1107

Vademecum 2015

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Preface

The 1107 *Vademecum*[1] seems to have filled a gap: a very small A5-sized gap in many a briefcase and purse, and a much bigger gap in the working life of the European regulatory professional. In many offices, both in industry and competent authorities, copies found their way to every desk, and the *Vademecum* is spotted on meeting tables where it sits at hand to help experts untangling the knots of Regulation (EC) No 1107/2009[2].

Since the publication of the first edition of the *Vademecum* in March 2014, the core legal text saw little change, but one or two new (revisions of) Guidance Documents were published every month. Comparative Assessment will soon become part of the authorisation process for products containing Candidates for Substitution, and the renewal of approved substances will now have to pass the hurdle of approval criteria.

This second edition of the *Vademecum* contains information on the status of all approved chemical substances, updated information on the renewal programme, and helpful information that will guide you in finding the most recent versions of the appropriate Guidance Document for the issues you are dealing with. When is a substance up for renewal? Is it a candidate for substitution? You find it all in the 1107 *Vademecum*. And of course you will find updated information on the EU decision-making process, the qualified majority voting system, the meeting schedule of the PAFF meetings for 2015, and many other bits of useful European and Brussels information.

The 1107 *Vademecum* is now also available in an electronic version[3], fully hyperlinked to help you jumping back and forth between the different articles and paragraphs, or to take you directly to other Regulations and Directives that are linked to Regulation 1107/2009.

For more printed copies of the *Vademecum* for your colleagues please contact me at Pappas & Associates[4].

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[1] Latin: "*go with me*"
[2] OJ L 309, 24.11.2009, p. 1.
[3] The PDF-version of the 1107 *Vademecum* can be downloaded from the Pappas & Associates website: http://www.pappaslaw.eu
[4] Contact Hans Mattaar at mattaar@pappaslaw.eu, at +31 611 929 009 or at +32 2 2315 704
[5] © European Union, http://eur-lex.europa.eu/

Pappas & Associates

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Introduction

Regulation 1107/2009 is the framework legislation setting out the rules and procedures regarding the placing on the market of plant protection products. The Regulation replaces the previous framework Directive 91/414/EEC. Although the Regulation entered into force on 14 June 2011, some of the provisions of Directive 91/414 continue to apply, mainly for processes that started already before the entry into force of the Regulation[1].

2-Step system and harmonisation

The Regulation describes the general proces for placing plant protection products on the market. This process consists of two steps: first the active substance(s) of a plant protection product must be approved at the European level, then as a second step the plant protection product must be authorised at the Member State level. The approval process focuses on a review of the intrinsic properties of the active substances, drafted by an allocated Rapporteur Member State, peer reviewed by all other Member States, and finally scrutinised by the EFSA[2]. The resulting commonly agreed endpoints allow the Member States to conduct risk assessments using the same input parameters, with commonly agreed risk assessment methodologies, and to decide on the granting of authorisations on the bases of the Uniform Principles, which are also laid down by the Regulation[3].

Mutual Recognition and zonal system

In order to reduce the workload for the individual Member States, and to improve harmonisation, the Regulation also lays down rules for Mutual Recognition. Because the environmental conditions, necessary for risk assessments, vary considerably from the Scandinavian to the Meditarranean countries, the Regulation establishes 3 (climatic/ regulatory) zones: North, Central and South (*see* Figure 1, the three zones). Within each zone, Member States shall grant an authorisation for a product/use, if a similar authorisation has already been granted by another Member State in the same zone. The worksharing within the zones is coordinated by Zonal Steering Committees.

Review & Renewal Programmes

The first Review Programme under Directive 91/414, to assess all substances that were already on the market before 15 July 1993, was completed in 2012.

The maximum duration of inclusion in Annex I (of Directive 91/414) was 10 years. With the entry into force of Regulation 1107/2009, all existing "Annex I inclusions" were re-named as "approvals"[4]. The maximum duration for an approval granted under Regulation 1107/2009 is 7–15 years, depending on the type of substance. Before the end of that period, interested parties can submit a supplementary dossier, in compliance with the data requirements at the time of submission, in order to secure renewal of an approval.

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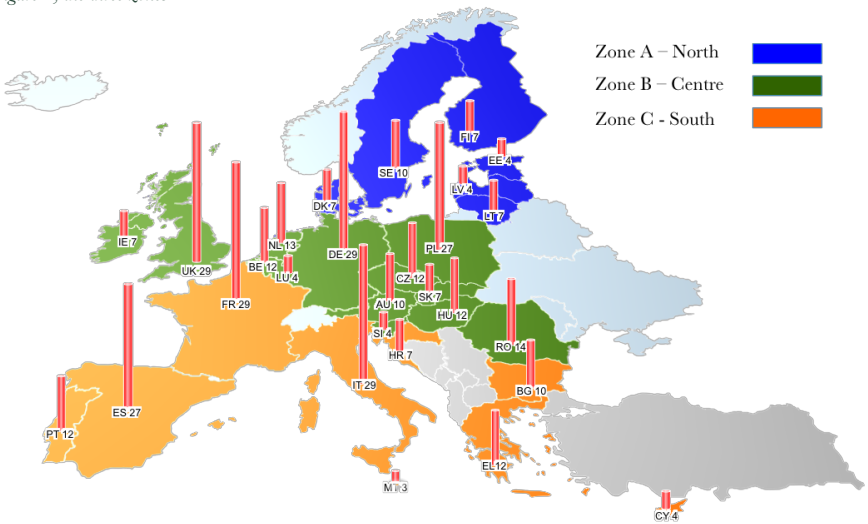
[1] *see* Article 80, "Transitional measures".
[2] European Food Safety Authority. *See also EFSA website*
[3] *see* Art. 29.6
[4] Regulation (EU) No 540/2011 of 25.5.2011, OJ L 153, 11.6.2011, p. 1.

Figure 1, the three zones



The Renewal Programme, also known as the Air[1] programme, groups substances based on their expiration dates, in order to manage and spread the workload of the renewal process. Information on all currently approved chemical active substances, as wel as details on the renewal programme (applications dates, dossier submission deadlines, etc.) can be found in Table 4.

AIR 1

The first pilot project[2], known as AIR 1, covered 7 active substances[3]. All 7 substance approvals were renewed for a period of 10 years (under transitory measures, following the "old" 91/414 provisions), with a common expiration date of 31-12-2021.

AIR 2

A second list of 31 substances, with expiry dates in 2011 and 2012, known as AIR 2, is scheduled for review through Regulation 1141/2010 [4]. Expiry dates for these substances were extended until 31 December 2015[5], and supplementary dossiers were submitted for 29 substances[6] between February and August 2012. Review of these dossiers is on-going. The renewal process for the AIR 2 substances started under the provisions of Directive 91/414.

AIR 3

For all other substances, the renewal process starts (or started) under the provisions of Regulation 1107/2009. Under these new provisions, applications have to be submitted no later

[1] "AIR" = **A**nnex **I** **R**enewal
[2] Regulation 737/2007 of 27 June 2007, OJ L 169, 29.6.2007, p. 10.
[3] azimsulfuron, azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, prohexadione-calcium, spiroxamine
[4] OJ L 322, 8.12.2010, p.10.
[5] Directive 2010/77/EU of 10.11.2010; OJ L 293, 11.11.2010, p.48
[6] not for cinidon-ethyl and for cyclanilide

than 3 years before the expiration date of the approval. For the first batches of substances (with approval expirations before 14 June 2014), it was not possible for applicants to submit supplementary dossiers in time; therefore the expiration dates for these substances were extended until a feasible date. For remaining batches, expiration dates were extended, or may be extended, in order to allow for an even spread of the workload for the competent authorities. For those substances for which no extensions are yet published, Table 4 presents the current expiration date, with a footnote referring to the expected new expiration date. Note that for these substances the "application date" and "submission date" (3 years and 2.5 years resp. before expiration) are related estimates.

Guidance Documents

Regulation 1107, as a legislative framework, already provides a high level of detail on procedures, criteria and methodologies. Nevertheless, the evaluation and decision process is highly complicated, and far more detailed instructions are required for many elements and provisions of the Regulation. Without detailed instructions, there is a risk of divergence in interpretation, jeopardizing the harmonisation that the Regulation aims to achieve. Therefore, in addition to the core text of the Regulation that can be found in its entirety in this *Vademecum*, the Commission continuously generates and updates Guidance Documents, in close cooperation with the Competent Authorities of the Member States, to ensure the highest possible level of harmonized interpretation and implementation.

Guidance Documents are, as the name implies, only guidance documents. Their adoption follows essentially the same process as the voting process for implementing or delegated acts (*see chapter on Comitology*), but the process is known as "noting" of a Guidance Document. Such decisions are not scrutinized by the European Parliament or the Council, since they do not amend or modify the existing text of the Regulation, but only present a commonly agreed interpretation and implementation of the provisions. For that reason, every Guidance Documents starts with a standard text explaining that the document "*does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.*" Nevertheless, Guidance Documents are the result of a common effort of Commission and Member States, with involvement of their legal services, and they may be expected to be the strongest possible interpretation of the legal text of the Regulation. In 2015, the process for noting Guidance documents is under discussion, and it may be subject to change in the future.

Guidance Documents are frequently updated in order to reflect the latest insights, and to cover upcoming new issues. Guidance documents can be found on the Commission website[1] or accessed directly via hyperlinks in the PDF-version of this *Vademecum*. Essentially, they can be divided into two categories: Technical Guidance and Procedural Guidance. They are identified by a code-number (usually "SANCO/number/year") and a Revision number. The more recent Guidance Documents contain information on the date of their implementation, to allow a smooth adjustment to the new guidance.

[1] http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents/active_substances_en.htm

In this *Vademecum* you will find two tables with information on Guidance Documents. Table 1 presents the most actual (procedural) Guidance documents sorted by the structure of the Regulation, with reference to the Chapters, (sub-)Sections and Articles of the Regulation that each Guidance document refers to. For the sake of readability, the titles in the table are abbreviated. Through the SANCO/nr of each GD you can find more details in Table 5.

Table 5 provides a detailed description of the content of the Guidance Document, with the latest Revision number. The electronic version of the *Vademecum* provides hyperlinks from Table 5 to the actual documents.

In addition, you will find in the legal text of the Regulation (*pages 25 and following*) references to the appropriate Guidance Documents in those articles for which further guidance is provided.

