Article 43 bis

Amendments to Regulation (EC) No 1107/2009 of European Parliament and the Council of 21 October 2009 concerning the placing of plant proception products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Regulation (EC) 1107/2009 is proposed amended as follows:

1) After Article 11(1), the following subparagraph is proposed to be added:

"Within 3 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall make an assessment according to Article 4 on whether the active substance complies with the criteria provided for in article 4 and point 5 of Annex II as a biocontrol low-risk active substance. If these criteria are met, the rapporteur Member State has an additional 6 months to complete the assessment in accordance to Articles 4 and 22 and perform the tasks set out in the first subparagraph of Article 11(1)."

Provided that Article 11(1) is amended as proposed, the period in Article 11(3) shall also be adjusted to 9 months by which the rapporteur Member State needs additional studies or information to make an assessment.

2) After Article 13(1), the following subparagraph is proposed to be added:

"For a biocontrol low-risk active substance as referred to in Article 22(1), the Commission shall perform the tasks set out in the first subparagraph of Article 13(1) within three months of receiving the conclusion from the Authority."

3) After Article 22(1), the following subparagraph is proposed added:

"A low-risk active substance, that complies with the criteria set out in point 5.3 of Annex II regarding biocontrol active substances, shall be approved for a period not exceeding **20 years**, provided that the other approval criteria in Article 22(1) and (2) are satisfied."

<u>Alternatively</u>

"A low-risk active substance, that complies with the criteria set out in point 5.3 of Annex II regarding biocontrol active substances, shall be approved for an **unlimited** period of time, provided that the other approval criteria in Article 22(1) and (2) are satisfied."

Provided that Article 22(1) is amended as proposed and biocontrol low-risk active substances are approved for an unlimited period of time, point 15 and/or point 17 in the preamble may be adjusted accordingly. Moreover, it should be clear from the list of approved active substances in accordance with the Regulation referred to in Article 13(4) and 22(2), which biocontrol low-risk active substances are approved for an unlimited period. Furthermore, it is proposed that it is explicitly defined that the Commission shall be empowered to include, restrict or remove a biocontrol low-risk active substance from the list of approved active substances in accordance with the Regulation referred to in Article 13(4) and 22(2).

4) Transitional measures
Provided that the proposed amendments are adopted, some transitional measures should be considered, which establish that the new provisions are applicable only to new approvals or renewal of approvals of biocontrol low-risk substances, which are included on the list of approved active substances in accordance with the Regulation referred to in Article 13(4) and 22(2), and not to the submitted applications that are under assessment at the time of entry into force of the proposed amendments.

5) In Annex II, the following subparagraph is proposed added:
"5.3. Biocontrol active substances
Biocontrol active substances means active substances of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, or invertebrate macro-organisms."