers referred to in recital 17 above as 'national fertilisers'. Therefore, the current application of the notified national provisions to such national fertilisers is lawful because the harmonisation rules are optional for the person placing the fertilisers on the market. However, the Slovak Republic now intends to apply the same notified national provisions as a derogation from Regulation (EU) 2019/1009 while they are not applied as a derogation from Regulation (EC) No 2003/2003.
- (48) This complexity raises the question whether the notification made by the Slovak Republic can be considered as maintaining national provisions for the purpose of Article 114(4) TFEU, rather than introducing national provisions after the adoption of the harmonisation measure pursuant to Article 114(5) TFEU.
- (49) It can first be noted that the notified national provisions have been in force at their current state since 2005. Thus, they were in force at the time of drawing up Regulation (EU) 2019/1009 and therefore predate that Regulation. The Slovak Republic is thus not requesting to introduce national provisions after the adoption of the harmonisation measure, as would be the case for a notification under Article 114(5) TFEU.
- (50) On the other hand, it could be questioned whether the notified national provisions will be maintained within the meaning of Article 114(4) TFEU, since the notified national provisions do not, in their current state, apply to EC fertilisers. However, it is the intention of the Slovak Republic to also apply the notified national provisions to EU fertilising products. In order for this to be the case, an adjustment in the Slovak legislation is needed.
- (51) In order to determine whether the notified national provisions are pre-existing within the meaning of Article 114(4) TFEU, although they would need to be slightly adapted in order to include EU fertilising products whereas EC fertilisers remain excluded, it is important to look at the purpose of the distinction between Article 114(4) and (5) TFEU.
- (52) This distinction has been addressed by case law of the Court. In the case C-3/00 Denmark v Commission, the Court concluded with respect to Article 95 TEC, which corresponds to Article 114 TFEU:

"The difference between the two situations envisaged in Article 95 is that, in the first, the national provisions predate the harmonisation measure. They are thus known to the Community legislature, but the legislature cannot or does not seek to be guided by them for the purpose of harmonisation. It is therefore considered acceptable for the Member State to request that its own rules remain in force. To that end, the EC Treaty requires that such national provisions must be justified on grounds of the major needs referred to in Article 30 EC or relating to the protection of the environment or the working environment. By contrast, in the second situation, the adoption of new national legislation is more likely to jeopardise harmonisation. The Community institutions could not, by definition, have taken account of the national text when drawing up the harmonisation measure. In that case, the requirements referred to in Article 30 EC are not taken into account, and only grounds relating to protection of the environment

<sup>&</sup>lt;sup>(7)</sup> See C-360/14 P, Germany v Commission.

or the working environment are accepted, on condition that the Member State provides new scientific evidence and that the need to introduce new national provisions results from a problem specific to the Member State concerned arising after the adoption of the harmonisation measure' (<sup>8</sup>).

- (53) In the light of the cited case-law, it should be considered that the purpose of the distinction between Article 114(4) and (5) TFEU is to impose higher justification requirements in cases where harmonisation is more likely to be jeopardised since the national provision in question was not known to the legislator at the time of the drawing up of the harmonised measure.
- (54) As has already been established, the notified national provisions have been in force at their current state since 2005. Thus, they were in force at the time of drawing up Regulation (EU) 2019/1009 and therefore also predate that Regulation.
- (55) Further, it is evident from the Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down the rules on the making available on the market of CE marked fertilising products (<sup>9</sup>) that the notified national provisions were known to the Union legislature when drawing up Regulation (EU) 2019/1009. Consequently, the notified national provisions should be considered as pre-existing in the light of Article 114(4) TFEU.
- (56) As has been noted above, Regulation (EU) 2019/1009 is considered the relevant harmonisation measure for this particular assessment. Therefore, the notified national provisions should be assessed in the light of that Regulation. It remains to be examined whether the notified national provisions are a derogation to Regulation (EU) 2019/1009 and are more stringent than that Regulation.

