Council of the European Union

Brussels, 13 April 2023
(OR. en)

8269/23

AGRILEG 65
PESTICIDE 21

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	15228/22
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products

Delegations will find in the Annex a letter from the Commission, addressed to the Presidency, concerning the above draft regulation. The Council's decision not to oppose the above-mentioned draft measure was considered to be taken on 23 January 2023, upon expiry of the two month deadline after receipt of the Commission's draft measure[1].

[1] WK 16693/2022, WK 1753/2022.

Ref. Ares(2023)2594358 - 12/04/2023

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/SM/ai(2023)1432989

Dear Ambassador, Dear Honourable Chair,

Subject: COMMISSION REGULATION (EU) …/…amending Annexes II, III, IV and V to Regulation (EC) No 396/2005of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (PE-E4-SANTE/10090/2022)

I refer to the above-mentioned draft Commission Regulation, which was sent to the European Parliament and the Council on 23 November 2022 in accordance with Article 5a(3) of Decision 1999/468/EC laying down the procedure for the exercise of implementing powers conferred on the Commission as amended by Decision 2006/512/EC (Reference: Document D076837/3 - Regulatory Procedure with Scrutiny).

I wish to inform you that a minor adjustment needs to be made in the text before its adoption by the European Commission, in order to correct a non-substantive/obvious mistake.

The issue is about the wording of recital 26 of the draft Regulation, which is not in line with the wording of Article 2. Recital 26 states that no transitional arrangement for nicotine in rose hips, teas **and capers** be provided. However, Article 2 of that same draft Regulation correctly states that only rose hips and teas are excluded from provisional arrangements, but not capers.

The text of recital 26 will therefore be adjusted as follows before adoption and publication in the Official Journal:

(26) For all active substances covered by this Regulation, in order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained. This is the case for all products except nicotine in ***rose hips and teas****.*

HE Mr Lars Danielsson
Ambassador of the Permanent Representation of Sweden to the EU

Mr Pascal Canfin
European Parliament
Chair of the Committee on the Environment, Public Health and Food Safety
Email: pascal.canfin@europarl.europa.eu

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
SANTE-DG@ec.europa.eu

The Comitology Register will be updated with the revised version of the Commission Regulation, after its publication.

My services are available in case you need any further information.

Yours sincerely,

[e-signed]
Sandra GALLINA

Enclosure: COMMISSION REGULATION (EU) …/…amending Annexes II, III, IV and V to Regulation (EC) No 396/2005of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (PE-E4-SANTE/10090/2022)

c.c.: Mr Niklas Montell, Chair of Council Working Party (niklas.montell@slv.se)

Mr Jerker Stattin, Counsellor at the Permanent Representation of Sweden to the EU (jerker.stattin@gov.se)

Ms Gunilla Eklund, Counsellor at the Permanent Representation of Sweden to the EU (gunilla.eklund@gov.se)

LIFE 3 (Council of the European Union) (LIFE.3@consilium.europa.eu)

ENVI Secretariat (European Parliament) (envi-secretariat@ep.europa.eu)

Ms C. Bury, Ms M. Moya Diaz, Mr K. Berend, Ms A. Bitterhof, Mr S. Messori (SANTE)

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10090/2022
(POOL/E4/2022/10090/10090-EN.docx)
D080714/03
[…](2022) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products

(Text with EEA relevance)

EN EN

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC[1], and in particular Article 14(1), point (a), and Article 18(1), point (b), thereof,

Whereas:

(1) For flutriafol, metazachlor, quizalofop-P, thiabendazole and triadimenol, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For profenofos, MRLs were set in Annex II and in Part B of Annex III to that Regulation. For benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC) and nicotine, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. Sodium aluminium silicate is included in Annex IV to that Regulation.

(2) BAC is not an approved active substance in plant protection products under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2]. DDAC was approved as an active substance in plant protection products for use on ornamental crops, but all authorisations for plant protection products containing DDAC have been revoked following the withdrawal of its approval[3]. However, both substances are used as biocides for disinfection. That use may lead to detectable residues in food. For both substances, temporary MRLs were therefore set by Commission Regulation (EU) No 1119/2014[4] for all products, since food business operators showed that residues of those substances are present in food products at

---

1 OJ L 70, 16.3.2005, p. 1.

2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

3 Commission Implementing Regulation (EU) No 175/2013 of 27 February 2013 amending Implementing Regulation (EU) No 540/2011 as regards the withdrawal of the approval of the active substance didecyldimethylammonium chloride (OJ L 56, 28.2.2013, p. 4).

4 Commission Regulation (EU) No 1119/2014 of 16 October 2014 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride and didecyldimethylammonium chloride in or on certain products (OJ L 304, 23.10.2014, p. 43).

levels that frequently exceed the default MRL of 0.01 mg/kg due to their use as a biocide. Those MRLs were to be revised based on monitoring data after 5 years.

