ANNEX

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

(1) Point 3.6.5. is replaced by the following:

"3.6.5. Endocrine disrupting properties

3.6.5.1. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

3.6.5.2. From [date of EIF], the following shall apply instead of the first, the third and the fourth paragraph of point 3.6.5.1.

3.6.5.2.1. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of the available evidence carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, it is not considered, in accordance with the criteria specified in point 3.6.5.2.2, to have endocrine disrupting properties that may cause adverse effect in humans, unless the risk to humans from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible, in particular where the product is used in closed systems or in other conditions which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection.

3.6.5.2.2. 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 (4) of point 3.6.5.2.3., it is a substance that meets all of the following criteria, unless there is information 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.

3.6.5.2.3. The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with point 3.6.5.2.2. shall be based on all of the following:

(1) all available relevant scientific data:

  (a) scientific data generated in accordance with internationally agreed study protocols (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo or in vitro studies informing about endocrine modes of action). In particular, those internationally agreed study protocols listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 shall be considered.

  (b) other relevant 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 Regulation (EC) No 1107/2009.

(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 point 3.6.5.2.2 are fulfilled.

(3) in applying the weight of evidence determination, the assessment of quality, reliability, reproducibility and consistency 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.

(4) 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) Point 3.8.2. is replaced by the following:

"3.8.2 Endocrine disrupting properties

3.8.2.1. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

3.8.2.2. From [date of EIF], the following shall apply instead point 3.8.2.1.

3.8.2.2.1 An active substance, safener or synergist shall only be approved if it is not considered, in accordance with the criteria specified in point 3.8.2.2.2, to have endocrine disrupting properties that may cause adverse effects on non-target organisms, unless the risk to the non-target organisms from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible.

3.8.2.2.2 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 point 3.8.2.2.3, it is a substance that meets all of the following criteria, unless there is information 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, considered relevant at the (sub)population level;

(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

3.8.2.2.3 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 point 3.8.2.2.2 shall be based on all of the following:

(1) all available relevant scientific data:

(a) scientific data generated in accordance with internationally agreed study protocols (in vivo studies or adequately validated alternative test systems

predictive of adverse effects in humans or animals; as well as in vivo or in vitro studies informing about endocrine modes of action). In particular, those internationally agreed study protocols listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with Regulation (EC) No 1107/2009 shall be considered.

(b) other relevant 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 Regulation (EC) No 1107/2009.

(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 point 3.8.2.2.2 are fulfilled.

(3) in applying the weight of evidence determination, the assessment of quality, reliability, reproducibility and consistency 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) 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 and growth/development, as these are the effects most likely to impact on (sub)populations. Adequate, reliable and representative field or monitoring data and/or results from population models shall 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.

(4) 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."