2.1.2. On the stringency of the notified national provisions in relation to Regulation (EU) 2019/1009

- (57) Whereas the limit value for the cadmium content in phosphate fertilisers laid down in point 3(a)(ii) PFC 1(B) and point 2(a)(ii) PFC 1(C)(I) of Part II of Annex I to Regulation (EU) 2019/1009, from which the notified national provisions derogate, is established at 60 mg/kg  $P_2O_5$  the notified national provisions set a limit value of 20 mg/kg  $P_2O_5$  for cadmium. It is therefore clear that the notified national provisions derogate from and are more stringent than the provisions of Regulation (EU) 2019/1009.
- (58) In light of the foregoing, the following conclusions can be drawn: 1) the notified national provisions predate the harmonisation measure and were known to the legislature at the time of drawing up the harmonisation measure, namely Regulation (EU) 2019/1009. They should therefore be considered as a pre-existing measure under Article 114(4) TFEU; and 2) the notified national provisions derogating from point 3(a)(ii) PFC 1(B) and point 2(a)(ii) PFC 1(C)(I) of Part II of Annex I to Regulation (EU) 2019/1009 are more stringent than Regulation (EU) 2019/1009.
- (59) The Commission therefore considers that the notification submitted by the Slovak Republic is admissible in its entirety under Article 114(4) TFEU.

#### 2.2. Assessment of merits

- (60) In accordance with Article 114(4) and first subparagraph of Article 114(6) TFEU, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Union harmonisation measure provided for in that Article are fulfilled.
- (61) In particular, the Commission must assess whether or not the notified national provisions are justified by the major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment and do not exceed what is necessary to attain the legitimate objective pursued. In addition, when the Commission considers that the national provisions fulfil the above conditions, it must verify, pursuant to Article 114(6) TFEU, whether or not the 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.

<sup>(\*)</sup> C-3/00 Denmark v Commission, paragraph 58. Further confirmed in e.g. T-234/04 Kingdom of the Netherlands v Commission, paragraph 58, Joined Cases T-366/03 and T-235/04 Land Oberösterreich and Austria v Commission, paragraph 62 and C-512/99 Germany v Commission, paragraph 41.

<sup>(&</sup>lt;sup>9</sup>) See the impact assessment accompanying the Commission's proposal which was specifically devoted to the cadmium limit, SWD (2016) 64 final, PART 2/2; https://ec.europa.eu/transparency/regdoc/rep/10102/2016/EN/SWD-2016-64-F1-EN-MAIN-PART-2.PDF; see in particular pages 5, 6, 25, 28, 29 and 32, and Annex I.

- (62) In the light of the time frame established by Article 114(6) TFEU, the Commission, when examining whether the national measures notified under Article 114(4) TFEU are justified, has to take as a basis the justifications put forward by the notifying Member State. The burden of proof lies with the requesting Member State that seeks to maintain its national measures.
- (63) However, where the Commission is in possession of information in the light of which the Union harmonisation measure from which the notified national provisions derogate may need to be reviewed, it can take such information into consideration in the assessment of the notified national provisions.

