COMMISSION DECISION (EU) 2020/1184

of 17 July 2020

on the national provisions notified by Hungary 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) 4862)

(Only the Hungarian 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 19 July 2019 Hungary 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 (1).

1.1. Union Legislation

- 1.1.1. Article 114(4) and (6) TFEU
- (2) Article 114, paragraphs 4 and 6 TFEU provide:
 - '4. 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.'

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 (²) 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.

⁽¹⁾ 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).

⁽²⁾ 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).

- (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 (P₂O₅)-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) That Regulation 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 (3), EC fertilisers with a phosphorus content of at least 5 % P₂O₅ 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 inorganic macronutrient fertilisers or organo-mineral fertilisers with a phosphorus content of at least 5 % P₂O₅.
- (13) The Regulation 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 Regulation (EU) 2019/1009, the cadmium content in phosphate fertilisers must not exceed the limit value of 60 mg/kg P₂O₅.

⁽³⁾ 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).

- (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 so-called 'national fertilisers' placed on the market of the Member States in accordance with national legislation. Producers can choose to market fertiliser as 'EC fertiliser' or as 'national fertiliser'.
- (18) Regulation (EU) 2019/1009 maintains unchanged the optional regime. Thus, it ensures the free movement in 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, which are outside the scope of Regulation (EU) 2019/1009. 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 Hungary ('the notified national provisions') are contained in the Hungarian Minister for Agriculture and Rural Development Decree No 36/2006 of 18 May 2006 on the authorisation, storage, marketing and use of fertilising products. Decree No 36/2006 contains certain conditions. In particular, Point 1.2 of Annex 3 to the Decree sets a national limit value of 20 mg/kg P_2O_5 for cadmium. This limit value applies to three categories of national fertilisers: phosphoric fertilisers, NPK fertilisers and NPK + micronutrient fertilisers irrespective of their content of P_2O_5 . In its letter dated 27 September 2019, Hungary confirmed that that limit value is not applicable to EC fertilisers.
- (23) Hungary has specified in its notification and the additional information submitted to the Commission that it intends to apply the above mentioned limit value to inorganic and organo-mineral fertilisers covered by Regulation (EU) 2019/1009 and made available on the market in Hungary. In particular, if approved, the notified national provisions will only apply as a derogation from the provisions on phosphate fertilisers 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. These provisions concern 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.

(24) Regarding the various conditions of Decree No 36/2006 other than the cadmium limits, Hungary has confirmed that, those other conditions are not to be considered as notified national provisions derogating from Regulation (EU) 2019/1009 to be approved by the Commission, as it has no intention to derogate from that Regulation beyond the limit value for cadmium.

1.4. Procedure

- (25) At the time of the adoption of Regulation (EU) 2019/1009, Hungary along with Slovakia 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.
- (26) By letter of 17 July 2019, registered on 19 July 2019, Hungary 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) read in conjunction with Article 36 TFEU, Hungary's justification is based on grounds of major needs relating to the long-term protection of the soil and the resulting protection of human health and the protection of the environment.
- (27) By letter of 26 July 2019, the Commission acknowledged receipt of the notification and informed the Hungarian authorities that the six-month period for its examination according to Article 114(6) TFEU started on 20 July 2019.
- (28) In support of their notification based on Article 114(4) TFEU, the Hungarian authorities sent by letters dated 27 September 2019 and 15 October 2019 additional information to the Commission. That information provides clarifications as regards the material scope of the national provisions that Hungary seeks to maintain, as well as detailed data on the fertilisers market in Hungary.
- (29) Further, the Commission published a notice regarding the notification in the Official Journal of the European Union (4) in order to inform interested parties of Hungary'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.
- (30) The Commission received comments within this deadline from two Member States, namely: Latvia and the Czech Republic. Latvia stated that it did not object to the intention of Hungary to maintain national provisions derogating from the provisions of Regulation (EU) 2019/1009 in relation to cadmium limit value of phosphate fertilisers. The Czech Republic mentioned that it does not have any comments as regards the notification. No comments were received following the publication of the notice in the Official Journal.
- (31) In its Decision notified on 17 January 2020 (5), pursuant to Article 114(6), third paragraph, TFEU, and 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 Article 114(6), first subparagraph, TFEU for a further period of six months expiring on 20 July 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.

2. ASSESSMENT

2.1. Admissibility

(32) Under 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.

⁽⁴⁾ OJ C 394, 21.11.2019, p. 2.

⁽⁵⁾ 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 Hungary pursuant to Article 114(4) of the Treaty (C(2020) 134 final).

