Commission Regulation (EU) No 588/2014 of 2 June 2014 amending Annexes III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for orange oil, Phlebiopsis gigantea, gibberellic acid, Paecilomyces fumosoroseus strain FE 9901, Spodoptera littoralis nucleopolyhedrovirus, Spodoptera exigua nuclear polyhedrosis virus, Bacillus firmus I-1582, s-abscisic acid, L-ascorbic acid and Helicoverpa armigera nucleopolyhedrovirus in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 588/2014

of 2 June 2014

amending Annexes III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for orange oil, *Phlebiopsis gigantea*, gibberellic acid, *Paecilomyces fumosoroseus* strain FE 9901, *Spodoptera littoralis* nucleopolyhedrovirus*, Spodoptera exigua* nuclear polyhedrosis virus, *Bacillus firmus* I-1582, s-abscisic acid, L-ascorbic acid and *Helicoverpa armigera* nucleopolyhedrovirus 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 gibberellic acid maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For *Phlebiopsis gigantea*, *Paecilomyces fumosoroseus* strain FE 9901, *Spodoptera littoralis* nucleopolyhedrovirus, *Spodoptera exigua* nuclear polyhedrosis virus, *Bacillus firmus* I-1582, orange oil, s-abscisic acid, L-ascorbic acid and *Helicoverpa armigera* nucleopolyhedrovirus, 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) As regards *Phlebiopsis gigantea*[(2)], *Paecilomyces fumosoroseus* strain FE 9901[(3)], *Spodoptera littoralis* nucleopolyhedrovirus[(4)], *Spodoptera exigua* nuclear polyhedrosis virus[(5)], *Bacillus firmus* I-1582[(6)] and *Helicoverpa armigera* nucleopolyhedrovirus[(7)] the European Food Safety Authority, (the Authority) concluded that these substances are not pathogenic to humans and do not require a quantitative consumer risk assessment. In view of that conclusion, the Commission considers that the inclusion of such substances in Annex IV to Regulation (EC) No 396/2005 is appropriate.

Changes to legislation: *Commission Regulation (EU) No 588/2014 is up to date with all changes known to be in force on or before 15 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(3) For orange oil[8], the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Orange oil is naturally occurring in plants and is used as a flavouring agent for medicine and food. 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 EFSA's reasoned opinion in accordance with Article 12(1).

(4) For gibberellic acid[9], the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Gibberellic acid is naturally occurring in a wide range of plants. The Authority did not propose MRLs for grapes as residues were shown to be below the LOQ in treated and control samples and since it would not be possible to distinguish between exogenous and natural occurring gibberellins. In view of these reasons it is considered appropriate to include this substance temporarily in Annex IV to Regulation (EC) No 396/2005 pending submission of EFSA's reasoned opinion in accordance with Article 12(1).

(5) For s-abscisic acid[10], the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. S-abscisic acid is naturally occurring in plants. 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 EFSA's reasoned opinion in accordance with Article 12(1).

(6) As regards L-ascorbic acid, the Authority concluded[11] that its inclusion in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(7) Based on the scientific opinion and conclusions 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) and Article 14(2) of Regulation (EC) No 396/2005.

(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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

1 In Annex III to Regulation (EC) No 396/2005 the column for gibberellic acid is deleted.

2 In Annex IV, the entries: 'orange oil[12]', '*Phlebiopsis gigantea*', 'gibberellic acid[12]', '*Paecilomyces fumosoroseus* strain FE 9901', '*Spodoptera littoralis* nucleopolyhedrovirus', '*Spodoptera exigua* nuclear polyhedrosis virus', '*Bacillus firmus* I-1582', 's-abscisic acid[12]', 'L-ascorbic acid', and '*Helicoverpa armigera* nucleopolyhedrovirus' are added, in alphabetical order.