ANNEX I

Definition of zones for the authorisation of plant protection products as referred to in Article 3(17)

Zone A — North

The following Member States belong to this zone:

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden
Zone B — Centre

The following Member States belong to this zone:

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom
Zone C — South

The following Member States belong to this zone:

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

ANNEX II

Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II

1. Evaluation

1.1. During the process of evaluation and decision-making provided for in Articles 4 to 21, the rapporteur Member State and the Authority shall cooperate with applicants to resolve any questions on the dossier quickly or to identify at an early stage any further explanations or additional studies necessary for the evaluation of the dossier, including information to eliminate the need for a restriction of the approval, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Regulation.

1.2. The evaluation by the Authority and the rapporteur Member State must be based on scientific principles and be made with the benefit of expert advice.

1.3. During the process of evaluation and decision-making provided for in Articles 4 to 21, Member States and the Authority shall take into consideration any further guidance developed in the framework of the Standing Committee on the Food Chain and Animal Health for the purposes of refining, where relevant, the risk assessments.

2. General decision-making criteria

2.1. Article 4 shall only be considered as complied with, where, on the basis of the dossier submitted, authorisation in at least one Member State is expected to be possible for at least one plant protection product containing that active substance for at least one of the representative uses.

2.2. Submission of further information

In principle an active substance, safener or synergist shall only be approved where a complete dossier is submitted.

In exceptional cases an active substance, safener or synergist may be approved even though certain information is still to be submitted where:

(a) the data requirements have been amended or refined after the submission of the dossier; or

(b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.

2.3. Restrictions on approval

Where necessary, the approval may be subject to conditions and restrictions as referred to in Article 6.

Where the rapporteur Member State considers that the dossier provided lacks certain information, to the effect that the active substance could only be approved subject to restrictions, it shall contact the applicant at an early stage to obtain more information which may possibly enable these restrictions to be removed.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossiers submitted pursuant to Article 7(1) shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).

In the case of an active substance, safener or synergist for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed, the dossier submitted pursuant to Article 7(1) shall contain the information necessary to carry out a risk assessment and for enforcement purposes.

The dossier shall in particular:

(a) permit any residue of concern to be defined;

(b) reliably predict the residues in food and feed, including succeeding crops;

(c) reliably predict, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;

(d) permit a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;

(e) permit, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.2. Efficacy

An active substance alone or associated with a safener or synergist shall only be approved where it has been established for one or more representative uses that the plant protection product,

consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.4. Composition of the active substance, safener or synergist

3.4.1. The specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.

3.4.2. The specification shall be in compliance with the relevant Food and Agriculture Organisation specification as appropriate, where such specification exists. However, where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

3.5. Methods of analysis

3.5.1. The methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

3.6. Impact on human health

3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population. When the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.

3.6.2. An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B.

3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data

and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

3.7. Fate and behaviour in the environment

3.7.1. An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP).

A substance that fulfils all three of the criteria of the points below is a POP.

3.7.1.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where there is evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than 2 months, or that its DT50 in soil is greater than 6 months, or that its DT50 in sediment is greater than 6 months.

3.7.1.2. Bioaccumulation

An active substance, safener or synergist fulfils the bioaccumulation criterion where there is:

— evidence that its bio-concentration factor or bioaccumulation factor in aquatic species is greater than 5 000 or, in the absence of such data, that the partition coefficient n-octanol/water (log Ko/w) is greater than 5, or

— evidence that the active substance, safener or synergist present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity.

3.7.1.3. Potential for long-range environmental transport:

An active substance, safener or synergist fulfils the potential for long-range environmental transport criterion where:

— measured levels of the active substance, safener or synergist in locations distant from the sources of its release are of potential concern,

— monitoring data show that long-range environmental transport of the active substance, safener or synergist, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species, or

— environmental fate properties and/or model results demonstrate that the active substance, safener or synergist has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For an active substance safener or synergist that migrates significantly through the air, its DT50 in air is to be greater than 2 days.

3.7.2. An active substance, safener or synergist shall only be approved if it is not considered to be a persistent, bioaccumulative and toxic (PBT) substance.

A substance that fulfils all three of the criteria of the points below is a PBT substance.

