Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms (Text with EEA relevance)

ANNEX

Annex VI is hereby amended as follows:
The title ‘Uniform Principles for evaluation and authorisation of plant...

2.1. Identity
- 2.1.1. Identity of the micro-organism in the plant protection product
- 2.1.2. Identity of the plant protection product

2.2. Biological, physical, chemical, and technical properties
- 2.2.1. Biological properties of the micro-organism in the plant protection product...
  - 2.2.1.1. The origin of the strain, where relevant, its natural habitat...
  - 2.2.1.2. The ability of micro-organisms to adapt to the environment must...
  - 2.2.1.3. The mode of action of the micro-organism should be evaluated...
  - 2.2.1.4. In order to evaluate possible effects on non-target organisms, information...
  - 2.2.1.5. Many micro-organisms produce antibiosis substances that cause normal interferences in...
- 2.2.2. Physical, chemical and technical properties of the plant protection product...
  - 2.2.2.1. Depending on the nature of the micro-organism and the formulation...
  - 2.2.2.2. Shelf-life and storage stability of the preparation must be evaluated,...
  - 2.2.2.3. Member States shall evaluate the physical and chemical properties of...
  - 2.2.2.4. Where the proposed label claims include requirements or recommendations for...

2.3. Further information
- 2.3.1. Quality control of the production of the micro-organism in the...
- 2.3.2. Quality control of the plant protection product

2.4. Efficacy
- 2.4.1. Where the proposed use concerns the control of or protection...
- 2.4.2. Member States shall evaluate whether significant damage, loss or inconvenience...
- 2.4.3. Member States shall evaluate the efficacy data provided for in...
- 2.4.4. Member States shall evaluate the performance of the plant protection...
- 2.4.5. Member States shall evaluate the degree of adverse effects on...
- 2.4.6. Where the plant protection product label includes requirements for use...
- 2.4.7. Where the available data indicate that the micro-organism or significant...
- 2.4.8. Where the proposed use of a plant protection product is...

2.5. Identification/detection and quantification methods
- 2.5.1. Analytical methods for the plant protection product
  - 2.5.1.1. Non-viable components
  - 2.5.1.2. Viable components
- 2.5.2. Analytical methods for the determination of residues
  - 2.5.2.1. Non-viable residues
  - 2.5.2.2. Viable residues

2.6. Impact on human or animal health
- 2.6.1. Effects on human or animal health arising from the plant...

2.6.1.1. Member States shall evaluate operator exposure to the micro-organism, and/or...
2.6.1.2. Member States shall examine information relating to the nature and...
2.6.1.3. Member States shall examine the nature and characteristics of the...
2.6.1.4. Member States shall evaluate the possibility of exposure of other...
2.6.2. Effects on human or animal health arising from residues
2.6.2.1. Non-viable residues
2.6.2.2. Viable residues
2.7. Fate and behaviour in the environment
2.7.1. Member States shall evaluate the possibility of contamination of ground...
2.7.2. Member States shall evaluate the risk for the aquatic compartment...
2.7.3. Member States shall evaluate the possibility of exposure of organisms...
2.7.4. Member States shall evaluate the possibility of exposure of organisms...
2.8. Effects on and exposure of non-target organisms
2.8.1. Member States shall evaluate the possibility of exposure of and...
2.8.1.1. A micro-organism may give rise to risks because of its...
2.8.1.2. A plant protection product may give rise to toxic effects...
2.8.2. Member States shall evaluate the possibility of exposure of and...
2.8.2.1. A micro-organism may give rise to risks because of its...
2.8.2.2. A plant protection product may give rise to toxic effects...
2.8.3. Member States shall evaluate the possibility of exposure of and...
2.8.3.1. A micro-organism may give rise to risks because of its...
2.8.3.2. A plant protection product may give rise to toxic effects...
2.8.4. Member States shall evaluate the possibility of exposure of and...
2.8.4.1. A micro-organism may give rise to risks because of its...
2.8.4.2. A plant protection product may give rise to toxic effects...
2.8.5. Member States shall evaluate the possibility of exposure of and...
2.8.5.1. A micro-organism may give rise to risks because of its...
2.8.5.2. A plant protection product may give rise to toxic effects...
2.8.6. Member States shall evaluate the possibility of exposure of and...

