Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/408

of 11 March 2015

on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution

(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 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[(1)], and in particular Article 78(2) thereof,

Whereas:

(1) Active substances are to be identified as candidates for substitution if they meet one or more criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009.

(2) Pursuant to Article 80(7) of Regulation (EC) No 1107/2009, the Commission has to establish a list of substances included in Annex I to Council Directive 91/414/EEC[(2)] which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009, hereinafter: 'list of candidates for substitution'.

(3) To ensure the consistency of the policy of the Union as regards active substances that have properties identifying them as candidates for substitution and to apply equal treatment to such substances, the Commission should also include in that list active substances approved under Regulation (EC) No 1107/2009 pursuant to the transitional provisions of Article 80(1).

(4) From the information contained in either the review report, or the conclusions of the European Food Safety Authority[(3)] or the Draft Assessment Report and related addenda and peer review reports, or from the classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(4)], it was possible to identify the substances which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009. These documents provide information, where relevant, concerning the applicable Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) or Acceptable Operator Exposure Level (AOEL), the information concerning

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/408. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

persistent, bio-accumulative and toxic (PBT) properties of the substances, information concerning critical effects referred to in the third indent of point 4 of Annex II to Regulation (EC) No 1107/2009, the proportion of non-active isomers, the classification in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B and toxic for reproduction category 1A or 1B, the endocrine disrupting properties. Based on that information, the substances set out in the Annex to this Regulation were identified as satisfying one or more criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009. The information has been consolidated and can be found in a support tool for the establishment of the list of candidates for substitution, which is available on the Commission website[(5)].

(5) The Acceptable Daily Intake (ADI) of the active substances 1-methylcyclopropene, amitrole, diclofop, dimethoate, ethoprophos, fenamiphos, fipronil, fluometuron, haloxyfop-P, metam, oxamyl, sulcotrione and triazoxide is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. The Acute Reference Dose (ARfD) of the active substances dimoxystrobin, fenamiphos, methomyl and oxamyl is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. The Acceptable Operator Exposure Level (AOEL) of the active substances amitrole, bromadiolone, difenacoum, dimethoate, diquat, ethoprophos, fenamiphos, fluquinconazole, metam, sulcotrione, triazoxide and warfarin is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(6) The active substances lufenuron, oxyfluorfen and quinoxyfen meet the criteria to be considered a persistent and bioaccumulative substance. The active substances amitrole, bifenthrin, bromuconazole, chlorotoluron (unstated stereochemistry), copper compounds (variants copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture and tribasic copper sulphate), cyproconazole, cyprodinil, difenoconazole, diflufenican, dimoxystrobin, diquat, epoxiconazole, fenbutatin oxide, fludioxonil, flufenacet, fluopicolide, fluquinconazole, haloxyfop-P, imazamox, imazosulfuron, isoproturon, isopyrazam, lenacil, lufenuron, metconazole, metribuzin, metsulfuron-methyl, myclobutanil, nicosulfuron, oxadiazon, oxyfluorfen, paclobutrazol, pirimicarb, prochloraz, propiconazole, propoxycarbazone, prosulfuron, quinoxyfen, tebuconazole, tebufenpyrad, tepraloxydim, tri-allate, triasulfuron and ziram meet the criteria to be considered a persistent and toxic substance. The active substances aclonifen, difenacoum, esfenvalerate, etofenprox, etoxazole, famoxadone, lambda-cyhalothrin, lufenuron, oxyfluorfen, pendimethalin and quinoxyfen meet the criteria to be considered a bioaccumulative and toxic substance. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(7) The active substances mecoprop and metalaxyl contain a significant proportion of non-active isomers. It is therefore appropriate to include those active substances in the list of candidates for substitution.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/408. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(8) The active substances carbendazim, epoxiconazole, flumioxazine, glufosinate, linuron, oxadiargyl, quizalofop-P (variant quizalofop-P-tefuryl) and warfarin are or are to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(9) Since measures concerning specific scientific criteria for the determination of endocrine disrupting properties, as referred to in the first paragraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, have not yet been adopted, it was to be established in accordance with the third paragraph thereof whether a substance is to be considered as having such properties. In accordance with that provision the active substances chlorotoluron (unstated stereochemistry), dimoxystrobin, epoxiconazole, molinate, profoxydim, tepraloxydim and thiacloprid are to be considered as having endocrine disrupting properties that may cause adverse effects in humans. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(10) Member States and interested parties should be provided with a reasonable period to adapt to the provisions of this Regulation.

(11) 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

Candidates for substitution

Active substances included in Annex I to Directive 91/414/EEC which fulfil the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009 shall be as set out in the list in the Annex to this Regulation.

The first paragraph shall also apply to active substances approved under Regulation (EC) No 1107/2009 pursuant to the transitional measures of Article 80(1).

Article 2

Transitional measures

Article 1 and the Annex shall not apply to applications for the authorisation of plant protection products submitted before 1 August 2015.

Article 3

Entry into force

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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/408. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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