#### 2.2.1. The position of the Slovak Republic

- (64) The Slovak Republic's position with regard to the cadmium content in phosphate fertilisers with at least 5 %  $P_2O_5$  is motivated by the long-term protection of the soil and the resulting protection of human health and the protection of the environment.
- (65) The Slovak Republic has, in its notification to the Commission, analysed the expected effects of the limit value of 60 mg/kg  $P_2O_5$  set in Regulation (EU) 2019/1009 in its national territory. This limit value raises important concerns as regards the protection of human health and of the environment. Cadmium is qualified as a carcinogenic substance, classified among the most toxic elements. Plants easily absorb cadmium and, in this way, cadmium enters into the food chain. The Slovak Republic therefore emphasises the need to reduce further exposure to cadmium entering the body with food.
- (66) In addition to human health concerns, the Slovak Republic also presents justifications related to the protection of the environment and the long-term protection of its soils which being in their majority acidic or extremely acidic, they are more vulnerable to cadmium accumulation and therefore stand in need of higher protection.
- (67) In its reasoning, the Slovak Republic relies on a number of studies linking the accumulation of cadmium in the human body to several health issues, such as adverse effects on the heart, lungs, bones, gonads and, in particular, the kidneys, as well as osteoporosis (<sup>10</sup>). In a similar manner, the Slovak Republic also relies on various sources in relation to the accumulation of cadmium in the soil (<sup>11</sup>). These sources maintain the existence of a direct link between the accumulation of cadmium in the soil, the inevitable uptake in food and feed and the adverse effects on human health.
- (68) In particular, it is argued that cadmium's soil-to-plant transfer factor is highly dependent on a soil's pH, with acidic soils representing the highest risk. The more acidic the soil, the more cadmium enters a plant (even if the soil has a fairly low cadmium content), subsequently making its way into the food chain faster and in greater quantities.
- (69) As cadmium is a non-degradable contaminant, it persists in the soil for 75 to 380 years and there are no mechanisms that would cause it to break down. On the contrary, it builds up, as it is much less mobile in soil than in air or water. It binds itself strongly to organic matter in soils' surface horizons. The main factors determining the mobility of cadmium in soil are soil pH, humus and water soluble organic substances content, the presence of oxihydroxides and competing ions and significant humidity.
- (70) More than 70 % of the Slovak agricultural soils are acidic or extremely acidic. In the context of the assessment of the mobility of cadmium in the soil-plant system, this is therefore a highly negative and significant factor.

<sup>(&</sup>lt;sup>10</sup>) For example Wexler P., 1999: Encyclopedia of Toxicology. Academic Press, 1999 and Ministry of Enterprise and Innovation Sweden, Swedish position on risks to human health posed by cadmium, N2016/02227/JM, 14 September 2016.

<sup>(&</sup>lt;sup>11</sup>) Čurlík J., 2012: Potenciálne toxické stopové prvky a ich distribúcia v pôdach Slovenska [Potentially toxic trace elements and their distribution in Slovakia's soils]. Faculty of Natural Sciences, Comenius University, Bratislava, pp. 285-287, (Čurlík, 2012). OECD, 1994: Cadmium: Risk reduction monograph No 5. Environmental Directorate OECD, Paris and Christensen, J.

<sup>(</sup>Curlik, 2012). OECD, 1994: Cadmium: Risk reduction monograph No 5. Environmental Directorate OECD, Paris and Christensen, J. B., Haung, P. M., 1999: Solid phase cadmium and the reaction of aqueous cadmium with soil surfaces. In: McLaughlin, M. J., Singh, B. r. (eds) Cadmium and plants. Kluwer Acad. Publ. London. Pp. 65-96.