- (33) Hungary is asking the Commission to grant a derogation allowing the placing on the Hungarian market of only those phosphate fertilisers with a phosphorus pentoxide (P₂O₅) content of at least 5 % P₂O₅ which contain no more than 20 mg cadmium/kg P₂O₅. In its letter dated 27 September 2019, Hungary 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.
- (34) To ascertain the admissibility of the request, the Commission has to assess if the notified national provisions concerned is a pre-existent measure derogating from the newly introduced harmonisation rule and if it is more stringent.
 - 2.1.1. On the pre-existence of the notified national provisions
- (35) For the purpose of this assessment, it is important to take note of the particular complexity of the situation at hand.
- (36) 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.
- (37) 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 seeks to address.
- (38) Third, Hungary, did not apply for a derogation from Regulation (EC) No 2003/2003, and currently does not apply any cadmium limit for the EC fertilisers.
- (39) 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.
- (40) 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.
- (41) 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. [...]'.
- (42) This interpretation is further supported by the difference in the material scopes 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.

- (43) 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 (6).
- (44) 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 to that Regulation, in accordance with the requirement of Article 114(4) TFEU.
- (45) 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, Hungary 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.
- (46) This complexity raises the question whether the notification made by Hungary 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.
- (47) It can first be noted that the notified national provisions have been in force at their current state since 2006. Thus, they were in force at the time of drawing up Regulation (EU) 2019/1009 and therefore predate that Regulation. Hungary 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.
- (48) 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 Hungary to also apply the notified national provisions to EU fertilising products. In order for this to be the case, an adjustment in the Hungarian legislation is needed.
- (49) 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 to the purpose of the distinction between Article 114(4) and (5) TFEU.
- (50) 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 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' (7).

⁽⁶⁾ See C-360/14 P Germany v European Commission.

⁽⁷⁾ C-3/00 Denmark v Commission, para. 58. Further confirmed in e.g. T-234/04 Kingdom of the Netherlands v Commission, para. 58, Joined Cases T 366/03 T-235/04 Land Oberösterreich and Austria v Commission, para. 62 and C-512/99 Germany v Commission, para. 41.

- (51) 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 adoption of the harmonised measure and was therefore not taken into account when the harmonisation measure was drawn up.
- (52) As has already been established, the notified national provisions have been in force at their current state since 2006. Thus, they were in force at the time of drawing up Regulation (EU) 2019/1009 and therefore also predate that Regulation.
- (53) 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 (8) 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.
- (54) 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
- (55) 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 P₂O₅, the notified national provisions set a limit value of 20 mg/kg P₂O₅ 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.
- (56) 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 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.
- (57) The Commission therefore considers that the notification submitted by Hungary is admissible in its entirety under Article 114(4) TFEU.

2.2. Assessment of merits

- (58) 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.
- (59) 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.
- (60) In the light of the timeframe 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.

⁽⁸⁾ 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.

- (61) 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 Hungary
- (62) Hungary's position with regard to the cadmium content in phosphate fertilisers with at least 5 % P₂O₅ is motivated by the long-term protection of the soil and the resulting protection of human health and the protection of the environment.
- (63) Hungary 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 raised 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. Hungary tops the ranking in the Union and in the world in lung cancer deaths. Hungary, therefore, emphasises the need to reduce further exposure to cadmium entering the body with food.
- (64) Given that exposure to cadmium in the general population has been statistically associated with increased risk of cancer, inter alia, in the lung, Hungary wishes to reduce further exposure of its population to cadmium by means of a lower limit value in phosphate fertilisers.
- (65) In addition to human health concerns, Hungary 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.
- (66) In its reasoning, Hungary relies on studies linking the accumulation of cadmium in the human body to several health issues, most severely to lung cancer, but also to chronic renal insufficiency and osteoporosis (9). In its notification, Hungary also relies on various sources in relation to the accumulation of cadmium in the soil (10). Hungary maintains the existence of a direct link between the accumulation of cadmium in the soil, the inevitable uptake in food and feed and the adverse health effects on humans.
- (67) The vast majority of phosphate fertilisers in the Hungarian market are EC fertilisers. Nevertheless, the majority of EC fertilisers on the Hungarian market have a cadmium content below 20 mg/kg P_2O_5 . As 95 % of imported fertilisers already respect the future 60 mg/kg P_2O_5 limit value set in Regulation (EU) 2019/1009, Hungary 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_2O_5 resulting in further accumulation of cadmium in soil and consequently transfer to the food chain.
 - 2.2.2. Evaluation of the position of Hungary
 - 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
- (68) The notified national provisions aim to achieve a higher level of protection of health and life of humans 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.

^(°) E.g. HORVÁTH O, MAKRAINÉ HORVÁTH A ZS., 2006. A csontritkulás, korunk "néma járványa". Nővér 2006 (19) 2, MÁTYUS J, OLÁH A, ÚJHELYI L, KÁRPÁTI I, BALLA J., 2008. Az idült vesebetegség epidémiája szükségessé teszi a glomerulus filtrációs ráta számítását. Orvosi Hetilap 149(2): 77-82 and IARC Monographs Volume 100C Cadmium and Cadmium Compounds. 2012.

⁽¹⁰⁾ E.g. ADRIANO, D.C., 2001. Trace Elements in Terrestrial Environments. Biogeochemistry, Bioavailability and Risks of Metals. (2nd edn.). Springer-Verlag. New York, ALLOWAY, B.J. (ed)., 1990. Heavy Metals in Soils. Blackie and Son Ltd. Glasgow and London. John Wiley and Sons Inc. New York.