Table 1

Schematic overview Procedural Guidance Documents.

⬇ Article number & title	SANCO/nr	Title (abbreviated)
Active substances, safeners, coformulants		
Active Substances		
Approval requirements & conditions		
4.3 Approval criteria efficacy	10054/2013 Rev.3	Data requirements efficacy new active substances
6 Conditions and restrictions	5634/2009 Rev.6.1	Confirmatory data guidance
Approval procedure		
7 Application 8 Dossier	10181/2013 Rev.3	Preparing substance dossiers for approval and renewal under Reg. 283/2013 and 284/2013
	12545/2014 Rev.1	Preparing micro-organism dossiers for approval and renewal under Reg. 283/2013 and 284/2013
	11244/2011 Rev.5	Preparation and submission of dossiers for PPPs according to the "risk envelope approach" (*also under Art.33*)
11 Draft assessment report	11114/2012 Rev.0	Template for assessment reports regarding level 3 of volume 1
	12483/2014 Rev.2	Template for the List of Endpoints
	12592/2012 Rev.0	Template for Assessment Reports
	10180/2013 Rev.1	Rules for revision of assessment reports
Renewal and review	11251/2012 Rev.4	Renewal of approval of active substances under Renewal Regulation 844/2012)
18 Work programme	11284/2012 Rev.14	Working document Renewal Programme
	10148/2014 Rev.2	Overview of renewal applications
21 Review of approval	10328/2004 Rev.8	Evaluation of new active substance data post approval
Derogations		
23 Basic substances	10069/2013 Rev.3	Working document, list of possible basic substances
	10363/2012 Rev.9	Procedure for application of basic substances
Plant Protection Products		
Authorisation		
Requirements and content		
Procedure	13169/2010 Rev.9	Guidance document on zonal evaluation & mutual recognition under Regulation 1107/2009 (*see also "Mutual Recognition procedure"*)
33 Application for (amendment of) authorisation	12544/2014 Rev.0	Template to notify intended zonal applications under Art. 33 and 43 of Regulation 1107/2009 (*also Art.43*)
		(*see also SANCO/11244/2011, Art. 7-8*)
	10055/2013 Rev.4	Efficacy composition of core dossier and national addenda
36 Examination for authorisation	6895/2009 Rev.1	Presentation and evaluation of Annex III dossiers of 91/414 in the format of a (draft) Registration Report

⬇ Article number & title	SANCO/nr	Title (abbreviated)
36.3	10532/2013 Rev.0	Template for Notification according to Art. 36(3) (refusal to mutually recognise)
38 Assessment of equivalence	10597/2003 Rev.10.1	Assessment of the equivalence of technical materials of substances under Regulation 1107/2009
	12823/2012 Rev.4	Equivalence of microbial strains tech. grade under 1107
	6075/2009 Rev.3	Finalisation of the reference specification for technical active substances after the peer review
Mutual Recognition Procedure	*See also 13169/2010 Rev.9 under "Procedure" above*	
Renewal, withdrawal & amendment	13170/2010 Rev.9	Renewal, withdrawal and amendment of authorisation under Regulation 1107/2009
43 Renewal of authorisation	*See also 12544/2014 Rev.0 under Art.33 above*	
45 Amendments at request of the authorisation holder	12638/2011 Rev.2	Significant and non-significant formulation changes
Special cases		
50 Comparative Assessment for ppps with CfS[1]	11507/2013 Rev.12	Comparative Assessment and Substitution of Plant Protection Products under Regulation 1107/2009
52 Parallel Trade	10524/2012 Rev.4	Parallel trade of plant protection products
Derogations		
53 Emergency situations in plant protection	10087/2013 Rev.0	Emergency situations according to Article 53 of Regulation 1107/2009
Data Protection and Data Sharing	12576/2012 Rev.11	Guidance document on data protection
60 List of test and study reports	12580/2012 Rev.3.1	Preparing lists of test and study reports according to Article 60 of Regulation 1107/2009
Transitional and final provisions		
the Guidance documents below do not reflect on Art. 80, but to procedures under Directive 91/414, which continue to be be valid under transitional measures, for certain issues. They are still valid, but will eventually become obsolete.		
80	10796/2003 Rev.12.2	Procedures relating to the authorisation of PPPs following Annex I inclusion of an existing active substance
	6896/2009 Rev.1	Process for intra & inter-zonal work-sharing to facilitate the (re-)authorisation of PPPs following Annex I inclusion
	11509/2013 Rev.3	Interpretation transitional measures for data requirements
	10387/2010 Rev.8	Renewal of Annex I included active to be assessed under Renewal Regulation 1141/2010

EU Decision-making

The description below is a simplified description of the EU Decision-making procedures, which in their entirety are very broad, all-encompassing, and complicated. The descriptions in this Vademecum highlight only those decision-making procedures that are most relevant to the European pesticides legislation. They do not claim to be complete or exhaustive: they are intended to provide a basic understanding of the day-to-day pesticides-related decision processes at European level.

Introduction

European decision-making leading to the adoption of EU legal acts can be broadly divided into two "levels": legislative acts and non-legislative acts. Legislative acts are legal acts adopted by the ordinary legislative procedure[2] (Co-Decision), non-legislative acts are the delegated acts[3] or implementing acts[4] adopted by the Commission, through Comitology.

[1] CfS = Candidates for Substitution
[2] Legislative procedure is the joint adoption by the EP and the Council of a Regulation, Directive or Decision, on a proposal from the Commission, according to the procedure defined in Art. 294, TFEU.
[3] Art. 290 TFEU
[4] Art. 291 TFEU

Co-decision

Legislative Acts (binding legal acts, such as Regulation 1107/2009, or the Residues Regulation 396/2005) are adopted through the ordinary legislative procedure, also known as the Co-decision procedure: on the basis of a proposal from the Commission, an Act is adopted in co-decision between the Council and the European Parliament. During this process, both Parliament and Council can make amendments to the original proposal and it is not uncommon for a final act to look significantly different from the original Commission proposal. For detailed information on this co-decision procedure and the role of the Commission, European Parliament and the Member States (through the Council), as well as about issues as first reading, second reading and conciliation, consult the websites of the Commission[1] or the European Parliament[2], or contact Pappas & Associates.

Comitology

When essential elements of a legislative act need to be changed or amended, this can only be done through the Co-decision procedure again: after all these acts are adopted by Council and Parliament, so their essence can only be changed or amended by those same institutions.

However, when new legislative acts are adopted, they often contain (non-essential) gaps that need to be filled (such as detailed data requirements for Regulation 1107/2009), and/or they refer to decisions that have to be taken at European level within their framework (such as the approvals of pesticides under Regulation 1107/2009). Such decisions are delegated to the Commission and to the Committees (consisting of Member State representatives) that are established for such tasks. Because of the role of those Committees, these procedures are usually referred to as "Comitology", and are laid down in Regulation 182/2011[3], or (for older acts like Regulation 1107/2009) in Council Decision 1999/468/EC[4].

In the context of Regulation 1107/2009, we can distinguish the two most important procedures: "regulatory procedure" and "regulatory procedure with scrutiny"[5]. The first one applies to decisions taken within the framework of the Regulation, like approvals, withdrawals, emergency measures, etc., the second one applies to amendments, *i.e.* changes to "non-essential elements" of the Regulation, such as detailed rules for research and development, rules for placing on the market of adjuvants, or data requirements for safeners and synergists. The basic act (1107) contains detailed instructions with regard to which procedure must be followed for each type of future decision.

The major part of the decision process is identical for both regulatory procedures (with and without scrutiny): the Commission drafts a proposal, and the Member States vote on that proposal in the Standing Committee, through qualified majority voting. The difference between the two procedures is mainly what happens after a decision is taken, or when there is no qualified majority in the Standing Committee.

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[1] http://ec.europa.eu/atwork/decision-making/index_en.htm
[2] http://www.europarl.europa.eu/code/information/guide_en.pdf
[3] OJ L 55, 28.2.2011, p. 13.
[4] OJ L 184, 17.7.1999, p. 23.
[5] The Regulation also refers to decisions taken under the "advisory procedure", which is not described here.

Standing Committee on the Plants, Animals, Food and Feed

The Commission is assisted by many Committees. One category of Committees is the "Regulatory Committee", and one of those Regulatory Committees is the "Standing Committee on the Plants, Animals, Food and Feed", also known as the PAFF Committee[1]. This Committee, set up by the General Food Law Regulation 178/2002, covers several (15) different Standing Committee meetings, only 2 of which deal directly with pesticides: the "Phytopharmaceuticals Legislation" meeting and the "Pesticides Residues" meeting. These meetings are chaired by the Commission, and are formed by representatives of the Member States. For the formal part of these Standing Committee meetings, each Member State is represented by one Member State representative, who will vote on behalf of his country on the Commission's proposals. Voting is done according to the "qualified majority" system (*see below*). A proposal is either adopted by qualified majority, or it is rejected (a negative opinion, or "no opinion" is delivered), depending on the results of the vote.

Table 2

PAFF Committee Meeting Schedule for 2015*

	Phytopharmaceuticals		
	Legislation	Sustainable Use	Residues
January	26-27		
February			12-13
March	19-20		
April			27
May	28-29		
June		25	11-12
July	13-14		
August			
September			21-22
October	5-6		
November			30-1
December	10-11	7	

Qualified Majority Voting

Since 1 November 2014

With the entry into force of the Lisbon Treaty, a new system of voting was introduced. This new system, known as "double majority voting", entered into force on 1 November 2014. The voting process in a Standing Committee follows the same rules as voting in the Council. Under the new system, for a proposal to be adopted, 2 types of majority are required:

1. a majority of Member States (at least 55% and at least 15), and
2. a majority of the total EU population (the countries in favour must represent at least 65% of the EU population).

For a blocking minority, at least 4 Member States[2] (representing more than 35% of the population) must vote against. However, until 31 March 2017, the old system may still be applied at the request of any Member State.