2.8.6.1. A micro-organism may give rise to risks because of its...
2.8.6.2. Member States shall evaluate the impact of exotic/ non-indigenous micro-organisms on...
2.8.6.3. A plant protection product may give rise to toxic effects...
2.9. Conclusions and proposals

C. DECISION-MAKING
1. General principles
1.1. Where appropriate, Member States shall impose conditions or restrictions on...
1.2. Member States shall ensure that decisions taken to grant authorisations,...
1.3. Member States shall ensure that the authorised amounts, in terms...
1.4. Member States shall ensure that decisions respect the principles of...
1.5. Since the evaluation is to be based on data concerning...
1.6. Before issuing an authorisation, Member States shall ensure that the...
1.7. Before issuing authorisations, Member States shall:
1.8. No authorisation shall be granted unless all the requirements referred...
1.9. Where an authorisation has been granted according to the requirements...
1.10. Member States shall ensure, as far as is practically possible,...
1.11. Where the micro-organism has been genetically modified, as defined in...
1.12. In accordance with Article 1(3) of this Directive, no authorisation shall...
1.13. No authorisation shall be granted if relevant metabolites/toxins (i.e. those...
1.14. Member States shall ensure that adequate quality control measures are...
2. Specific principles
2.1. Identity
2.2. Biological and technical properties
2.2.1. There must be sufficient information to permit assessment of the...
2.2.2. No authorisation shall be granted if, at any stage in...
2.3. Further information
2.4. Efficacy
2.4.1. Performance
2.4.1.1. No authorisation shall be granted where the proposed uses include...
2.4.1.2. The level, consistency and duration of control or protection or...
2.4.1.3. Where relevant, yield response when the plant protection product is...
2.4.1.4. Conclusions as to the performance of the preparation must be...
2.4.1.5. Where proposed label claims include requirements for use of the...
2.4.1.6. If there is evidence of a development of resistance of...
2.4.1.7. Only plant protection products containing non-viable micro-organisms may be authorised...

2.4.2. Absence of unacceptable effects on plants and plant products
2.4.2.1. There must be no relevant phytotoxic effects on treated plants...
2.4.2.2. There must be no reduction of yield at harvest due...
2.4.2.3. There must be no unacceptable adverse effects on the quality...
2.4.2.4. There must be no unacceptable adverse effects on treated plants...
2.4.2.5. There must be no unacceptable impact on succeeding crops, except...
2.4.2.6. There must be no unacceptable impact on adjacent crops, except...
2.4.2.7. Where proposed label claims include requirements for use of the...
2.4.2.8. The proposed instructions for cleaning the application equipment must be...

2.5. Identification/detection and quantification methods
2.5.1. No authorisation shall be granted unless there is an adequate...
2.5.2. No authorisation shall be granted unless there are adequate methods...

2.6. Impact on human and animal health
2.6.1. Effects on human and animal health arising from the plant...
2.6.1.1. No authorisation shall be granted if on the basis of...
2.6.1.2. No authorisation shall be granted if the micro-organism and/or the...
2.6.1.3. All micro-organisms should be regarded as potential sensitisers, unless it...
2.6.1.4. No authorisation shall be granted if it is known that...
2.6.1.5. Plant protection products which, because of particular properties, or which,...
2.6.1.6. Waiting and re-entry safety periods or other precautions must be...
2.6.1.7. Waiting and re-entry safety periods or other precautions must be...
2.6.1.8. Waiting and re-entry periods or other precautions to ensure that...
2.6.1.9. The conditions of authorisation shall be in compliance with Council...
2.6.2. Effects on human and animal health arising from residues
2.6.2.1. No authorisation shall be granted unless there is sufficient information...
2.6.2.2. No authorisation shall be granted unless viable residues and/or non-viable...

2.7. Fate and behaviour in the environment
2.7.1. No authorisation shall be granted if the available information indicates...
2.7.2. No authorisation shall be granted if contamination of ground water,...
2.7.3. No authorisation shall be granted if the contamination of groundwater...
2.7.4. No authorisation shall be granted if the contamination of surface...
2.7.5. No authorisation shall be granted if it is known that...

2.7.6. No authorisation shall be granted unless there is sufficient information...
2.7.7. No authorisation shall be granted if it can be expected...
2.8. Effects on non-target organisms
2.8.1. Where there is a possibility of birds and other non-target...
2.8.2. Where there is a possibility of aquatic organisms being exposed,...
2.8.3. Where there is a possibility of bees being exposed, no...
2.8.4. Where there is a possibility of arthropods other than bees...
2.8.5. Where there is a possibility of earthworms being exposed, no...
2.8.6. Where there is a possibility of non-target soil micro-organisms being...

(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/99/EC (OJ L 309, 16.10.2004, p. 6).

(**2**) OJ L 164, 20.6.2001, p. 1.

(**3**) OJ L 194, 25.7.1975, p. 26. Directive to be repealed from 22.12.2007 by Directive 2000/60/EC (OJ L 327, 22.12.2000, p. 1).

(**4**) OJ L 20, 26.1.1980, p. 43. Directive to be repealed from 22.12.2013 by Directive 2000/60/EC.

(**5**) OJ L 330, 5.12.1998, p. 32. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(**6**) OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

(**7**) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).