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

CHAPTER II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 4

Derogations

Article 22

Low-risk active substances

1 An active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding 15 years by way of derogation from Article 5, where it is considered a low-risk active substance and where it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1).

2 Articles 4 and 6 to 21 and point 5 of Annex II shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).

3 The Commission may review and if necessary specify new criteria for approving an active substance as low-risk active substance in accordance with Article 78(1)(a).

Article 23

Approval criteria for basic substances

1 Basic substances shall be approved in accordance with paragraphs 2 to 6. By way of derogation from Article 5, the approval shall be for an unlimited period.

For the purpose of paragraphs 2 to 6, a basic substance is an active substance which:

a is not a substance of concern; and

b does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

c is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

d is not placed on the market as a plant protection product.

For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

2 By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other Community legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

3 By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission.

The application shall be accompanied by the following information:

a any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and

b other relevant information on its possible effects on human or animal health or the environment.

4 The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the date of the request.

5 Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).

6 The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval.

Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraphs 1 to 3 it shall inform the Member States, the Authority and the interested party, setting a period for their comments to be submitted.

The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 24

Candidates for substitution

1 An active substance complying with the criteria provided for in Article 4 shall be approved, for a period not exceeding seven years, as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding seven years.

2 Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in the Regulation referred to in Article 13(4).

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Subsection 4.