- (71) Apart from being highly acidic, the soils of Slovakia are also becoming increasingly poorer in organic matter. The regular and sufficient intake of organic matter by the soil can be achieved by a form of organic fertilisation closely linked to livestock farming. The organic carbon content and quality of organic matter in the Slovak agricultural soils has changed significantly since 1990, when livestock numbers began to fall. In the EU, the Slovak Republic is one of the countries with the lowest number of livestock units per hectare. This is therefore another reason why the possibility of not increasing cadmium levels in the Slovak soils is so important.
- (72) Further, the Slovak Republic highlights that eliminating or limiting the entry of cadmium from phosphate fertilisers into agricultural land is of high importance because some of its soils are found to have high concentrations of cadmium due to various factors ranging from natural geochemical composition, atmospheric deposition or previous industrial activities near these areas. In agricultural areas, the cadmium concentration is mainly of anthropogenic origin, resulting to a large extent from the use of phosphate fertilisers. Further pressure on soil in the aforementioned areas due to the application of phosphate fertilisers is therefore undesirable and could lead to adverse effects to human health.
- (73) The vast majority of phosphate fertilisers in the Slovak market are EC fertilisers. Nevertheless, the majority of EC fertilisers on the Slovak market have a cadmium content below 20 mg/kg P<sub>2</sub>O<sub>5</sub>. The Slovak Republic is concerned that even if 95 % of imported fertilisers already respect the future 60 mg/kg P<sub>2</sub>O<sub>5</sub> limit value set in Regulation (EU) 2019/1009, there are areas in Slovakia where cadmium content is increasing both in the soil and in agricultural products. The effect thereof has already resulted in an increased cadmium content in infant food. Further, the Slovak Republic is concerned that the pattern of imports will change in the future leading to a significant increase in the marketing of products with higher cadmium levels than 20 mg/kg P<sub>2</sub>O<sub>5</sub> resulting in further accumulation of cadmium in soil and consequently transfer to the food chain.
- (74) Finally, the Slovak Republic states that there are no manufacturers of phosphate fertilisers in Slovakia, which means that there is no need to fear that the derogation applied for could benefit a national producer.
  - 2.2.2. Evaluation of the position of the Slovak Republic
  - 2.2.2.1. Justification on grounds of major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment
- (75) The notified national provisions aim to achieve a higher level of protection of human health and the environment than that provided in Regulation (EU) 2019/1009 with regard to exposure to cadmium, by preventing the further accumulation of cadmium in the soil. The means for achieving this objective is maintaining a lower maximum limit value of cadmium in phosphate fertilisers containing at least 5 %  $P_2O_5$  by mass compared to the harmonised limit value set out in Regulation (EU) 2019/1009.
- (76) As regards the protection of human health, it should be noted that cadmium is a non-essential and toxic element for humans, and has no benefit for plants or animals. In particular, cadmium oxide has been classified as a carcinogen substance, category 2 under Regulation (EC) No 1272/2008 (<sup>12</sup>).
- (77) The presence of cadmium in plants and cadmium intake from foodstuffs could eventually lead to adverse effects on human health in the longer term. Further, once absorbed by the human body, it is efficiently retained and accumulates in it throughout one's life (<sup>13</sup>).
- (78) Cadmium can damage the kidneys, causing excess production of proteins in the urine. The duration and level of exposure to cadmium determines the severity of the effect. Skeletal damage is another critical effect of chronic cadmium exposure at levels somewhat higher than those where protein in the urine would be an early indicator. Mainly stored in the liver and kidneys, excretion of cadmium is slow, and it can remain in the human body for decades.

<sup>(&</sup>lt;sup>12</sup>) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>(&</sup>lt;sup>13</sup>) See the scientific report of the European Food Safety Authority on Cadmium dietary exposure in the European population of 2012, published at: https://www.efsa.europa.eu/sites/default/files/scientific\_output/files/main\_documents/2551.pdf, EFSA Journal 2012;10(1).

