Commission Regulation (EU) 2015/1608 of 24 September 2015 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/1608

of 24 September 2015

amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea 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 5(1) thereof,

Whereas:

(1) For capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea, no specific MRLs were set nor were the substances included in Annex IV to Regulation (EC) No 396/2005, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.

(2) Capric acid is approved under Commission Directive 2008/127/EC[(2)]. No relevant impurities were identified for that substance. In addition, natural exposure to capric acid is far higher than the one linked to the use of that substance as a plant protection product. In view of this, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

(3) For paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5) and paraffin oil (CAS 97862-82-3)[(3)(4)], the Authority concluded that if it could be demonstrated that paraffin oils are of high purity, no toxicological concern would be raised and no acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD) would be required. On 20 November 2012 the Standing Committee on Food Chain and Animal Health took note of an amended version of the review reports in which it is explained that the technical specifications comply with pharmaceutical grade (high purity). In view of this, it is

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considered appropriate to include these substances in Annex IV to Regulation (EC) No 396/2005.

(4) For lime sulphur[5], the Authority could not conclude on the dietary risk assessment for consumers as some information on the potential presence of polysulfide residues was not available. However, the sulphur and calcium residue from the use of lime sulphur (calcium polysulfide) is ubiquitous in the environment. In view of this, it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of the reasoned opinion of the Authority in accordance with Article 12(1).

(5) For urea[6], the Authority considered that a quantitative consumer dietary risk assessment was not necessary due to the specific methods of application of that substance. Urea (carbamide) is approved as a food additive in accordance with Regulation (EU) No 1129/2011 of the European Parliament and of the Council[7]. In addition, the natural exposure to that substance is far higher than the one linked to the use of urea as a plant protection product. In view of this, it is considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005.

(6) Based on the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the relevant requirements of Article 5(1)) of Regulation (EC) No 396/2005.

(7) The substances listed in Annex IV to Regulation (EC) No 396/2005 may also need to comply with the requirements provided for in Union food and/or feed legislation. In view of this, it is appropriate to modify the wording of footnote 2 in that Annex to refer to other specific Union food and/or feed legislation. Such legislation might also start to apply to a substance after its inclusion in Annex IV to Regulation (EC) No 396/2005. In view of this, it is appropriate to make that footnote applicable to all substances included in Annex IV.

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

(9) 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

Annex IV to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

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Done at Brussels, 24 September 2015.

For the Commission

The President

Jean-Claude JUNCKER