The old voting system

The general concept is that each country has a certain weighted number of votes (*see* Figure 1 *or* Table 3*):* the bigger a country's population, the more votes it has (in fact, the numbers are

[1] Formerly known as the Standing Committee on the Food Chain and Animal Health, SCoFCAH.
[2] to avoid that just 3 of the largest Member States together might block a proposal
* Meeting schedule as foreseen in February 2015. Meeting schedules are subject to change, for the most recent schedule check the website of DG Sante, http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/planning_sc_meetings_2015.pdf

weighted in favour of the smaller countries). When a vote is taken in the Standing Committee, "qualified majority voting" applies. A qualified majority decision is reached when:

1. 260 (out of the total of 352) votes are cast in favour, and
2. at least 15 Member States vote in favour, *and*
3. more than 62% of the EU population is represented by the votes in favour.

On the other hand, a **blocking minority**, leading to "no opinion", requires at least

1. 93 votes against (or abstentions), *and*
2. at least 14 Member States against (or abstentions), *and*
3. more than 38% of the EU population is represented by the votes against (or abstentions)

Table 3

Member State voting numbers

EU-28	Votes	Population*		EU-28	Votes	Population*	
		#	(%)			#	(%)
DE Germany	29	80,780,000[e]	15.92%	AT Austria	10	8,507,786	1.68%
FR France	29	65,856,609[p]	12.98%	BG Bulgaria	10	7,245,677	1.43%
UK UK	29	64,308,261[p]	12.67%	DK Denmark	7	5,627,235	1.11%
IT Italy	29	60,782,668	11.98%	FI Finland	7	5,451,270	1.07%
ES Spain	27	46,507,760[p]	9.17%	SK Slovakia	7	5,415,949	1.07%
PL Poland	27	38,495,659	7.59%	IE Ireland	7	4,604,029[p]	0.91%
RO Romania	14	19,942,642[p]	3.93%	HR Croatia	7	4,246,700[p]	0.84%
NL Netherlands	13	16,829,289	3.32%	LT Lithuania	7	2,943,472	0.58%
EL Greece	12	10,992,589[e]	2.17%	SI Slovenia	4	2,061,085	0.41%
BE Belgium	12	11,203,992[p]	2.21%	LV Latvia	4	2,001,468	0.39%
PT Portugal	12	10,427,301[e]	2.05%	EE Estonia	4	1,315,819	0.26%
CZ Czech	12	10,512,419	2.07%	CY Cyprus	4	858,000[p]	0.17%
HU Hungary	12	9,879,000[p]	1.95%	LU Luxemburg	4	549,680	0.11%
SE Sweden	10	9,644,864	1.90%	MT Malta	3	425,384	0.08%
				Total	352	507,416,607	100.00%

* Source: Eurostat 2.4.0-r1-2014-12-11 (PROD), code tps00001
[e] = estimated, [p] = provisional

Regulatory Procedure ("*implementing acts*")

When a proposal for an implementing act[1] is accepted by a qualified majority in the Standing Committee, it is adopted by the Commission, and published.
When there is (at least) a blocking minority in the Standing Committee against the proposal, the Commission can either submit an amended proposal to the Standing Committee, or refer the rejected proposal to the appeals committee. If the appeals committee (chaired by the Commission) manages to find a compromise that has the support of the Commission, and that finds a qualified majority, the Commission will adopt the amended proposal. If the appeals

[1] *i.e.* for an approval or non-approval, or other decision under the "regulatory procedure" without scrutiny, referred to in the Regulation to its Art. 79(3)

committee delivers no opinion (*i.e.* there is no compromise, or no qualified majority for a compromise), the Commission will adopt the implementing act. Only if there is a qualified majority vote against the draft proposal, the Commission can not adopt it, and will have to redraft a new proposal to submit to the Standing Committee.

Although Council and Parliament always have the "right of scrutiny", they cannot directly intervene in this process. They can at best inform the Commission when they believe that a draft implementing act exceeds the implementing powers that the original act (read: Regulation 1107/2009) granted the Commission. The Commission then has to decide whether it maintains, withdraws, or amends the draft implementing act.

Regulatory Procedure with scrutiny ("*delegated acts*")

Decisions on "non-essential elements" of an act grant, under the Lisbon Treaty, more power to the European Parliament (and the Council). The biggest difference with the regulatory procedure without scrutiny is the fact that Parliament[1] can stop the adoption of a draft proposal, even if the Standing Committee voted by a qualified majority.

Proposals for such "non-essential elements", such as detailed data requirements, rules for the authorisation of adjuvants, labelling requirements or any other change or amendment to the Regulation that refers to its Art. 79(4), when they receive a qualified majority vote in the Standing Committee, are submitted for scrutiny to the Parliament and the Council. If Parliament does not oppose the measure within 3 months, it will be adopted by the Commission. If, however, within 3 months, Parliament opposes (by majority of its component members) the measure, the Commission cannot adopt it, and will have to redraft a new proposal to submit to the Standing Committee.

In the case that a proposal under this regulatory procedure with scrutiny does not get a qualified majority in the Standing Committee, the Commission will refer the proposal to the Council and Parliament. If the Council votes, within two months, with a qualified majority against the proposal, it will not be adopted. If the Council adopts the proposal (by qualified majority), or does not act within 2 months, the proposal will be delivered to the Parliament for scrutiny. If Parliament does not oppose the proposal within 4 months of the first referral by the Commission, it will be adopted. If it opposes it within that period, the Commission cannot adopt it, and will have to redraft a new proposal to submit to the Standing Committee.

Lists and Tables

Table 4

List of approved substances with dates, RMS, CfS[2] listing, Air listing, CMR class

Part & row.nr. 540/2011	CfS	Substance	Approval date	Expiration date	Air		Appl. date	Subm. date	RMS	Co-RMS	CMR current	CMR intent
A 333		1-decanol	01.06.11	31.05.21					IT			
A 117	×	1-methylcyclopropene	01.04.06	31.10.17	3	6	31.03.13	30.04.15	UK	PT		
B 12	×	1-naphthylacetamide	01.01.12	31.12.21					FR			
B 13		1-naphthylacetic acid	01.01.12	31.12.21					FR			
B 68		1,4-dimethylnaphthalene	01.07.14	30.06.24					NL			
A 299		2-phenylphenol (incl.salts)	01.01.10	31.12.19					ES			

[1] Council can equally stop the adoption of a proposal, but since such proposal is already voted by qualified majority by the Member States in the Standing Committee, it is highly unlikely that the same Member States would take a different position in Council.

[2] CfS = Candidate for Substitution

Part & row.nr. 540/2011	CfS	Substance	Approval date	Expiration date	Air		Appl. date	Subm. date	RMS	Co-RMS	CMR current	CMR intent
A 27		2,4-D	01.10.02	31.12.15	2			29.02.12	EL	PL		
A 47		2,4-DB	01.01.04	31.10.16	3	2	31.10.13	30.04.14	BE	EL		
A 265		2,5-Dichlorobenzoic acid methylester	01.09.09	31.08.19					DE			
A 317		6-Benzyladenine	01.06.11	31.05.21					FR			
B 18		8-hydroxyquinoline	01.01.12	31.12.21					ES			R2†
A 210		Abamectin	01.05.09	30.04.19					NL			R2†
B 72		Acequinocyl	01.09.14	31.08.24					NL			
A 91		Acetamiprid	01.01.05	30.04.17	3	4	30.04.14	31.10.14	NL	ES		
A 218		Acetic acid	01.09.09	31.08.19					DE			
A 20		Acibenzolar-s-methyl	01.11.01	31.12.15	2			29.02.12	FR	ES		
A 215	×	Aclonifen	01.08.09	31.07.19					DE			C2†
B 19		Acrinathrin	01.01.12	31.12.21					FR			
A 83		Alpha-cypermethrin	01.03.05	31.07.17	3	5	31.07.14	31.01.15	BE	EL		
A 219		Aluminium ammonium sulphate	01.09.09	31.08.19					PT			
A 260		Aluminium phosphide	01.09.09	31.08.19					DE			
A 220		Aluminium silicate	01.09.09	31.08.19					HU			
A 346		Aluminium sulfate	01.06.11	31.05.21					NL			
B 33		Ametoctradin	01.08.13	31.07.23					NL			
A 169		Amidosulfuron	01.01.09	31.12.18	3	10	31.12.15	30.06.16	FI	HR		
B 77		Aminopyralid	01.01.15	31.12.24					UK			
B 69		Amisulbrom	01.07.14	30.06.24					UK			C2††
A 14	×	Amitrole	01.01.02	31.12.15	2			29.02.12	FR	HU	R2	
A 221		Ammonium acetate	01.09.09	31.08.19					PT			
A 343		Azadirachtin	01.06.11	31.05.21					DE			R2†
B 3		Azimsulfuron	01.01.12	31.12.21	1		31.12.18	30.06.19	SE			
B 4		Azoxystrobin	01.01.12	31.12.21	1		31.12.18	30.06.19	UK			
A 158		Beflubutamid	01.12.07	30.11.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	DE	LT		
A 84		Benalaxyl	01.03.05	31.07.17	3	5	31.07.14	31.01.15	RO	PT		
B 58		Benalaxyl-M	01.05.14	30.04.24					PT			
A 188		Benfluralin	01.03.09	28.02.19					BE			
A 271		Bensulfuron	01.11.09	31.10.19					IT			
A 11		Bentazone	01.08.01	31.12.15	2			29.02.12	NL	DE		
A 163		Benthiavalicarb	01.08.08	31.07.18	3	10	31.07.15	31.01.16	PL	FR		
A 79		Benzoic acid	01.06.04	31.01.17	3	3	31.01.14	31.07.14	HU	NL		
A 48		Beta-cyfluthrin	01.01.04	31.10.16	3	2	31.10.13	30.04.14	DE	HU		
A 109		Bifenazate	01.12.05	31.07.17	3	5	31.07.14	31.01.15	SE	IT		
A 180		Bifenox	01.01.09	31.12.18	3	10	31.12.15	30.06.16	PL	BE		
B 23	×	Bifenthrin	01.08.12	31.07.19					FR			C2†
B 1		Bispyribac	01.08.11	31.07.21					IT			
B 43		Bixafen	01.10.13	30.09.23					UK			
A 222		Blood meal	01.09.09	31.08.19					BE			
A 164		Boscalid	01.08.08	31.07.18	3	10	31.07.15	31.01.16	SK	FR		
A 347	×	Bromadiolone	01.06.11	31.05.21					SE			R1a†
A 85		Bromoxynil	01.03.05	31.07.17	3	5	31.07.14	31.01.15	FR	DE	R2	
A 318	×	Bromuconazole	01.02.11	31.01.21					BE			
A 330		Bupirimate	01.06.11	31.05.21					NL			C2†
A 320		Buprofezin	01.02.11	31.01.21					UK			
A 223		Calcium carbide	01.09.09	31.08.19					PT			
A 261		Calcium phosphide	01.09.09	31.08.19					DE			
A 145		Captan	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	AT	IT	C2	
A 144	×	Carbendazim	01.06.11	30.11.14	3	4	30.11.11		DE	SI	1B	
A 336		Carbetamide	01.06.11	31.05.21					FR			C2†
A 225		Carbon dioxide	01.09.09	31.08.19					UK			
A 337		Carboxin	01.06.11	31.05.21					UK			C2††
A 60		Carfentrazone ethyl	01.10.03	31.07.16	3	1	31.07.13	31.01.14	BE	FR		