3.7.2.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where:

— the half-life in marine water is higher than 60 days,

— the half-life in fresh or estuarine water is higher than 40 days,

— the half-life in marine sediment is higher than 180 days,

— the half-life in fresh or estuarine water sediment is higher than 120 days, or

— the half-life in soil is higher than 120 days.

Assessment of persistency in the environment shall be based on available half-life data collected under appropriate conditions, which shall be described by the applicant.

3.7.2.2. Bioaccumulation

An active substance, safener or synergist fulfils the bioaccumulation criterion where the bioconcentration factor is higher than 2 000.

Assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from both freshwater and marine water species can be used.

3.7.2.3. Toxicity

An active substance, safener or synergist fulfils the toxicity criterion where:

— the long-term no-observed effect concentration for marine or freshwater organisms is less than 0,01 mg/l,

— the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) pursuant to Regulation (EC) No 1272/2008, or

— there is other evidence of chronic toxicity, as identified by the classifications STOT RE 1 or STOT RE 2 pursuant to Regulation (EC) No 1272/2008.

3.7.3. An active substance, safener or synergist shall only be approved if it is not considered to be a very persistent and very bioaccumulative substance (vPvB).

A substance that fulfils both of the criteria of the points below is a vPvB substance.

3.7.3.1. Persistence

An active substance, safener or synergist fulfils the ‘very persistent’ criterion where:

— the half-life in marine, fresh- or estuarine water is higher than 60 days,

— the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or

— the half-life in soil is higher than 180 days.

3.7.3.2. Bioaccumulation

An active substance, safener or synergist fulfils the ‘very bioaccumulative’ criterion where the bioconcentration factor is greater than 5 000.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:

— will result in a negligible exposure of honeybees, or

— has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

3.9. Residue definition

An active substance, safener or synergist shall only be approved if, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.

3.10. Fate and behaviour concerning groundwater

An active substance shall only be approved where it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

4. Candidate for substitution

An active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met:

— its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,

— it meets two of the criteria to be considered as a PBT substance,

— there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones),

— it contains a significant proportion of non-active isomers,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,

— if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.

5. Low-risk active substances

An active substance shall not be considered of low risk where it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as at least one of the following:

— carcinogenic,

— mutagenic,

— toxic to reproduction,

— sensitising chemicals,

— very toxic or toxic,

— explosive,

— corrosive.

It shall also not be considered as of low risk if:

— persistent (half-life in soil is more than 60 days),

— bioconcentration factor is higher than 100,
— it is deemed to be an endocrine disrupter, or
— it has neurotoxic or immunotoxic effects.

ANNEX III

List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27

ANNEX IV

Comparative assessment pursuant to Article 50

1. Conditions for comparative assessment

Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered, referred to as 'substitution', the alternative must, in the light of scientific and technical knowledge, show significantly lower risk to health or the environment. An assessment of the alternative shall be performed to demonstrate whether it can be used with similar effect on the target organism and without significant economic and practical disadvantages to the user or not.

Further conditions for refusal or withdrawal of an authorisation are as follows:

(a) substitution shall be applied only where other methods or the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism;

(b) substitution shall be applied only to plant protection products where their use presents a significantly higher level of risk to human health or the environment; and

(c) substitution shall be applied only after allowing for the possibility, where necessary, of acquiring experience from use in practice, where not already available.

2. Significant difference in risk

A significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment shall also be considered.

For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk.

3. Significant practical or economic disadvantages

Significant practical or economic disadvantage to the user is defined as a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient

control of the target organism. Such a major impairment might be, for example, where no technical facilities for the use of the alternative are available or economically feasible.

Where a comparative assessment indicates that restrictions on and/or prohibitions of use of a plant protection product could cause such disadvantage, then this shall be taken into account in the decision-making process. This situation shall be substantiated.

The comparative assessment shall take authorised minor uses into account.

ANNEX V

Repealed Directives and their successive amendments as referred to in Article 83

A.