- (69) As regards the protection of health and life of humans, 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) 1272/2008 of the European Parliament and of the Council (11).
- (70) 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 (12).
- (71) Cadmium can damage the kidneys, causing excess production of beta-2-microglobulin, a protein excreted in the urine, which is a biological indicator of kidney function. 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 the protein beta-2-microglobulin 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.
- (72) 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 (13). Further, health risks cannot be excluded for adult smokers and people with depleted iron body stores and/or living near industrial sources (14).
- (73) Given the high rate of lung cancer deaths in Hungary, its interest to avoid further exposure to cadmium is justified.
- (74) 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. Approximately half of Hungary's soils are acidic or extremely acidic, which leads to a situation specific to that Member State making it particularly vulnerable to cadmium accumulation in soils.
- (75) 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 (15). 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'.
- (76) 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.
- (77) 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.
- (11) 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).
- (¹²) 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).
- (13) EFSA Journal 2012;10(1).
- (14) EU Risk assessment report on cadmium and cadmium oxide, as quoted in SWD(2016) 64 final, p. 11.
- (15) OJ C 30, 4.2.1988, p. 1.

- (78) In its proposal for Regulation (EU) 2019/1009 (16), 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.
- (79) 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. (17) Regulation (EU) 2019/1009 sets a limit value of 60 mg/kg P₂O₅ 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.
- (80) 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.
- (81) 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.
 - 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
- (82) Article 114(6) TFEU requires the Commission to verify that maintaining the notified measures are not a means of arbitrary discrimination. According to the jurisprudence of the Court (18), in order for there to be no discrimination, similar 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.
- (83) The notified national provisions apply to both domestic products and products produced 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
- (84) 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 (19).
- (16) COM/2016/0157 final 2016/084 (COD).
- (17) 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,
- (18) E.g. C-492/14, Essent Belgium, p. 80, Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para. 52 (OJ L 118, 14.5.2018, p. 7), Commission Decision 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, 2006/348/EC, para. 38, Commission Decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 39, Commission Decision 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, 2006/349/EC, para. 39.
- (19) Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para 54 Commission Decision 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, 2006/348/EC, para. 40, Commission Decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 41, Commission Decision 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, 2006/349/EC, para. 41.

- (85) 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.
- (86) 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 to 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
- (87) 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 (20).
- 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 Hungarian legislation is effective in protecting the health and life of humans on the one hand, and the environment on the other.
- (89) The notified national provisions seek to protect the human health and the environment by avoiding the accumulation of cadmium in soil. In its notification to the Commission, Hungary motivates the necessity of the derogation by referring to the specific circumstances of the special vulnerability of the Hungarian population due to the high numbers of lung cancer deaths and of the acidity of the soil.
- (90) Hungary tops the ranking in the Union and in the world in lung cancer deaths. Due to this fact, Hungary emphasises the need to reduce further exposure to cadmium entering the body with food. Additionally, approximately half of Hungary's soils are acidic or extremely acidic, which leads to a situation specific to that Member State making it particularly vulnerable to cadmium accumulation in soils.
- (91) Further, a maximum limit value of 20 mg/kg P₂O₅ or less of cadmium concentration in fertilisers has been identified as efficient to avoid long-term soil accumulation of cadmium over 100 years.
- (92) Taking also into account the elements related to the specific situation of Hungary, the notified national provisions may be considered to be necessary to achieve the aims pursued by them.
- (93) Furthermore, Hungary claims that the majority of fertilisers on the market have a cadmium content below the limit of 20 mg/kg P₂O₅, though this is currently not required for EC fertilisers. Therefore, setting a limit value at 20 mg/kg P₂O₅ will not cause significant disruption to the market.
- (20) Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para. 55 (OJ L 118, 14.5.2018, p. 7), Commission Decision 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, 2006/348/EC, para. 42, Commission decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 43, Commission Decision 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, 2006/349/EC, para. 43.

- (94) 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.
- (95) In the light of this 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

- (96) 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 Hungary, 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 Hungarian limit value.
- (97) The harmonised limit value could only be set at or below the level of the Hungarian 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.
- (98) 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 or lower than the national ones are applicable at Union level.
- (99) The approval of the notified national provisions should therefore apply until a revised harmonised limit value equal or lower to the Hungarian limit value is applicable at Union level.

3. CONCLUSIONS

- (100) In the light of the foregoing, it should be concluded that the notification by Hungary for maintaining national provisions derogating from Regulation (EU) 2019/1009 as submitted on 19 July 2019 is admissible.
- (101) 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.
- (102) The Commission therefore considers that the notified national provisions should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions notified by Hungary 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 Hungarian 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 Hungarian limit value is applicable at Union level.

Article 2)
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This Decision is addressed to Hungary.

Done at Brussels, 17 July 2020.

For the Commission
Thierry BRETON
Member of the Commission