Commission Regulation (EU) 2016/805 of 20 May 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Streptomyces K61 (formerly S. griseoviridis), Candida oleophila strain O, FEN 560 (also called fenugreek or fenugreek seed powder), methyl decanoate (CAS 110-42-9), methyl octanoate (CAS 111-11-5) and terpenoid blend QRD 460 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/805

of 20 May 2016

amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards *Streptomyces* K61 (formerly *S. griseoviridis*), *Candida oleophila* strain O, FEN 560 (also called fenugreek or fenugreek seed powder), methyl decanoate (CAS 110-42-9), methyl octanoate (CAS 111-11-5) and terpenoid blend QRD 460

(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 *Streptomyces* K61 (formerly *S. griseoviridis*), *Candida oleophila* strain O, FEN 560 (also called fenugreek or fenugreek seed powder) and terpenoid blend QRD 460 no specific MRLs were set. As those substances were not included in Annex IV to Regulation (EC) No 396/2005, the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies. Methyl decanoate (CAS 110-42-9) and methyl octanoate (CAS 111-11-5) belong to the group of fatty acids C7-C20 which is included in Annex IV to Regulation (EC) No 396/2005.

(2) As regards FEN 560 (also called fenugreek or fenugreek seed powder), the European Food Safety Authority ('the Authority') concluded[(2)] that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(3) As regards terpenoid blend QRD 460, the Authority concluded[(3)] that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(4) As regards *Streptomyces* K61 (formerly *S. griseoviridis*)[(4)] 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 necessary. Such further consideration was reflected in the review report[(5)] which concluded that the risk to

Changes to legislation: *Commission Regulation (EU) 2016/805 is up to date with all changes known to be in force on or before 24 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*

humans through metabolites from this substance is negligible. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.

(5) As regards *Candida oleophila* strain O[(6)] 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 necessary. Such further consideration was reflected in the review report[(7)] which concluded that the risk to humans through metabolites from this substance is negligible. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.

(6) Methyl decanoate (CAS 110-42-9) was included in Annex I to Council Directive 91/414/EEC[(8)] by Commission Directive 2008/127/EC[(9)] and is deemed to have been approved under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(10)]. No relevant impurities were identified for that substance. In addition, natural exposure to methyl decanoate is far higher than the one linked to the use of that substance as a plant protection product. It is therefore appropriate to maintain that substance in Annex IV to Regulation (EC) No 396/2005 but separately from the group fatty acids C7-C20 to ensure transparency.

(7) Methyl octanoate (CAS 111-11-5) was included in Annex I to Directive 91/414/EEC by Directive 2008/127/EC and is deemed to have been approved under Regulation (EC) No 1107/2009. No relevant impurities were identified for that substance. In addition, natural exposure to methyl octanoate is far higher than the one linked to the use of that substance as a plant protection product. It is therefore appropriate to maintain that substance in Annex IV to Regulation (EC) No 396/2005, but separately from the group fatty acids C7-C20 to ensure transparency.

(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

In Annex IV to Regulation (EC) No 396/2005, the following entries are inserted in alphabetical order: '*Streptomyces* K61 (formerly *S. griseoviridis*)', '*Candida oleophila* strain O', 'FEN 560 (also called fenugreek or fenugreek seed powder)', 'Methyl decanoate (CAS 110-42-9)', 'Methyl octanoate (CAS 111-11-5)' and 'Terpenoid blend QRD 460'.

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.