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A 165		Carvone	01.08.08	31.07.18	3	10	31.07.15	31.01.16	NL	SE		
C 2		Chitosan hydrochloride	01.07.14									
B 62		Chlorantraniliprole	01.05.14	30.04.24					IE			
A 185		Chloridazon	01.01.09	31.12.18	3	10	31.12.15	30.06.16	DE	PL		
A 276		Chlormequat	01.12.09	30.11.19					UK			
A 101		Chlorothalonil	01.03.06	31.10.17	3	6	28.02.13	30.04.15	NL	BE	C2	
A 102	×	Chlorotoluron	01.03.06	31.10.17	3	6	28.02.13	30.04.15	BG	FR	C2R2	
A 78		Chlorpropham	01.02.05	31.07.17	3	5	31.07.14	31.01.15	NL	ES	C2	
A 111		Chlorpyrifos	01.07.06	31.01.18	3	7	30.06.13	31.07.15	ES	PL		
A 112		Chlorpyrifos-methyl	01.07.06	31.01.18	3	7	30.06.13	31.07.15	ES	PL		
A 282		Chlorsulfuron	01.01.10	31.12.19					EL			
A 33		Cinidon-ethyl	01.10.02	30.09.12	2				HU	UK	C2	
A 240		Citronella oil (plant oils)	01.09.09	31.08.19					UK			
A 329		Clethodim	01.06.11	31.05.21					NL			
A 123		Clodinafop	01.02.07	30.04.18	3	8	31.01.14	31.10.15	EL	DE		
A 171		Clofentezine	01.01.09	31.12.18	3	10	31.12.15	30.06.16	ES	NL		
A 162		Clomazone	01.11.08	31.10.18	3	10	31.10.15	30.04.16	DK	DE		
A 129		Clopyralid	01.05.07	30.04.18	3	8	30.04.14	31.10.15	FI	PL		
A 121		Clothianidin	01.08.06	31.01.18	3	7	31.07.13	31.07.15	DE	ES		
A 241		Clove oil (plant oils)	01.09.09	31.08.19					UK			
A 277	×	Copper compounds	01.12.09	31.01.18	3	7	30.11.13	31.07.15	FR	DE		
A 46		Cyazofamid	01.07.03	31.07.16	3	1	31.07.13	31.01.14	FR	LV		
A 21		Cyclanilide	01.11.01	31.10.11	2				AT	EL		
A 316		Cycloxydim	01.06.11	31.05.21					AT			
A 296		Cyflufenamid	01.04.10	31.03.20					UK			
B 31		Cyflumetofen	01.06.13	31.05.23					NL			
A 49		Cyfluthrin	01.01.04	30.04.14	3	2	31.10.13		DE	HU		
A 34		Cyhalofop butyl	01.10.02	31.12.15	2			31.08.12	IT	AT		
A 263		Cymoxanil	01.09.09	31.08.19					AT			R2†
A 103		Cypermethrin	01.03.06	31.10.17	3	6	28.02.13	30.04.15	BE	DE		
A 338	×	Cyproconazole	01.06.11	31.05.21					IE		R2	C2R1b†
A 130	×	Cyprodinil	01.05.07	30.04.18	3	8	30.04.14	31.10.15	FR	BG		
A 283		Cyromazine	01.01.10	31.12.19					EL			
A 104		Daminozide	01.03.06	31.10.17	3	6	28.02.13	30.04.15	CZ	HU		
A 339		Dazomet	01.06.11	31.05.21					BE			
A 40		Deltamethrin	01.11.03	31.10.16	3	2	31.10.13	30.04.14	UK	AT		
A 226		Denathonium benzoate	01.09.09	31.08.19					PT			
A 86		Desmedipham	01.03.05	31.07.17	3	5	31.07.14	31.01.15	FI	DK		
A 172		Dicamba	01.01.09	31.12.18	3	10	31.12.15	30.06.16	DK	RO		
A 133		Dichlorprop-P	01.06.07	30.04.18	3	8	31.05.14	31.10.15	IE	PL		
A 344	×	Diclofop	01.06.11	31.05.21					FR			
A 324		Diethofencarb	01.06.11	31.05.21					FR			
A 290	×	Difenacoum	01.01.10	30.12.19					FI			R1a†
A 173	×	Difenoconazole	01.01.09	31.12.18	3	10	31.12.15	30.06.16	ES	UK		
A 174		Diflubenzuron	01.01.09	31.12.18	3	10	31.12.15	30.06.16	EL	SK		
A 181	×	Diflufenican	01.01.09	31.12.18	3	10	31.12.15	30.06.16	UK	CZ		
A 284		Dimethachlor	01.01.10	31.12.19					DE			
A 67		Dimethenamid-p	01.01.04	31.10.16	3	2	31.10.13	30.04.14	DE	BG		
A 149	×	Dimethoate	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	IT	BG		
A 150		Dimethomorph	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	PL	DE		
A 128	×	Dimoxystrobin	01.10.06	31.01.18	3	7	30.09.13	31.07.15	HU	IE		
A 15	×	Diquat	01.01.02	31.12.15	2			31.05.12	UK	SE	C2R2	
B 54		Disodium phosphonate	01.02.14	31.01.24					FR			
A 351		Dithianon	01.06.11	31.05.21					EL			
A 192		Diuron	01.10.08	30.09.18	3	10	30.09.15	31.03.16	DE	DK	C2	
A 264		Dodemorph	01.09.09	31.08.19					NL			R2†
A 323		Dodine	01.06.11	31.05.21					PT			

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B 49		Emamectin	01.05.14	30.04.24					NL			
A 211	×	Epoxiconazole	01.05.09	30.04.19					DE		C2R2	R1b†
A 10	×	Esfenvalerate	01.08.01	31.12.15	2			29.02.12	UK	PT		
A 142		Ethephon	01.08.07	31.07.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	NL	PL		
A 29		Ethofumesate	01.03.03	31.07.16	3	1	31.07.13	31.01.14	AT	DK		
A 155	×	Ethoprophos	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	IT	IE		
A 43		Ethoxysulfuron	01.07.03	31.03.14	3	1	31.07.13		IT	AT		
A 227		Ethylene	01.09.09	31.08.19					UK			
A 285	×	Etofenprox	01.01.10	31.12.19					IT			
A 99	×	Etoxazole	01.06.05	31.07.17	3	5	31.07.14	31.01.15	EL	UK		
A 325		Etridiazole	01.06.11	31.05.21					NL		C2	
B 45		Eugenol	01.12.13	30.11.23					UK			
A 35	×	Famoxadone	01.10.02	31.12.15	2			31.08.12	UK	FI		
A 229		Fat distillation residues	01.09.09	31.08.19					CZ			
A 230		Fatty acids C7 to C20	01.09.09	31.08.19					IE			
A 62		Fenamidone	01.10.03	31.07.16	3	1	31.07.13	31.01.14	CZ	FR		
A 141	×	Fenamiphos	01.08.07	31.07.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	EL	CY		
A 342		Fenazaquin	01.06.11	31.05.21					EL			
A 315		Fenbuconazole	01.05.11	30.04.21					UK			
A 13		Fenhexamid	01.06.01	31.12.15	2			29.02.12	UK	IT		
A 182		Fenoxaprop-P	01.01.09	31.12.18	3	10	31.12.15	30.06.16	AT	FI		
A 332		Fenoxycarb	01.06.11	31.05.21					NL			C2†
A 183		Fenpropidin	01.01.09	31.12.18	3	10	31.12.15	30.06.16	CZ	DE		
A 212		Fenpropimorph	01.05.09	30.04.19					DE		R2	
B 25		Fenpyrazamine	01.01.13	31.12.22					AT			
A 213		Fenpyroximate	01.05.09	30.04.19					DE			
A 308		Fenugreek	01.11.10	31.10.20					FR			
A 22		Ferric phosphate	01.11.01	31.12.15	2			29.02.12	DE	PL		
A 157	×	Fipronil	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	AT	NL		
A 248		Fish oil	01.09.09	31.08.19					EL			
A 80		Flazasulfuron	01.06.04	31.01.17	3	3	31.01.14	31.07.14	ES	FR		
A 305		Flonicamid (IKI-220)	01.09.10	31.08.20					FR			
A 36		Florasulam	01.10.02	31.12.15	2			31.08.12	PL	BE		
B 15		Fluazifop P	01.01.12	31.12.21					FR			
A 189		Fluazinam	01.03.09	28.02.19					AT			R2†
B 74		Flubendiamide	01.09.14	31.08.24					EL			
A 161	×	Fludioxonil	01.11.08	31.10.18	3	10	31.10.15	30.04.16	FR	ES		
A 65	×	Flufenacet	01.01.04	31.10.16	3	2	31.10.13	30.04.14	PL	FR		
A 39	×	Flumioxazine	01.01.03	31.12.15	2			29.02.12	CZ	FR	R1b	No R†
A 335	×	Fluometuron	01.06.11	31.05.21					EL			
A 297	×	Fluopicolide	01.06.10	31.05.20					UK			
B 51		Fluopyram	01.02.14	31.01.24					DE			C2†
A 166		Fluoxastrobin	01.08.08	31.07.18	3	10	31.07.15	31.01.16	UK	CZ		
A 19		Flupyrsulfuron-methyl	01.07.01	31.12.15	2			31.05.12	FR	DK		
B 14	×	Fluquinconazole	01.01.12	31.12.21					IE			
A 354		Flurochloridone	01.06.11	31.05.21					ES			
B 9		Fluroxypyr	01.01.12	31.12.21	1		31.12.18	30.06.19	DE			
A 64		Flurtamone	01.01.04	31.10.16	3	2	31.10.13	30.04.14	CZ	IE		
A 187		Flutolanil	01.03.09	28.02.19					FI			
A 353		Flutriafol	01.06.11	31.05.21					UK			
B 24		Fluxapyroxad	01.01.13	31.12.22					UK			
A 146		Folpet	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	AT	IT	C2	
A 44		Foramsulfuron	01.07.03	31.07.16	3	1	31.07.13	31.01.14	FI	SK		
A 118		Forchlorfenuron	01.04.06	31.10.17	3	6	31.03.13	30.04.15	ES	EL	C2	
A 147		Formetanate	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	ES	EL		
A 131		Fosetyl	01.05.07	30.04.18	3	8	30.04.14	31.10.15	FR	EE		
A 69		Fosthiazate	01.01.04	31.10.16	3	2	31.10.13	30.04.14	DE	EL		