- (79) The general public is exposed to cadmium from multiple sources, including smoking. For the non-smoking population, food stands for the most dominant source of cadmium intake. Cadmium is primarily toxic to the kidney, but can also cause bone demineralisation and has been statistically associated with increased risk of cancer in the lung, endometrium, bladder and breast (<sup>14</sup>). Further, health risks cannot be excluded for adult smokers and people with depleted iron body stores and/or living near industrial sources (<sup>15</sup>).
- (80) Moreover, in addition to human health impacts, further cadmium accumulation in soils could have negative effects on soil biodiversity and therefore soil functions (e.g. decay of organic matter) as well as on groundwater quality via leaching in soils. Both toxicity and bioavailability of cadmium are influenced by soil characteristics. Cadmium mobility and bioavailability are higher in more acidic soils, and lower in chalky/lime soils. Taking into consideration that: 1) approximately 70 % of the agricultural soils in Slovakia are acidic or extremely acidic; 2) the Slovaki agricultural soils are becoming increasingly poor in organic matter due to the low numbers of livestock in Slovakia; and 3) the Slovak soils are already highly contaminated with cadmium due to the various factors described above, we can conclude that a situation specific to that Member State exists, which makes it particularly vulnerable to cadmium accumulation in soils.
- (81) Concerns regarding the risks posed by cadmium to human health and the environment were already referred to by the Council in its Resolution of 25 January 1988 (<sup>16</sup>). The Council emphasized the importance of reducing inputs of cadmium into soils from all sources including diffuse sources (e.g. atmospheric deposition, phosphate fertilisers, sewage sludge...) by among others 'appropriate control measures for the cadmium content of phosphate fertilisers based on suitable technology not entailing excessive costs and taking into account environmental conditions in the different regions of the Community'.
- (82) In 2002, the Scientific Committee on Health and Environmental Risks concluded that a limit of 40 mg/kg  $P_2O_5$  or more would lead to cadmium accumulation in most European Union soils. By contrast, a limit of 20 mg/kg  $P_2O_5$  or less was not expected to result in long-term soil accumulation over 100 years if other cadmium inputs are not considered.
- (83) In recital 15 of Regulation (EC) No 2003/2003, the Commission's intention to address the issue of unintentional cadmium content in mineral fertilisers was already announced.
- (84) In its proposal for Regulation (EU) 2019/1009 (<sup>17</sup>), based on the scientific data available when assessing the impacts, the Commission concluded that cadmium metal and cadmium oxide in general can pose serious risks to health. The Commission proposed setting a limit value of 60 mg/kg  $P_2O_5$  in phosphate fertilisers and reducing gradually this limit value to 20 mg/kg  $P_2O_5$  in 12 years after the application of the new Regulation.
- (85) 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 (<sup>18</sup>). Regulation (EU) 2019/1009 sets a limit value of 60 mg/kg  $P_2O_5$  applicable as of 16 July 2022. The vast majority of fertilisers available on the European market already comply with this limit value. While the introduction of this limit is a step in the right direction, based on available scientific data, it is not likely to significantly decrease the accumulation of cadmium in soils over long term.
- (86) Recognising the need for a more ambitious harmonised limit value for cadmium in phosphate fertilisers in the future, Regulation (EU) 2019/1009 sets an obligation upon the Commission to reassess these limits with the purpose of lowering them if feasible.
- (87) Based on the above, it must be considered that the maximum limit value set out in the notified national provisions is justified by needs to protect human health and life and the environment.

<sup>(&</sup>lt;sup>14</sup>) EFSA Journal 2012;10(1).

<sup>(15)</sup> EU Risk assessment report on cadmium and cadmium oxide, as quoted in SWD(2016) 64 final, p. 11.

<sup>(&</sup>lt;sup>16</sup>) OJ C 30, 4.2.1988, p. 1.

<sup>&</sup>lt;sup>(17)</sup> COM/2016/0157 final – 2016/084 (COD).

<sup>(18)</sup> See the study Revisiting and updating the effect of phosphate fertilizers to cadmium accumulation in European agricultural soils' by Erik Smolders & Laetitia Six, commissioned by Fertilizers Europe in 2013, published at http://ec.europa.eu/health/scientific\_committees/ environmental\_risks/docs/scher\_o\_168\_rd\_en.pdf