(3) The Commission analysed the monitoring data for BAC, which showed that residues of this substance still occur in several products, at levels higher than the limit of determination (LOD) and similar to the existing temporary MRL. The Commission also analysed the monitoring data for DDAC, which showed that residues of this substance still occur in some products of animal origin, at levels higher than the LOD and similar to the existing temporary MRL. In products of plant origin, the residue levels of DDAC have decreased and are consistently below the existing temporary MRLs. It is therefore appropriate to lower the existing temporary MRLs for DDAC in those products accordingly. The temporary MRLs for BAC and DDAC should be reviewed within seven years from the publication of this Regulation to evaluate new data and information that will become available.

(4) The active substance chlorpropham is not approved in the Union. A temporary MRL for chlorpropham in potatoes was set by Commission Regulation (EU) 2021/155[5] since monitoring data showed potential contamination of potatoes above the LOD when stored in facilities with a history of chlorpropham use. That Regulation also required potato trade organisations and manufacturers to develop and implement new and more efficient cleaning practices to reduce such contamination, and to submit to the Commission new monitoring data that would allow the Commission to review that temporary MRL.

(5) The temporary MRL for chlorpropham in potatoes was reviewed based on monitoring data submitted to the Commission by 31 December 2021. As recent monitoring data showed that a lower MRL than 0.4 mg/kg is currently achievable, this MRL should be set at 0.35 mg/kg.

(6) This temporary MRL should be reviewed based on monitoring data submitted to the Commission by 31 December 2022 and thereafter by 31 December of each subsequent year. It will allow the Commission to regularly re-assess the situation and gradually reduce the MRL, where appropriate, as implementation of better cleaning methodology progresses. A report on the progress and implementation of cleaning practices should be submitted to the Commission together with the monitoring data by 31 December 2022, and updates to it in the subsequent years. The relevant footnote for potatoes in Annex III should be amended accordingly.

(7) An application for import tolerance pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 was submitted for flutriafol used in the United States on cucurbits with inedible peel. The applicant provided data showing that the authorised uses of that substance on those crops in the United States lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation into the Union of those crops. With this application, the applicant also submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 on the nature of residues in processed commodities for flutriafol in pome fruits and wine grapes, for residue trials in rice, and for storage conditions of the samples from the

[5] Commission Regulation (EU) 2021/155 of 9 February 2021 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products (OJ L 46, 10.2.2021, p. 5).

feeding studies and storage stability for pig liver, bovine liver, sheep liver, goat liver, equine liver and other terrestrial animals liver.

(8) In accordance with Article 8 of Regulation (EC) No 396/2005, the application for flutriafol was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The European Food Safety Authority ('the Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs[6]. It forwarded this opinion to the applicant, the Commission and the Member States and made it available to the public. The Authority concluded that all requirements with respect to completeness of data submission were met and that the modification to the MRLs requested by the applicant was acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to the substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.

(9) For flutriafol in cucurbits with inedible peel, it is appropriate to set the MRL at the level identified by the Authority. The Authority examined the supplementary data submitted and concluded that, for beetroots, a risk management consideration was needed, while all other MRLs for which data gaps were identified during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 are now fully supported by data. For flutriafol in beetroots, it is appropriate to extrapolate the data concerning residue trials from sugar beets, confirming the existing MRL. Therefore, all respective footnotes in Annex II highlighting the need for additional data should be deleted and the MRL for beetroots should be maintained. Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to modify the MRLs as set forth in the Annex to this Regulation.

(10) As regards metazachlor, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 on residue trials for metazachlor in head cabbages and kohlrabies, demonstrating that the MRLs are fully supported by data[7]. The applicant also submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 on residue trials for metazachlor on flowering brassica and kales, that permits the setting of MRLs lower than the currently established ones and that are still fully supported by data. As regards metazachlor on radishes, data concerning residue trials are still missing. The livestock dietary burden calculation was updated based on the new information. Based on that updated calculation, a lower MRL of 0.15 mg/kg for swine liver, which is safe for consumers, can be set.

(11) In accordance with Article 8 of Regulation (EC) No 396/2005, the application for metazachlor was evaluated by the Member State concerned and the evaluation report

---

6 EFSA 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for flutriafol in cucurbits (inedible peel). EFSA Journal 2020;18(12):6315.

7 EFSA 2019. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for metazachlor in various commodities. EFSA Journal 2019;17(10):5819.

was forwarded to the Commission. The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs[8]. The Authority forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public. The Authority concluded that all requirements with respect to completeness of data submission were met and that the modification to the MRLs requested by the applicant was acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to that substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.