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A 190		Fuberidazole	01.03.09	28.02.19					UK			C2[2]
A 231		Garlic extract	01.09.09	31.08.19					PL			
B 46		Geraniol	01.12.13	30.11.23					UK			
A 232		Gibberellic acid	01.09.09	31.08.19					HU			
A 233		Gibberellins	01.09.09	31.08.19					HU			
A 151	×	Glufosinate	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	DE	FR	R1b	
A 25		Glyphosate	01.07.02	31.12.15	2			31.05.12	DE	SK		
B 35		Halosulfuron-methyl	01.10.13	30.09.23					IT			
A 309	×	Haloxyfop-P	01.01.11	31.12.20					DK			
A 298		Heptamaloxyloglucan	01.06.10	31.05.20					FR			
A 352		Hexythiazox	01.06.11	31.05.21					FI			C2††
A 234		Hydrolysed proteins	01.09.09	31.08.19					EL			
A 322		Hymexazol	01.06.11	31.05.21					FI			R2††
B 5		Imazalil	01.01.12	31.12.21	1		31.12.18	30.06.19	NL			C2†
A 41	×	Imazamox	01.07.03	31.07.16	3	1	31.07.13	31.01.14	FR	IT		
A 175		Imazaquin	01.01.09	31.12.18	3	10	31.12.15	30.06.16	BE	IE		
A 94	×	Imazosulfuron	01.04.05	31.07.17	3	5	31.07.14	31.01.15	SI	FI		
A 216		Imidacloprid	01.08.09	31.07.19					DE			
A 326		Indolylbutyric acid	01.06.11	31.05.21					FR			
A 119		Indoxacarb	01.04.06	31.10.17	3	6	31.03.13	30.04.15	FR	ES		
A 66		Iodosulfuron	01.01.04	31.10.16	3	2	31.10.13	30.04.14	SE	FI		
A 87		Ioxynil	01.03.05	28.02.15*	3	5	28.02.12		FR	AT	R2	
B 73		Ipconazole	01.09.14	31.08.24					UK			R2††
A 50		Iprodione	01.01.04	31.10.16	3	2	31.10.13	30.04.14	FR	BE	C2	
A 30		Iprovalicarb	01.07.02	31.12.15	2			31.05.12	IE	IT		C2††
A 235		Iron sulphate	01.09.09	31.08.19					UK			
A 28	×	Isoproturon	01.01.03	31.12.15	2			31.08.12	DE	CZ	C2	R2††
B 27	×	Isopyrazam	01.04.13	31.03.23					UK			
A 334		Isoxaben	01.06.11	31.05.21					SE			
A 63		Isoxaflutole	01.10.03	31.07.16	3	1	31.07.13	31.01.14	IT	SI	R2	
A 236		Kieselgur	01.09.09	31.08.19					EL			
B 8		Kresoxim-methyl	01.01.12	31.12.21	1		31.12.18	30.06.19	BE		C2	
B 66		L-ascorbic acid	01.07.14	30.06.24					NL			
A 12	×	Lambda-cyhalothrin	01.01.02	31.12.15	2			29.02.12	SE	ES		
A 95		Laminarin	01.04.05	31.07.17	3	5	31.07.14	31.01.15	NL	FR		
A 176	×	Lenacil	01.01.09	31.12.18	3	10	31.12.15	30.06.16	BE	AT		
A 345		Lime sulphur	01.06.11	31.05.21					ES			
A 237		Limestone	01.09.09	31.08.19					AT			
A 51	×	Linuron	01.01.04	31.07.16	3	1	31.07.13	31.01.14	IT	DE	C2R1b	
A 286	×	Lufenuron	01.01.10	31.12.19					PT			
A 262		Magnesium phosphide	01.09.09	31.08.19					DE			
A 300		Malathion	01.05.10	30.04.20					FI			
A 52		Maleic hydrazide	01.01.04	31.10.16	3	2	31.10.13	30.04.14	DK	BE		
B 44		Maltodextrin	01.10.13	30.09.23					UK			
A 114		Mancozeb	01.07.06	31.01.18	3	7	30.06.13	31.07.15	UK	EL	R2	
B 34		Mandipropamid	01.08.13	31.07.23					AT			
A 113		Maneb	01.07.06	31.01.18	3	7	30.06.13	31.07.15	IT	UK	R2	
A 107		MCPA	01.05.06	31.10.17	3	6	30.04.13	30.04.15	PL	NL		
A 108		MCPB	01.05.06	31.10.17	3	6	30.04.13	30.04.15	PL	NL		
A 56	×	Mecoprop	01.06.04	31.01.17	3	3	31.01.14	31.07.14	PL	IE		
A 57		Mecoprop-P	01.06.04	31.01.17	3	3	31.01.14	31.07.14	PL	IE		
A 90		Mepanipyrim	01.10.04	30.04.17	3	4	30.04.14	31.10.14	BE	EL	C2	
A 191		Mepiquat	01.03.09	28.02.19					UK			
A 75		Mesosulfuron	01.04.04	31.01.17	3	3	31.01.14	31.07.14	FR	PL		
A 61		Mesotrione	01.10.03	31.07.16	3	1	31.07.13	31.01.14	UK	BE		
B 78		Metaflumizone	01.01.15	31.12.24					UK			
A 304	×	Metalaxyl	01.07.10	30.06.20					PT			

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A 37		Metalaxyl-M	01.10.02	31.12.15	2			31.08.12	BE	EL		
A 340		Metaldehyde	01.06.11	31.05.21					AT			
B 22	×	Metam	01.07.12	30.06.22					BE			
A 266		Metamitron	01.09.09	31.08.19					UK			
A 217		Metazachlor	01.08.09	31.07.19					UK			C2†
A 134	×	Metconazole	01.06.07	30.04.18	3	8	31.05.14	31.10.15	BE	UK	R2	
A 148		Methiocarb	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	UK	DE		
A 270	×	Methomyl	01.09.09	31.08.19					UK			
A 96		Methoxyfenozide	01.04.05	31.07.17	3	5	31.07.14	31.01.15	UK	SK		
A 238		Methyl nonyl ketone	01.09.09	31.08.19					BE			
A 115		Metiram	01.07.06	31.01.18	3	7	30.06.13	31.07.15	IT	UK		
B 76		Metobromuron	01.01.15	31.12.24					FR			
A 312		Metosulam	01.05.11	30.04.21					FR			C2†
A 137		Metrafenone	01.02.07	30.04.18	3	8	31.01.14	31.10.15	LV	SK		
A 152	×	Metribuzin	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	EE	DE		
A 7	×	Metsulfuron methyl	01.07.01	31.12.15	2			31.08.12	SI	SE		
B 110		Milbemectin	01.12.05	31.07.17	3	5	31.07.14	31.01.15	DE	NL		
A 72	×	Molinate	01.08.04	31.07.14	3	4	31.07.11		EL	PT	C2R2	
A 319	×	Myclobutanil	01.06.11	31.05.21					BE		R2	
A 310		Napropamide-7	01.01.11	31.12.20					DK			
A 170	×	Nicosulfuron	01.01.09	31.12.18	3	10	31.12.15	30.06.16	LV	NL		
B 56		Orange oil	01.05.14	30.04.24					FR			
A 327		Oryzalin	01.06.11	31.05.21					FR			
A 45	×	Oxadiargyl	01.07.03	31.03.14	3	1	31.07.13		PL	IT	R1a	
A 177	×	Oxadiazon	01.01.09	31.12.18	3	10	31.12.15	30.06.16	IT	ES		
A 116	×	Oxamyl	01.08.06	31.01.18	3	7	31.07.13	31.07.15	IT	FR		
A 42		Oxasulfuron	01.07.03	31.07.16	3	1	31.07.13	31.01.14	IT	AT		
B 11	×	Oxyfluorfen	01.01.12	31.12.21					ES			
A 348	×	Paclobutrazol	01.06.11	31.05.21					UK			
A 295		Paraffin oil	01.01.10	31.12.19					EL			
A 294		Paraffin oils	01.01.10	31.12.19					EL			
A 287		Penconazole	01.01.10	31.12.19					DE			R2?
A 349		Pencycuron	01.06.11	31.05.21					NL			
A 53	×	Pendimethalin	01.01.04	31.07.16	3	1	31.07.13	31.01.14	NL	ES		
B 55		Penflufen	01.02.14	31.01.24					UK			C2††
A 301		Penoxsulam	01.08.10	31.07.20					IT			
B 57		Penthiopyrad	01.05.14	30.04.24					UK			
A 239		Pepper (PDER)	01.09.09	31.08.19					UK			
A 122		Pethoxamid	01.08.06	31.01.18	3	7	31.07.13	31.07.15	AT	CZ		
A 88		Phenmedipham	01.03.05	31.07.17	3	5	31.07.14	31.01.15	FI	DK		
A 153		Phosmet	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	ES	EL		
B 28		Phosphane	01.04.13	31.03.23					DE			
A 178		Picloram	01.01.09	31.12.18	3	10	31.12.15	30.06.16	PL	CZ		
A 38		Picolinafen	01.10.02	31.12.15	2			31.08.12	DE	LV		
A 68		Picoxystrobin	01.01.04	31.10.16	3	2	31.10.13	30.04.14	CZ	RO		
A 124	×	Pirimicarb	01.02.07	30.04.18	3	8	31.01.14	31.10.15	UK	SE		C2†
A 156		Pirimiphos-methyl	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	UK	FR		
A 244		Potassium hydrogen carbonate	01.09.09	31.08.19					IE			
B 40		Potassium phosphonate	01.10.13	30.09.23					FR			
B 20	×	Prochloraz	01.01.12	31.12.21					IE			
B 2	×	Profoxydim	01.08.11	31.07.21					ES		C2R2	
B 6		Prohexadione	01.01.12	31.12.21	1		31.12.18	30.06.19	FR			
A 154		Propamocarb	01.10.07	30.09.17[a]	3	9	*31.07.15*[a]	*31.01.16*[a]	PT	BE		
A 278		Propaquizafop	01.12.09	30.11.19					IT			
A 58	×	Propiconazole	01.06.04	31.01.17	3	3	31.01.14	31.07.14	FI	UK		
A 54		Propineb	01.04.04	31.01.17	3	3	31.01.14	31.07.14	IT	RO		