- 2.2.2.2. Absence of any arbitrary discrimination, any disguised restriction on trade between Member States or any obstacle to the functioning of the internal market
- (a) Absence of arbitrary discrimination
- (88) Article 114(6) TFEU requires the Commission to verify that maintaining the notified measures is not a means of arbitrary discrimination. According to the case-law of the Court (<sup>19</sup>), in order for there to be no discrimination, comparable situations must not be treated in different ways and different situations must not be treated in the same way unless objectively justified. 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.
- (89) The Slovak Republic has indicated that there is currently no production of phosphate fertilisers in Slovakia. Furthermore, the Commission notes that, should such production be established in Slovakia in the future, the notified national provisions would in any event apply to both domestic products and products manufactured in other Member States. In the absence of any evidence to the contrary, it can be concluded that the notified national provisions are not a means of arbitrary discrimination.
  - (b) Absence of a disguised restriction on trade
- (90) National measures, which set more stringent conditions for placing on the market of products than a Union Regulation, would normally constitute a barrier to trade. This is because some of the products that are lawfully placed on the market in the rest of the Union are not expected, as a result of the national provision, to be placed on the market in the Member State concerned. The pre-conditions laid down in Article 114(6) TFEU are intended to prevent restrictions based on the criteria set out in paragraphs 4 and 5 thereof from being applied for inappropriate reasons, and constituting in effect economic measures to impede the importation of products from other Member States, that is to say, a means of indirectly protecting national production (<sup>20</sup>).
- (91) Given that the notified national provisions also impose a stricter limit value to cadmium content in phosphate fertilisers on economic operators based in other Member States in an otherwise harmonised area, they are liable to constitute a disguised restriction on trade or an obstacle to the functioning of the internal market.
- (92) In the absence of any evidence suggesting that the national provisions constitute in effect a measure intended to protect national production, it can be concluded that they are not a disguised restriction on trade between Member States. Therefore, it remains for the Commission to consider, whether the notified national provisions present an obstacle to the functioning of the internal market.
  - (c) Absence of obstacles to the functioning of the internal market
- (93) Article 114(6) TFEU requires the Commission to verify whether or not maintaining the notified measures constitutes an obstacle to the functioning of the internal market. The condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the functioning of the internal market. Indeed, any national measure derogating from a harmonisation measure aimed at the establishment and operation of the internal market constitutes in substance a measure likely to affect the internal market. Consequently, in order to preserve the useful character of the procedure laid down in Article 114 TFEU, the concept of obstacle to the functioning of the internal market must, in the context of Article 114(6) TFEU, be understood as a disproportionate effect in relation to the pursued objective (<sup>21</sup>).

<sup>(&</sup>lt;sup>19</sup>) E.g. C-492/14, Essent Belgium, paragraph 80, Commission Decision (EU) 2018/702 of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, paragraph 52 (OJ L 118, 14.5.2018, p. 7), Commission Decision 2006/348/EC of 3 January 2006 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, paragraph 38 (OJ L 129, 17.5.2006, p. 25), 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, paragraph 39 (OJ L 129, 17.5.2006, p. 21), 17.5.2006, p. 19), Commission Decision 2006/349/EC of 3 January 2006 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, paragraph 39 (OJ L 129, 17.5.2006, p. 19), Commission Decision 2006/349/EC of 3 January 2006 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, paragraph 39 (OJ L 129, 17.5.2006, p. 31).

<sup>(20)</sup> Decision (EU) 2018/702, paragraph 54, Decision 2006/348/EC, paragraph 40, Decision 2006/347/EC, paragraph 41, Decision 2006/349/EC, paragraph 41.

 <sup>(&</sup>lt;sup>21</sup>) Decision (EU) 2018/702, paragraph 55, Decision 2006/348/EC, paragraph 42, Decision 2006/347/EC, paragraph 43, Decision 2006/349/EC, paragraph 43.

