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Subject:	ANNEX to COMMISSION REGULATION (EU) .../...of XXX amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances

Delegations will find attached document D046260/03 ANNEX 1.

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ANNEX 1

ANNEX

to the

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

amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances

ANNEX

Point 5 of Annex II to Regulation (EC) No 1107/2009 is replaced by the following:

"5. Low-risk active substances

5.1. Active substances other than micro-organisms

5.1.1. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it corresponds to any of the following:

(a) it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as any of the following:

- carcinogenic category 1A, 1B or 2;
- mutagenic category 1A, 1B or 2;
- toxic to reproduction category 1A, 1B or 2;
- skin sensitiser category 1;
- serious damage to eye category 1;
- respiratory sensitiser category 1;
- acute toxicity category 1, 2 or 3;
- specific Target Organ Toxicant, category 1 or 2;
- toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests;
- explosive;
- skin corrosive, category 1A, 1B or 1C.

(b) it has been identified as priority substance under the Directive 2000/60/EC of the European Parliament and of the Council¹;

(c) it is deemed to be an endocrine disruptor;

(d) it has neurotoxic or immunotoxic effects.

5.1.2. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

However, a naturally occurring active substance which does not correspond to any of points (a) to (d) of point 5.1.1 may be considered as being of low-risk, even if it is

¹ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

5.1.3. An active substance, other than a micro-organism, emitted and used by plants, animals and other organisms for communication, shall be considered as being of low-risk where it does not correspond to any of points (a) to (d) of point 5.1.1.

5.2. Micro-organisms

5.2.1. An active substance which is a micro-organism may be considered as being of low-risk unless at strain level it has demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.

5.2.2. Baculoviruses shall be considered as being of low-risk unless at strain level they have demonstrated adverse effects on non-target insects."