



Brussels, **XXX**
PLAN/2023/2195
[...] (2023) **XXX** draft

ANNEXES 1 to 3

ANNEXES

to the

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

defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

ANNEX II

Content of notification of interest to apply for the approval of a safener or synergist as referred to in Article 4(1)

- 1. Identification data on the notifying party:**
 - 1.1. manufacturer of the substance (name, address, including location of plant);
 - 1.2. notifying company (name, address, etc.) (if different from 1.1):
 - 1.2.1. acting as sole representative designated by the manufacturer?: Yes / No;
 - 1.3. Identification of the contact person responsible for the notification and further engagements:
 - 1.3.1. Name;
 - 1.3.1.1. Postal address;
 - 1.3.1.2. Email;
 - 1.3.1.3. Primary phone number;
 - 1.3.1.4. Alternative phone number.
- 2. Identification of the safener or synergist:**
 - 2.1. name of the safener or synergist;
 - 2.2. CAS number safener or synergist;
 - 2.3. EC number safener or synergist.

ANNEX III

Supplementary data requirements for submission of applications for the approval of safeners and synergists as referred to in Article 9(1), points (a) and (b)

1. A description of the intended purpose of the use of the safener or synergist and the dose and manner of their use or proposed use.
2. An evaluation of the nature and extent of benefits that accrue from the presence of the safener or synergist following use of the plant protection product, in comparison to an untreated control and in comparison to the use of the same plant protection product not containing the safener or synergist.
3. Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the activity or dose range finding of the safeners or synergists contained in a plant protection product, when requested by the competent authority. These reports must provide additional information for the competent authority in order to justify the recommended dose of the safener or synergist, and when several are used their ratio.
4. sufficient information to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product.
 - 4.1. In case of safeners, the following three types of studies:

- (a) an investigation of the effects of a treatment on a representative use with a plant protection product containing the relevant safener in relation to the control of the target organism and effect on the treated plants or plant products;
- (b) an investigation of the effects of a treatment on a representative use with the same plant protection product without the relevant safener in relation to the control of the target organism and effect on the treated plants or plant products in order to prove that the safener eliminates or reduces phytotoxic effects of the plant protection product;
- (c) an investigation of the effects of a treatment on a representative use with the same plant protection product containing the relevant safener but no active substance in order to prove that the safener has no efficacy on its own.

4.2. In case of synergists, the following three types of studies:

- (a) an investigation of the effects of a treatment on a representative use with a plant protection product containing the relevant synergist in relation to the control of the target organism and effect on the treated plants or plant products;
- (b) an investigation of the effects of a treatment on a representative use with the same plant protection product without the relevant synergist in relation to the control of the target organism and effect on the treated plants or plant products in order to prove that the synergist increases the efficacy of the product against the treated pests;
- (c) an investigation of the effects of a treatment on a representative use with the same plant protection product containing the relevant synergist but no active substance in order to prove that the synergist has no efficacy on its own.