DIRECTIVE 91/414/EEC

Acts amending Directive 91/414/EEC	Deadline for transposition
Directive 93/71/EEC	3 August 1994
Directive 94/37/EC	31 July 1995
Directive 94/79/EC	31 January 1996
Directive 95/35/EC	30 June 1996
Directive 95/36/EC	30 April 1996
Directive 96/12/EC	31 March 1997
Directive 96/46/EC	30 April 1997
Directive 96/68/EC	30 November 1997
Directive 97/57/EC	1 October 1997
Directive 2000/80/EC	1 July 2002
Directive 2001/21/EC	1 July 2002
Directive 2001/28/EC	1 August 2001
Directive 2001/36/EC	1 May 2002
Directive 2001/47/EC	31 December 2001
Directive 2001/49/EC	31 December 2001
Directive 2001/87/EC	31 March 2002
Directive 2001/99/EC	1 January 2003
Directive 2001/103/EC	1 April 2003
Directive 2002/18/EC	30 June 2003
Directive 2002/37/EC	31 August 2003
Directive 2002/48/EC	31 December 2002

Directive 2002/64/EC	31 March 2003
Directive 2002/81/EC	30 June 2003
Directive 2003/5/EC	30 April 2004
Directive 2003/23/EC	31 December 2003
Directive 2003/31/EC	30 June 2004
Directive 2003/39/EC	30 September 2004
Directive 2003/68/EC	31 March 2004
Directive 2003/70/EC	30 November 2004
Directive 2003/79/EC	30 June 2004
Directive 2003/81/EC	31 January 2005
Directive 2003/82/EC	30 July 2004
Directive 2003/84/EC	30 June 2004
Directive 2003/112/EC	30 April 2005
Directive 2003/119/EC	30 September 2004
Regulation (EC) No 806/2003	—
Directive 2004/20/EC	31 July 2005
Directive 2004/30/EC	30 November 2004
Directive 2004/58/EC	31 August 2005
Directive 2004/60/EC	28 February 2005
Directive 2004/62/EC	31 March 2005
Directive 2004/66/EC	1 May 2004
Directive 2004/71/EC	31 March 2005
Directive 2004/99/EC	30 June 2005
Directive 2005/2/EC	30 September 2005
Directive 2005/3/EC	30 September 2005
Directive 2005/25/EC	28 May 2006
Directive 2005/34/EC	30 November 2005
Directive 2005/53/EC	31 August 2006
Directive 2005/54/EC	31 August 2006
Directive 2005/57/EC	31 October 2006
Directive 2005/58/EC	31 May 2006
Directive 2005/72/EC	31 December 2006
Directive 2006/5/EC	31 March 2007
Directive 2006/6/EC	31 March 2007

Directive 2006/10/EC	30 September 2006
Directive 2006/16/EC	31 January 2007
Directive 2006/19/EC	30 September 2006
Directive 2006/39/EC	31 July 2007
Directive 2006/41/EC	31 January 2007
Directive 2006/45/EC	18 September 2006
Directive 2006/64/EC	31 October 2007
Directive 2006/74/EC	30 November 2007
Directive 2006/75/EC	31 March 2007
Directive 2006/85/EC	31 January 2008
Directive 2006/104/EC	1 January 2007
Directive 2006/131/EC	30 June 2007
Directive 2006/132/EC	30 June 2007
Directive 2006/133/EC	30 June 2007
Directive 2006/134/EC	30 June 2007
Directive 2006/135/EC	30 June 2007
Directive 2006/136/EC	30 June 2007
Directive 2007/5/EC	31 March 2008
Directive 2007/6/EC	31 July 2007
Directive 2007/21/EC	12 December 2007
Directive 2007/25/EC	31 March 2008
Directive 2007/31/EC	1 September 2007
Directive 2007/50/EC	31 May 2008
Directive 2007/52/EC	31 March 2008
Directive 2007/76/EC	30 April 2009
Directive 2008/40/EC	30 April 2009
Directive 2008/41/EC	30 June 2009
Directive 2008/45/EC	8 August 2008
Directive 2008/66/EC	30 June 2009

B.

DIRECTIVE 79/117/EEC

Acts amending Directive 79/117/EEC	**Deadline for transposition**
Directive 83/131/EEC	1 October 1984

Directive 85/298/EEC	1 January 1986
Directive 86/214/EEC	—
Directive 86/355/EEC	1 July 1987
Directive 87/181/EEC	1 January 1988 and 1 January 1989
Directive 87/477/EEC	1 January 1988
Directive 89/365/EEC	31 December 1989
Directive 90/335/EEC	1 January 1991
Directive 90/533/EEC	31 December 1990 and 30 September 1990
Directive 91/188/EEC	31 March 1992
Regulation (EC) No 807/2003	—
Regulation (EC) No 850/2004	—