- (94) When assessing whether the notified national provisions are appropriate and necessary for achieving its objective, a number of factors need to be taken into account. The Commission has to evaluate whether the level of protection stemming from the cadmium limit value set in the notified national provisions is higher than in the harmonisation measure and effective in protecting the health and life of humans on the one hand, and the environment on the other.
- (95) The notified national provisions seek to protect the human health and the environment by preventing the accumulation of cadmium in soil. In its notification to the Commission, the Slovak Republic justifies the necessity of the derogation by referring to the specific circumstances related to the high acidity and low organic matter of the Slovak agricultural soils and the subsequent negative effects to the cadmium levels of the soil and to the health of the country's population. Approximately 70 % of the Slovak agricultural soils are acidic or extremely acidic and many of them are becoming increasingly poor in organic matter which leads to a situation specific to this Member State making it particularly vulnerable to cadmium accumulation in soils.
- (96) Further, a maximum limit value of  $20 \text{ mg/kg } P_2O_5$  or less of cadmium concentration in fertilisers has been identified as efficient to avoid long-term soil accumulation of cadmium over 100 years.
- (97) Taking also into account the elements related to the specific situation of the Slovak Republic, the notified national provisions may be considered to be necessary to achieve the aims pursued by them.
- (98) Furthermore, the Slovak Republic claims that the majority of fertilisers on the market have a cadmium content below the limit of 20 mg/kg P<sub>2</sub>O<sub>5</sub>, though this is currently not required for EC fertilisers. Therefore, setting a limit value at 20 mg/kg P<sub>2</sub>O<sub>5</sub> will not cause significant disruption to the market.
- (99) The application of other measures such as use restrictions would be very hard to control in practice and could not attain the objective pursued. The Commission considers that maintaining the notified national provisions is not disproportionate and does not constitute an obstacle to the functioning of the internal market in the sense of Article 114(6) TFEU.
- (100) In the light of that analysis, the Commission considers that the condition relating to the absence of obstacles to the functioning of the internal market is fulfilled.

2.2.2.3. Limitation in time

- (101) In order to ensure that the national measure and the potential obstacle to the functioning of the internal market is limited to what is strictly necessary to achieve the objectives pursued by the Slovak Republic, the national derogation should be limited in time. The derogation would cease to be necessary if, in the future, the harmonised limit value would be set at or below the level of the Slovak limit value.
- (102) The harmonised limit value could only be set at or below the level of the Slovak limit value through a decision of the European Parliament and the Council based on a proposal from the Commission, for example in the context of the review referred to in Article 49(b) of Regulation (EU) 2019/1009. The period for which the derogation is granted should therefore not be limited to a certain date by this Decision, but be aligned with such a future decision by the legislator.
- (103) This is in line with Article 3(2) of Regulation (EU) 2019/1009, which provides that derogations from Regulation (EC) No 2003/2003 in accordance with Article 114(4) TFEU in relation to cadmium content may continue to apply until harmonised limit values for cadmium content in phosphate fertilisers which are equal to or lower than the national ones are applicable at Union level.
- (104) The approval of the notified national provisions should therefore apply until a revised harmonised limit value equal to or lower than the Slovak limit value is applicable at Union level.

# 3. CONCLUSIONS

(105) In the light of the foregoing, it should be concluded that the notification by the Slovak Republic for maintaining national provisions derogating from Regulation (EU) 2019/1009 as submitted on 9 August 2019 is admissible.

(106) Moreover, the Commission finds that the notified 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,
- do not constitute a disguised restriction on trade between Member States.

(107) The Commission therefore considers that the notified national provisions can be approved,

HAS ADOPTED THIS DECISION:

#### Article 1

The national provisions notified by the Slovak Republic pursuant to Article 114(4) of the Treaty on the Functioning of the European Union, derogating from Regulation (EU) 2019/1009 as regards cadmium content in phosphate fertilisers, i.e. the prohibition of the placing on the Slovak market of phosphate fertilisers containing at least 5 %  $P_2O_5$  by mass referred to in points 3(a)(ii) in PFC 1(B) and 2(a)(ii) in PFC 1(C)(I) in Annex I to Regulation (EU) 2019/1009 with a cadmium content exceeding 20 mg/kg,  $P_2O_5$ , are approved until a revised harmonised limit value equal to or lower than the Slovak limit value is applicable at Union level.

# Article 2

This Decision is addressed to the Slovak Republic.

Done at Brussels, 6 August 2020.

For the Commission Thierry BRETON Member of the Commission