(12) For metazachlor in head cabbages and kohlrabies, it is appropriate to maintain the MRL at the existing levels. For metazachlor in flowering brassica and kales, it is appropriate to lower the MRLs to the level recommended by the Authority. For metazachlor on radishes, it is appropriate to lower the MRL to the LOD. The respective footnotes in Annex II highlighting the need for additional data for those products should be deleted. For metazachlor in swine liver, it is appropriate to lower the MRL to the level recommended by the Authority. Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of that Regulation.

(13) For nicotine, temporary MRLs were set by Commission Regulation (EU) No 812/2011[9] for rose hips, "herbs and edible flowers", wild fungi (fresh), teas, "herbal infusions" and "spices" until 19 October 2021, pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in those products. Scientific evidence is not conclusive to demonstrate that nicotine occurs naturally in those products and to elucidate the mechanism of formation. The Authority and food business operators submitted recent monitoring data showing that, while residues of this substance still occur in those products at levels higher than the LOD, the residue levels have decreased. In addition, for rose hips and teas, the Authority identified unacceptable risks for consumers from the existing MRLs[10]. Therefore, taking into account EFSA's opinion and based on monitoring data, it is appropriate to set the MRLs for nicotine in rose hips at 0.2 mg/kg, for nicotine in "herbs and edible flowers" at 0.1 mg/kg, for nicotine in wild fungi (fresh) at 0.02 mg/kg, for nicotine in teas at 0.5 mg/kg, for nicotine in "herbal infusions" at 0.3 mg/kg, for nicotine in "seed spices" and "fruit spices" at 0.02 mg/kg, and for all other spices at 0.07 mg/kg. For all other products, for which no specific MRL were set under Regulation (EC) No 396/2005, it is appropriate to indicate that the LODs apply.

---

8 EFSA 2019. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for metazachlor in various commodities. EFSA Journal 2019;17(10):5819.

9 Commission Regulation (EU) No 812/2011 of 10 August 2011 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, fluopicolide, mandipropamid, metrafenone, nicotine and spirotetramat in or on certain products (OJ L 208, 13.8.2011, p. 1).

10 EFSA 2022. Statement on the short-term (acute) dietary exposure assessment for the temporary maximum residue levels for nicotine in rose hips, teas and capers. EFSA Journal 2022;20(9):7566.

(14) It is appropriate to continue to monitor the levels of nicotine in rose hips, "herbs and edible flowers", "herbal infusions" and "spices" and to review these MRLs based on monitoring data submitted to the Commission within seven years from the publication of this Regulation. Regarding nicotine in teas, the temporary MRL will be valid for three years after the publication of this Regulation. After that date, the MRL will be 0.4 mg/kg unless further modified by a Regulation in light of new information provided by 30 June 2025 at the latest. Regarding nicotine in wild fungi (fresh), it is appropriate to align the revision of this MRL with the revision of the temporary MRL for wild fungi (dry), that will be based on monitoring data submitted to the Commission within seven years from the publication of Regulation (EU) 2022/1290[11], which is revising temporary MRLs for this substance in other products.

(15) For profenofos, a temporary MRL was set by Commission Regulation (EU) No 1096/2014[12] for "herbs and edible flowers" until 18 October 2021, pending the submission of monitoring data on the occurrence of this active substance in these products. The Authority and food business operators submitted recent monitoring data showing that, while residues of this active substance higher than the LOD still occur in "herbs and edible flowers", the residue levels have decreased. Therefore, the MRL for "herbs and edible flowers" should be set at 0.03 mg/kg. It is appropriate to continue to monitor the levels of profenofos in "herbs and edible flowers" and to review this MRL based on monitoring data submitted to the Commission within seven years from the publication of this Regulation.

(16) An application pursuant to Article 6(1) of Regulation (EC) No 396/2005, requesting a modification of the existing MRLs for quizalofop-P resulting from the use of quizalofop-P-ethyl on caraway, was submitted.

(17) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL[13]. The Authority forwarded this opinion to the applicant, the Commission and the Member States and made it available to the public. The Authority concluded that all requirements with respect to completeness of data submission were met and proposed, based on the available data, setting a lower MRL that is acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to these substances via consumption of all food products that may contain them, nor the short-term exposure

[11] Commission Regulation (EU) 2022/1290 of 22 July 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlormequat, dodine, nicotine, profenofos and Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in or on certain products (OJ L 196, 25.7.2022, p. 74).

[12] Commission Regulation (EU) No 1096/2014 of 15 October 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbaryl, procymidone and profenofos in or on certain products (OJ L 300, 18.10.2014, p. 5).

[13] Reasoned Opinion on the modification of the existing maximum residue level for quizalofop (resulting from the use of quizalofop-P-ethyl) in caraway. EFSA Journal 2021;19(12):6957, 32 pp. EFSA scientific reports available online: https://www.efsa.europa.eu.

due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded. Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to modify the MRLs as set forth in the Annex to this Regulation.