Part & row.nr. 540/2011	CfS	Substance	Approval date	Expiration date	Air		Appl. date	Subm. date	RMS	Co-RMS	CMR current	CMR intent
A 76	×	Propoxycarbazone	01.04.04	31.01.17	3	3	31.01.14	31.07.14	SE	EE		
A 55		Propyzamide	01.04.04	31.01.17	3	3	31.01.14	31.07.14	SE	UK	C2	
A 302		Proquinazid	01.08.10	31.07.20					UK			C2†
A 160		Prosulfocarb	01.11.08	31.10.18	3	10	31.10.15	30.04.16	PT	SE		
A 31	×	Prosulfuron	01.07.02	31.12.15	2			31.05.12	FR	SK		
A 168		Prothioconazole	01.08.08	31.07.18	3	10	31.07.15	31.01.16	UK	FR		
A 245		Putrescine	01.09.09	31.08.19					AT			
A 23		Pymetrozine	01.11.01	31.12.15	2			29.02.12	DE	BE	C2	R2††
A 81		Pyraclostrobin	01.06.04	31.01.17	3	3	31.01.14	31.07.14	DE	HU		
A 24		Pyraflufen-ethyl	01.11.01	31.12.15	2			31.05.12	NL	LT		
A 246		Pyrethrins	01.09.09	31.08.19					IT			
A 313		Pyridaben	01.05.11	30.04.21					NL			
B 64		Pyridalyl	01.07.14	30.06.24					NL			
A 16		Pyridate	01.01.02	31.12.15	2			31.05.12	AT	LV		
A 135		Pyrimethanil	01.06.07	30.04.18	3	8	31.05.14	31.10.15	CZ	AT		
B 53		Pyriofenone:	01.02.14	31.01.24					UK			
A 179		Pyriproxyfen	01.01.09	31.12.18	3	10	31.12.15	30.06.16	NL	ES		
B 61		Pyroxsulam	01.05.14	30.04.24					UK			
A 247		Quartz sand	01.09.09	31.08.19					AT			
A 311		Quinmerac	01.05.11	30.04.21					UK			
A 184		Quinoclamine	01.01.09	31.12.18	3	10	31.12.15	30.06.16	SE	DE		
A 82	×	Quinoxyfen	01.09.04	30.04.17	3	4	30.04.14	31.10.14	UK	AT		
A 279		Quizalofop-P	01.12.09	30.11.19					FI			
A 279	×	Quizalofop-P tefuryl	01.12.09	30.11.19					FI		R1b	C2†R2††
A 242		Rape seed oil (plant oils)	01.09.09	31.08.19					ES			
A 249		*Repellents by smell /sheep fat*	01.09.09	31.08.19					EL			
A 250		*Repellents by smell /tall oil crude*	01.09.09	31.08.19					EL			
A 251		*Repellents by smell / tall oil pitch*	01.09.09	31.08.19					EL			
A 125		Rimsulfuron	01.02.07	30.04.18	3	8	31.01.14	31.10.15	SI	FI		
B 65		S-abscisic acid	01.07.14	30.06.24					NL			
A 97		S-metolachlor	01.04.05	31.07.17	3	5	31.07.14	31.01.15	IE	BE		
A 252		Sea-algae extract	01.09.09	31.08.19					IT			
B 48		Sedaxane	01.02.14	31.01.24					FR			
A 70		Silthiofam	01.01.04	31.10.16	3	2	31.10.13	30.04.14	DE	FR		
A 341		Sintofen	01.06.11	31.05.21					FR			
A 272		Sodium 5-nitroguaiacolate	01.11.09	31.10.19					EL			
A 253		Sodium aluminium silicate	01.09.09	31.08.19					HU			
A 254		Sodium hypochlorite	01.09.09	31.08.19					NL			
A 273		Sodium o-nitrophenolate	01.11.09	31.10.19					EL			
A 274		Sodium p-nitrophenolate	01.11.09	31.10.19					EL			
B 63		Sodium silver thiosulfate	01.05.14	30.04.24					NL			
A 243		Spear mint oil (plant oils)	01.09.09	31.08.19					SE			
B 67		Spinetoram	01.07.14	30.06.24					UK			
A 139		Spinosad	01.02.07	30.04.18	3	8	31.01.14	31.10.15	NL	FR		
A 303		Spirodiclofen	01.08.10	31.07.20					NL			C1bR2††
B 41		Spiromesifen	01.10.13	30.09.23					UK			
B 60		Spirotetramat	01.05.14	30.04.24					AT			R2†
B 7		Spiroxamine	01.01.12	31.12.21	1		31.12.18	30.06.19	DE			R2†
C 3		Sucrose	01.01.15								*Basic substance*	
A 267	×	Sulcotrione	01.09.09	31.08.19					DE			R2?
A 32		Sulfosulfuron	01.07.02	31.12.15	2			31.05.12	SE	IE		
A 307		Sulfuryl fluoride	01.11.10	31.10.20					UK			
A 292		sulphur	01.01.10	31.12.19					FR			
A 328		Tau-fluvalinate	01.06.11	31.05.21					DK			
A 228		Tea tree extract	01.09.09	31.08.19					LV			
A 268	×	Tebuconazole	01.09.09	31.08.19					DK		R2	
A 350		Tebufenozide	01.06.11	31.05.21					DE			

Part & row.nr. 540/2011	CfS	Substance	Approval date	Expiration date	Air		Appl. date	Subm. date	RMS	Co-RMS	CMR current	CMR intent
A 275	×	Tebufenpyrad	01.11.09	31.10.19					DE			
A 280		Teflubenzuron	01.12.09	30.11.19					FR			
B 10		Tefluthrin	01.01.12	31.12.21					DE			
B 59		Tembotrione	01.05.14	30.04.24					AT			
A 100	×	Tepraloxydim**	01.06.05	31.05.15	3	5	31.07.14		ES	PL	C2R2	
B 16		Terbuthylazine	01.01.12	31.12.21					UK			C2†
A 293		Tetraconazole	01.01.10	31.12.19					IT			
A 17		Thiabendazole	01.01.02	31.12.15	2			31.05.12	ES	NL		
A 92	×	Thiacloprid	01.01.05	30.04.17	3	4	30.04.14	31.10.14	UK	DE		C2R2†
A 140		Thiamethoxam	01.02.07	30.04.18	3	8	31.01.14	31.10.15	FR	ES		
B 71		Thiencarbazone	01.07.14	30.06.24					UK			
		Thiencarbazone-methyl	01.07.14	30.06.24							C2	C2††
A 26		Thifensulfuron-methyl	01.07.02	31.12.15	2			31.08.12	UK	AT		
A 105		Thiophanate-methyl	01.03.06	31.10.17	3	6	28.02.13	30.04.15	SE	FI		
A 73		Thiram	01.08.04	30.04.17	3	4	30.04.14	31.10.14	FR	BE		
B 47		Thymol	01.12.13	30.11.23					UK			
A 126		Tolclofos-methyl	01.02.07	30.04.18	3	8	31.01.14	31.10.15	SE	DK		
A 214		Tralkoxydim	01.05.09	30.04.19					UK		C2	C2†
A 288	×	Tri-allate	01.01.10	31.12.19					UK			
A 269		Triadimenol	01.09.09	31.08.19					UK		R2	R2†
A 9	×	Triasulfuron	01.08.01	31.12.15	2			31.08.12	FR	DK		
B 17	×	Triazoxide	01.10.11	30.09.21					UK			
A 106		Tribenuron	01.03.06	31.10.17	3	6	28.02.13	30.04.15	SE	LV		
A 136		Triclopyr	01.06.07	30.04.18	3	8	31.05.14	31.10.15	PL	HU		
A 59		Trifloxystrobin	01.10.03	31.07.16	3	1	31.07.13	31.01.14	UK	EL		
A 306		Triflumizole	01.07.10	30.06.20					NL			R1b†
321		Triflumuron	01.04.11	31.03.21					IT			
A 289		Triflusulfuron	01.01.10	31.12.19					FR			C2†
A 256		Trimethylamine hydrochloride	01.09.09	31.08.19					BE			
A 132		Trinexapac	01.05.07	30.04.18	3	8	30.04.14	31.10.15	LT	LV		
A 127		Triticonazole	01.02.07	30.04.18	3	8	31.01.14	31.10.15	AT	UK		
A 186		Tritosulfuron	01.12.08	30.11.18	3	10	30.11.15	31.05.16	SI	AT		
A 257		Urea	01.09.09	31.08.19					EL			
B 70		Valifenalate	01.07.14	30.06.24					HU			
A 120	×	Warfarin	01.10.06	31.03.14	3	1	31.07.13		SE	DE	R1a	
A 258		Z-13-hexadecen-11-yn-1-yl acetate	01.09.09	31.08.19					AT			
A 259		Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate	01.09.09	31.08.19					AT			
A 281		Zeta-cypermethrin	01.12.09	30.11.19					BE			
A 314		Zinc phosphide	01.05.11	30.04.21					DE			
A 74	×	Ziram	01.08.04	30.04.17	3	4	30.04.14	31.10.14	IT	MT		
A 77		Zoxamide	01.04.04	31.01.17	3	3	31.01.14	31.07.14	LV	FR		

