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Delegations will find attached document D076406/05 ANNEX.

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ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...

amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms

ANNEX

Annex II to Regulation (EC) No 1107/2009 is amended as follows:

(1) Point 3.1(b) is replaced by the following:

'(b) reliably predict the residues in food and feed, including succeeding crops, on the basis of information provided in accordance with the data requirements for active substances;';

(2) Point 3.4 is replaced by the following:

'3.4. Composition of the active substance, safener or synergist

3.4.1. For chemical active substances, safeners and synergists, the specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/ diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.

3.4.2. For chemical active substances, safeners and synergists, the specification shall be in compliance with the relevant Food and Agriculture Organisation specification as appropriate, where such specification exists. However, where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

3.4.3. Active substances that are micro-organisms shall be deposited at an internationally recognised culture collection and shall have an accession number. The species' name of the micro-organisms shall be identified unequivocally, based on the latest scientific information, and the micro-organisms shall be named at the strain level, including any other designation which may be relevant (e.g. isolate level, if relevant for viruses). It shall be indicated whether or not the micro-organisms are wild types, spontaneous or induced mutants, or genetically modified organisms.

3.4.4. For active substances that are micro-organisms, the specification shall define the minimum and maximum content of the micro-organism, the identity and content of relevant contaminating micro-organisms, metabolites of concern and impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.';

(3) Point 3.5 is replaced by the following:

‘3.5. Methods of analysis

3.5.1. The methods of analysis of chemical active substances, safeners or synergists as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for chemical active substances and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation shall have been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

3.5.4. For active substances that are micro-organisms, the methods of analysis to identify and quantify them, and relevant contaminating micro-organisms, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.5. For active substances that are micro-organisms, the methods of analysis of metabolites of concern and relevant impurities shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.’;

(4) The following point 3.6.6 is added after point 3.6.5:

‘3.6.6. Active substances that are micro-organisms shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that the strain of the micro-organism is not pathogenic to humans.

In addition:

(a) viruses shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that the isolate of the virus is not infective to humans;

(b) strains of bacteria shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that they do not have any known, functional and transferable gene coding for resistance to relevant antimicrobial agents as defined in accordance with the data requirements.’;

(5) Point 5.2 is replaced by the following:

‘5.2. Micro-organisms

5.2.1. An active substance that is a micro-organism other than a virus may be considered a low-risk active substance unless its susceptibility to at least two classes of antimicrobial agents has not been demonstrated.

5.2.2. An active substance that is a virus may be considered a low-risk active substance unless it is:

(a) a baculovirus with demonstrated adverse effects on non-target insects; or

(b) a non-virulent variant of a plant pathogen with demonstrated adverse effects on non-target plants.’.