(18) All applications for the renewal of the approval of the active substance sodium aluminium silicate were withdrawn and the renewal procedure was terminated before the EFSA risk assessment. The approval of sodium aluminium silicate expired on 31 August 2019[14]. Sodium aluminium silicate was temporarily included in Annex IV pending the finalisation of its evaluation either under Directive 91/414/EEC, and pending its review according to Article 12 of Regulation (EC) No 396/2005. Following the expiration of the approval, of this substance, the Authority included it in its statement on pesticide active substances that do not require a review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005[15]. In that statement, the Authority stated that evidence to conclude on the safety of this substance is insufficient, since a complete toxicological data set is not available. Therefore, and also taking into consideration the fact that sodium aluminium silicate adds to the overall human dietary exposure to aluminium, which already exceeds the Tolerable Weekly Intake for a significant part of the European population[16], it is appropriate to set all MRLs for that active substance to the LOD and list them in Annex V in accordance with Article 14(1)(a) in conjunction with Article 17 of Regulation (EC) No 396/2005.

(19) As regards thiabendazole, in the framework of the submission of several applications pursuant to Article 6(1) and 6(4) of Regulation (EC) No 396/2005, requesting modifications of the existing MRLs for thiabendazole in several crops, one applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 on analytical methods for thiabendazole in "products of animal origin".

(20) In accordance with Article 8 of Regulation (EC) No 396/2005, the applications for thiabendazole were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission. The Authority assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs[17]. The Authority forwarded this opinion to the applicant, the Commission and the Member States and made it available to the public. The Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific

---

14 Commission Implementing Regulation (EU) 2019/324 of 25 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances bifenthrin, carboxin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate (J L 57, 26.2.2019, p. 1).

15 EFSA 2019. Statement on the pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(12):5954.

16 Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. The EFSA Journal (2008) 754, 1-34.

17 EFSA 2021. Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for thiabendazole in various crops. EFSA Journal 2021;19(5):6586.

European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substance. Neither the long-term exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.

(21) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs for products of plant origin were implemented by Commission Regulation (EU) 2021/1807[18].

(22) For thiabendazole in "commodities from bovine", "commodities from goat", cattle milk, and goat milk, the available data are sufficient to derive an MRL at the LOD of 0.01 mg/kg on the basis of the updated EU livestock dietary burden. Therefore, it is appropriate to set lower MRLs corresponding to MRLs for veterinary medical products set by Commission Regulation No 37/2010[19,20], because exposure from use in veterinary medicinal products is expected to be higher than from use in plant protection products. For poultry muscle, poultry fat and "bird eggs", the existing MRLs correspond to CXLs which are not fully supported by data. Therefore, it is appropriate to lower the existing MRLs to the LOD. For all other products of animal origin, the available data are sufficient to derive an MRL at the LOD of 0.01 mg/kg on the basis of the updated EU livestock dietary burden. It is therefore appropriate to lower the existing MRLs to the LOD. The respective footnotes in Annex II highlighting the need for additional data for these products should be deleted. Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to modify the MRLs as set forth in the Annex to this Regulation.

(23) All applications for the renewal of the approval of the active substance triadimenol were withdrawn and the renewal procedure was terminated before the EFSA risk assessment. Therefore, the approval of triadimenol expired on 31 August 2019. As regards cucurbits with inedible peel and globe artichokes, the existing CXLs are not fully supported by data[21] and as regards grapes, the existing CXL is not compatible with Union residue definitions[22]. The MRLs for those products should therefore be lowered to the LOD. For all other products, it is appropriate to lower the existing MRLs set out in Annex II of Regulation (EC) No 396/2005 to the LODs in accordance with Article 14(1)(a) in conjunction with Article 17 of that Regulation

(24) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.

---

18 Commission Regulation (EU) 2021/1807 of 13 October 2021 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products (OJ L 365, 14.10.2021, p. 1).

19 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

20 EFSA 2021. Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for thiabendazole in various crops. EFSA Journal 2021;19(5):6586.

21 EFSA 2016. Reasoned opinion on the review of the existing maximum residue levels for triadimenol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(1): 4377.

22 EFSA 2016. Reasoned opinion on the review of the existing maximum residue levels for triadimenol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2016;14(1): 4377.

(25) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(26) For all active substances covered by this Regulation, in order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained. This is the case for all products except nicotine in rose hips~~,~~ and teas ~~and capers~~.

(27) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which result from the amendments.

(28) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III, IV and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before [*Office of Publications: please insert date 6 months after entry into force of this Regulation*], except for nicotine in rose hips and teas.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*Office of Publication: please insert date 6 months after entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN