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ANNEX 1

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to the

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

amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties

ANNEX

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

(1) In Point 3.6.5. the following paragraphs are added after the fourth paragraph:

"From [date of application], an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effect in humans if, based on points (1) to (3) of the sixth paragraph it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant to humans:

(1) it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(3) the adverse effect is a consequence of the endocrine mode of action.

The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with the fifth paragraph shall be based on all of the following:

(1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action):

(a) scientific data generated in accordance with internationally agreed study protocols, in particular those listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;

(b) other scientific data selected applying a systematic review methodology, in particular following guidance on literature data which is listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;

(2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the fifth paragraph are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall, in particular, consider all of the following factors:

(a) both positive and negative results;

(b) the relevance of the study designs, for the assessment of adverse effects and of the endocrine mode of action;

(c) the biological plausibility of the link between the adverse effects and the endocrine mode of action;

(d) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;

(e) the route of exposure, toxicokinetic and metabolism studies;

(f) the concept of the limit dose, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;

(3) adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor."

(2) In Point 3.8.2. the following paragraphs are added after the sole paragraph:

"From [date of application], an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effects on non-target organisms if, based on points (1) to (4) of the third paragraph, it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant at the (sub)population level for non-target organisms:

(1) it shows an adverse effect in non-target organisms, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(3) the adverse effect is a consequence of the endocrine mode of action.

The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effects on non-target organisms in accordance with the second paragraph shall be based on all of the following:

(1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action):

(a) scientific data generated in accordance with internationally agreed study protocols, in particular, those listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;

(b) other scientific data selected applying a systematic review methodology, in particular following guidance listed in the Commission Communications in the framework of setting out the data requirements

for active substances and plant protection products, in accordance with this Regulation;

(2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the second paragraph are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall consider all of the following factors:

(a) both positive and negative results, discriminating between taxonomic groups (e.g. mammals, birds, fish, amphibians) where relevant;

(b) the relevance of the study design for the assessment of the adverse effects and its relevance at the (sub)population level, and for the assessment of the endocrine mode of action;

(c) the adverse effects on reproduction, growth/development, and other relevant adverse effects which are likely to impact on (sub)populations. Adequate, reliable and representative field or monitoring data and/or results from population models shall as well be considered where available;

(d) the biological plausibility of the link between the adverse effects and the endocrine mode of action;

(e) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different taxonomic groups;

(f) the concept of the limit dose and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity.

(3) Adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms;

(4) If the intended plant protection mode of action of the active substance being assessed, within the meaning of point 3.6. of Part A of the Annex to Commission Regulation (EU) No 283/2013*, consists of controlling target organisms via their endocrine systems, the effect on organisms being of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms.

* Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1)."