[a] to be extended till 31.07.18, application and submission dates are estimated accordingly
* no applications were received. current expiration dates are automatically final expiration dates.
** no longer defended at EU level
† ongoing or completed consultation
†† announced intention
RMS: for substances in the Air programme: allocated RMS for upcoming/ongoing review. For other substances: previous RMS
CMR: current is actual classification under Regulation 1272/2008[1]; intent is registered "intention" [2] or submitted proposal with ongoing or completed consultations[3]

[1] OJ L 353, 31.12.2008, p. 1.
[2] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions
[3] http://echa.europa.eu/web/guest/harmonised-classification-and-labelling-previous-consultations

Table 5

Guidance Documents listed by year/number

Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009	
SANCO/**10597/2003** Rev. 10.1 of 13.07.2012 This amended guidance document should be implemented as from 13 July 2012	This guidance document is intended to establish a harmonised procedure for assessing the equivalence between different sources of technical material according to Article 38 of the Regulation. Changes concerning the source of the technical material after the authorisation of a PPP are dealt with by Article 45(2). The assessment of the change (e.g. new source, amended specification, manufacturing process, or manufacturing location) has to be conducted according to the procedure in Article 38 and this guidance document. By the comparison of the specification(s) for the reference source(s) with the corresponding specifications for new sources or changes to those already assessed, equivalence of technical materials regarding their hazard potential can be considered or data gaps can be identified where further toxicological and ecotoxicological testing is needed.
Guidance document on the procedures relating to the authorisation of PPPs following inclusion of an existing active substance in Annex I of Council Directive 91/414/EEC	
Sanco/**10796/2003** Rev 12.2 of 15.07.2011 The current version of this guidance document should be implemented as from 15th July 2011	This document provides guidance to the Competent Authorities of the Member States on the authorisation of PPPs post-Annex I inclusion, and has been developed primarily with respect to products containing existing active substances. The aims are: - to establish a harmonised approach in this area to avoid unnecessary duplication of effort - to improve co-operation between the Competent Authorities of the MSs such that the limited resources of the Member States are used in a more efficient way, and - to improve consistency in decision making between MSs. This document identifies the key steps in the re-registration process where harmonisation of procedures across MSs could be achieved. All MSs retain the right to request data more urgently and take decisions earlier if deemed necessary.
Guidance document on the evaluation of new active substance data post approval	
SANCO/**10328/2004** Rev 8 of 24.01.2012 This document was finalised on 15.7.2005 and amended on 24.01.2012. It should be implemented as from 24.01.2012 (date of noting of the amended version).	This guidance document aims to give a systematic overview on the different reasons for submissions of further active substance data after approval and the handling of such data with respect to (a) authorisation of PPPs (Regulation 1107/2009, Art. 29) and (b) potential consequences for the approval of an active substance such as an amendment of the list of end-points or a review of the approval of the respective active substance according to Art. 21. For data submitted in the framework of (a) confirmatory data (GD SANCO/5634/2009), (b) technical specification (GD SANCO/6075/2009) and (c) equivalence assessment (GD SANCO/10597/2003) reference is also made to the respective Guidance Documents. The aim is: - to establish a harmonised approach in this area in order to avoid unnecessary duplication of effort, - to improve co-operation between the Competent Authorities of the MSs to get a harmonised data background for the national and/or zonal authorisation of the plant protection products and MRL setting. In general, this guidance has been developed in relation to the re-registration of PPPs containing approved active substances, but could equally apply to the consideration of new data for the authorisation of new products. It was also originally developed with regard to new active substance data, but could equally apply to the evaluation of key product data.
Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation 1107	

SANCO/**5634/2009** Rev. 6.1 of 12.2013 This amended version to be implemented as from 1 March 2014	An approval may be subject to a request for submission of further confirmatory information, where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge (Article 6(f)). In exceptional cases an active substance may be approved with a request for the submission of information 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* (Annex II, point 2.2). Such request for confirmatory information is specified in the approval decision, with a time limit (usually 2 years after EiF of the approval Regulation) to submit the information to the Member States, the Commission and the Authority. This guidance document describes the procedures for submission and assessment of this confirmatory information.
Guidance document on the finalisation of the reference specification for technical active substances after the peer review	
SANCO/**6075/2009** Rev.3 of 07.2009	The specification of the technical material used in plant protection products (PPPs) is the basis of the assessment according to the criteria of the Regulation. Therefore, the specification of technical material should be harmonised before the respective active substance is approved. However, this is not always the case, for different reasons. This can cause problems during the assessment of sources of technical material that are different the ones assessed in the Annex I review process. This document provides guidance on handling such issues.
Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report	
SANCO/**6895/2009** Rev 1 of 02.10.2009 Applications submitted from 02.10.2010 should be submitted in dRR format.	This guideline describes in detail the structure and content of the draft registration report (dRR), a format for applicant submissions for plant protection products. It also describes how MS should evaluate these submissions. Previously, the same presentation requirements were used as prescribed by Working document 1663/VI/94 "Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in annex I of Directive 91/414 (Article 5.3 and 8.2)", which was modified by the introduction of the OECD formatting system by the document Sanco/10518/2005 (Guideline on the preparation and presentation of complete dossier for the Annex I inclusion of active substances (Article 5.3 and 8.2)). Those guidelines were developed for annex I inclusions. This new guidance was specifically developed for national applications for PPPs. Guidance document Sanco/10796/2003 (on the format for registration reports for the assessment of PPPs following Annex I inclusion) described a 'skeleton' format for the evaluation of product applications by the MS. This new guidance document develops the structure of that registration report further.
GD on a process for intra & inter-zonal work-sharing to facilitate the (re-) authorisation of PPPs following inclusion of an active substance in annex I of Directive 91/414/EEC	
SANCO/**6896/2009** Rev 1 of 2.10.2009 The procedures should be applied from 2 October 2009 (date of noting by the Standing Committee on the Food Chain and Animal Health).	This document proposes a procedure for the submission and assessment of applications for registration and re-registration following Annex I inclusion of an active substance under Directive 91/414. This procedure is compatible with the proposed new format for the Registration Report, and complements existing informal work-sharing arrangements The work-sharing provisions in this document will eventually be replaced by the zonal authorisation process in the Regulation 1107/2009. It should be noted however that new product applications ongoing at the time of application of the new Regulation, and re-registration applications for all existing products will fall outside the new Regulation, and should be assessed using the procedures in this document. See Article 80.5 of the Regulation for details of transitional arrangements.
Guidance Document on the renewal of active substances included in Annex I of Directive 91/414 to be assessed in compliance with Regulation 1141/2010 (the Renewal Regulation)	

SANCO/**10387/2010** rev. 8 of 28.10.2010	This document provides guidance for the handling of the second set of substances requiring a renewal assessment, since their renewal application will be made under Directive 91/414, but the criteria in Regulation 1107/2009 will apply to decisions to be taken on the substances. It includes certain elements to supplement the renewal regulation, and also to provide further details on the procedures to be followed. This guidance document should be read in conjunction with the renewal regulation, Directive 91/414 and Regulation (EC) 1107/2009.
Guidance document on zonal evaluation & mutual recognition under Regulation 1107/2009	
SANCO/**13169/2010** Rev. 9 of 11.07.2014 It applies for applications which are made, or due to be made, after 14 June 2011. Transitional measures are also covered in the document.	This guidance document has been developed to elaborate the procedures contained in Regulation 1107/2009 for zonal evaluation (Art. 33–39) and mutual recognition (Art. 40-42). The Regulation provides for a more efficient system of mutual recognition, built on the assumption that any assessment done by one Member State (MS) shall not be repeated by another MS when recognising an authorisation, except for clearly defined circumstances. The Regulation provides for a general system of zonal evaluation. Mutual recognition is an important part of this. Under the Regulation an authorisation in one MS can be used for mutual recognition in another MS. Therefore it is appropriate to set out procedures for the zonal evaluation in more detail.
Guidance document on renewal, withdrawal and amendment of authorisation under Regulation 1107/2009	
SANCO/**2010/13170** Rev. 9 of 12.12.2014 Renewals of authorisations based on active substances that are renewed under Reg. 1107	This guidance document was developed to elaborate the procedures for renewal, withdrawal and amendment of authorisations contained in Regulation 1107/2009. It starts from the basic principle that products that will be renewed under the Regulation have already been authorised in accordance with the Directive 91/414, and therefore comply with the data requirements and Uniform Principles of that Directive.
Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"	
SANCO/**11244/2011** Rev. 5 of 14.03.2011 To be implemented as from 5 May 2011 (date of noting of the original version by the Standing Committee).	The current re-registration and new authorisation procedure to plant protection products creates a high workload in MS, in particular where older authorisations were not granted according to the Uniform Principles. Especially for PPPs with multiple crops and GAPs, this may result in a considerable amount of work for risk assessors and regulators. Hence, the "risk envelope approach" was developed to keep the workload at an acceptable level, yet being sufficient and appropriate for general use for product authorisations under Regulation 1107. Risk assessment, risk management and decision-making on applications for authorisation of products need to be comprehensive and transparent. This working document describes the procedure and the rational to be followed by applicants for the preparation and submission of dossiers according to the "risk envelope approach"
Guidance document on significant and non-significant changes of the chemical composition of authorised PPPs under Regulation 1107/2009	
SANCO/**12638/2011** Rev. 2 of 20.11.2012 Applies to applications submitted from 01.03.2013 onwards.	The key objective of this guideline is to harmonise the approach to significant and non-significant changes of the chemical composition of plant protection products in the EU, and to provide information on a process and timeframe for such a procedure. This guidance document has been developed to elaborate the possibilities and procedures according to Regulation 1107/2009. However, the guidance document can also be used for assessments that still have to be conducted according to Directive 91/414.
Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation 1107/2009	
SANCO/**10363/2012** Rev.9 of 21.03.2014	This document aims to provide guidance for the submission of applications concerning active substances which could be approved as "basic substances" according to provisions laid

applicable	down by Regulation 1107/2009. It aims to clarify the procedural steps for approval.
Guidance document concerning the parallel trade of plant protection products	
SANCO/**10524/2012** Rev.4 of 31.05.2012	Article 28.2(e) of the Regulation states that PPPs for which a parallel trade permit has been issued are exempted from an authorisation. Therefore, the Regulation makes a clear distinction between applications for parallel trade permit and applications for authorisation of plant protection products. The requirements as well as the procedure for granting parallel trade permits are described in Article 52 of the Regulation. This guidance document is intended to facilitate the implementation of Article 52 of the Regulation in a harmonised and consistent way by MS competent authorities.
Template to be used for assessment reports regarding level 3 of volume 1	
SANCO/**11114/2012** Rev. 0 of 01.06.2012 For substances applied for approval after 1.6.2012, and substances covered by Regulation 1141/2010.	This template is intended to align the current structure of Level 3 with the assessment that the Rapporteur Member State has to carry out against the approval criteria as set out in Regulation 1107/2009. This template also identifies amongst other things data gaps, risk management measures, critical areas of concern and the overall proposal on approval for which a number of items corresponds to the issues dealt with in a "Conclusion on the peer review of the pesticide risk assessment of an active substance" as prepared by the European Food Safety Authority (EFSA).
Working document Renewal Programme	
SANCO/**2012/11284** Rev. 14 of 12.2014	This document provides an overview of indicative submission dates for supplementary dossiers for the renewal of substances expiring between 1 January 2013 and 31 December 2018. The document is updated regularly. It is recommended to refer to the dates provided in the relevant acts adopted as published in the Official Journal.
Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation 844/2012 (the Renewal Regulation)	
SANCO/**2012/11251** Rev. 4 of 12.12.2014 Applicable to all active substances to be renewed under Regulation 844/2012	The renewal programme will be based on the provisions of Regulation 1107/2009. The approval criteria in Regulation 1107/2009 will apply to decisions to be taken on these substances. It is preferred to include certain elements in a guidance document to supplement the renewal regulation, and also to provide further details on the procedures to be followed. This guidance document should be read in conjunction with the Renewal Regulation and Regulation 1107/2009.
Guidance document on data protection	
SANCO/**12576/2012** Rev. 1.1 of 01.02.2013 Applicable depending on specific situation. Scenarios described in detail in the GD.	This document provides MSs and applicants with guidance on the procedures and policies surrounding various elements of data protection, as related to plant protection products legislation. It considers the practical application of the legal provisions of Articles 59–62 and 80 of Regulation 1107/2009. This guideline is intended to help MS apply the rules in a consistent way, and for applicants to understand those rules. The Guidance document covers 2 main areas: - Section 1 - explaining the periods of protection applied to studies under different circumstances – the 'why, when and how long', - Section 2 - clarification of the special procedures and provisions that apply to vertebrate data sharing.
Guidance document on preparing lists of test and study reports according to Article 60 of Regulation 1107/2009	
SANCO/**12580/2012** Rev. 3.1 of 17.05.2013 This document was	The existing Guidance document on preparation of lists of studies relied upon with a view to Annex I inclusion of existing active substances (SANCO/10435/2004 15 April 2005 rev 7) was developed for substances for stages 2 till 4 of the review programme carried out under Directive 91/414. Because all decisions in the framework of the review programme have

finalised on 15 March 2013. It will apply to applications submitted from 1 January 2014 onwards	been taken it was not considered appropriate to update the existing guidance document but rather prepare a complete new guidance taking into account the provisions of Regulation (EC) No 1107/2009. The relevant provisions in this respect are laid down in Articles 59–62 of Regulation 1107/2009. This Guidance document deals with applications for approval submitted under Regulation 1107/2009, amendment of approval conditions or renewal of approval of active substances and related first authorisation, amendment of authorisation conditions or renewal of the authorisation of plant protection product. This Guidance document is applicable to active substances as well as safeners, synergists and adjuvants.
Template to be used for Assessment Reports	
SANCO/**12592/2012** Rev.0 of 20.11.2012 This template should be used for assessment reports prepared for active substances covered by Regulation 844/2012 and for active substances for which an application for the approval has been submitted as from 1 January 2014.	This template is intended to align the current structure of the assessment report with the dossier as well as the revised data requirements. It also aims to reduce duplication of information in different parts of the assessment report and to separate out the active substance part from product related exposure and risk. This structure will support the risk envelope approach for products and it will facilitate the setting of MRLs, the preparation of a "Conclusion on the peer review of the pesticide risk assessment of an active substance" as prepared by the EFSA, as well as a "Proposal for Harmonised Classification and Labelling" (CLH report) as prepared by ECHA. This template should be used in conjunction with the "Template to be used for assessment reports regarding level 3 of Volume 1" (SANCO/11114/2012).
Guidance document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under Regulation 1107/2009	
SANCO/**12823/2012** Rev. 4 of 12.12.2014 Applies to applications as from 1 April 2015.	This Guidance Document is applicable for changes to the same strain only in the framework of application for authorisations for plant protection products at Member State level. The purpose of this document is to provide guidance for the assessment of technical equivalence of micro-organisms used in PPPs and may also be helpful for dossier preparation.
Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products	
SANCO/**10054/2013** Rev.3 of 11.07. 2013	This document aims to provide guidance on efficacy requirements for new active substances, and in particular explains the principal objective of an efficacy assessment at the active substance approval stage. The aim should be to avoid a duplication of evaluation work for at least some of the individual GAP. The principal objective of the efficacy evaluation of an active substance is to confirm that the doses are realistic for the GAP submitted for risk evaluation and approval and representative for all subsequent authorisations. A summary dossier (as proposed in the appendix of this document) should be submitted. (It should be noted that the efficacy requirements for existing active substances when considered in the renewal procedure are different and are presented in Guidance Document SANCO/10387/2010, point 4.7.2).
Guidance document on the efficacy composition of core dossier and national addenda submitted to support the authorization of plant protection products under Regulation 1107	
SANCO/**10055/2013** Rev.4 of 03.10.2013 Applicable from 03.04.2014	Regulation 1107 specifies that the assessment of PPPs should be conducted on a zonal basis, with a nominated zonal rapporteur (zRMS) assessing the application on behalf of all other MSs to which an application has been made (the concerned MSs or cMS). The application should include the Biological Assessment Dossier (BAD), and any national addenda to address specific MS issues, as described in SANCO/6896/2009. Regulation 1107 also includes provisions for Mutual Recognition (MR) of authorisations. Mutual Recognition application may be accompanied by national addenda. The purpose of this guidance is to indicate areas of the efficacy data requirements that

	should be considered as part of the core zonal dossier, and what relevant issues may need to be addressed under national addenda.
Draft list of possible candidates for basic substances	
SANCO/**10069/2013** Rev.3 of 03.06. 2014	This is a Commission staff working document, containing a draft list of substances that have been identified by MSs and stakeholders as possible candidates for applications under the provisions of Article 23 on basic substances. The aim of this list is only to facilitate work-sharing in the future preparation of applications. This list has a pure informative objective.
Working document on emergency situations according to Article 53 of Regulation 1107/2009	
SANCO/**10087/2013** Rev. 0 of 01.02.2013 This working document applies to applications for emergency authorisations submitted after 11 February 2013	This guidance lays down the procedure for Member States when granting an authorisation under Article 53: *'in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means*.' Use of this Article should be exceptional, and restricted to cases of obvious dangers to plant production or ecosystems that cannot be contained by any other reasonable means. Member States should demonstrate, based on the application received, that the use authorised is justified in this sense and share detailed information about the situation and any measures taken to ensure consumer safety with the other Member States and the Commission.
Guidance document on rules for revision of assessment reports	
SANCO/**10180/2013** Rev. 1 of 15.03.2013 Noted 15.03.2013. To be be used for assessment reports prepared for active substances submitted to the Commission as from 1 May 2013.	The 'Template to be used for Assessment Reports' (SANCO/12592/2012) will already increase transparency and consistency in the documentation submitted and assessed for an approval of an active substance. A next step is to move away from addenda to a consolidated Assessment Report which underpins the approval decision and supports future reviews/renewals. This document provides guidance on when and how to update assessment reports. It refers not only to approvals, but also to amendment of approvals, renewal of approvals and the assessment of confirmatory information.
Guidance document for applicants on preparing dossiers for approval of a chemical new active substance and for renewal of approval under Regulations 283/2013 and 284/2013	
SANCO/**10181/2013** Rev. 3 of 12.12.2013 To be used for dossiers prepared for substances covered by Regulation 844/2012 (Air3) and for substances submitted as from 1 January 2014.	This guidance document describes how the applicant should submit a dossier for the approval or the renewal of approval of a chemical active substance to comply with the Table of Contents described in Annex to Regulations 283/2013 and 284/2013. The Guidance Document addresses the following aspects relating to delivering submissions for addressing Regulation 283/2013 and Regulation 284/2013: • Cross-walk of data points from OECD Table of Contents to revised EU Table of Contents; • Documents to be included in the Submission Dossier, including consideration of special situations like the cases where agreed test methods are not yet available for specific data requirement points;; • Electronic Submission (CADDY[1]) Table of Contents.
Template for Notification according to Art. 36(3) of Regulation (EC) No 1107/2009	
SANCO/**10532/2013** rev.0	Template to be used by Member States for notifying a refusal of zonal or mutual recognition) authorisation.

[1] CADDY is an electronic format for the exchange, archiving and evaluation of complex dossiers, developed jointly by industry and regulatory authorities. It was developed for the interchange of plant protection products dossiers, and is currently adopted http://caddy.ecpa.eu

applicable	
Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation 1107/2009	
SANCO/**11507/2013** Rev. 12 of 10.10.2014 This guidance applies for applications submitted as from 1 April 2015	The objective of this document is to give Member States guidance on how to conduct the comparative assessment when evaluating an application for authorisation of a plant protection product. The European and Mediterranean Plant Protection Organization (EPPO) has developed guidance on how to perform comparative assessment (Bulletin OEPP/EPPO Bulletin (2011) 41, 256–259). EPPO standard PP 1/271 Guidance on comparative assessment concentrates on assessment of efficacy, practicability, economical disadvantages, alternative measures, and effects on minor uses. This document is meant to supplement the EPPO standard, *i.e.* to give Member States guidance on how to perform the comparative assessment of risks to health and the environment, and to provide an overall framework for comparative assessment.
Guidance document on interpretation of transitional measures for data requirements for chemical active substances and PPPs according to Regulations 283/2013 and 284/2013	
SANCO/**11509/2013** Rev. 3 of 12.12. 2014 Details on application of new data requirements are described in detail in the Guidance Document.	The "old" data requirements are laid down in Regulation 544/2011 for active substances and in Regulation 545/2011 for PPPs and continued to apply till 31 December 2013. "New" data requirements have been adopted by the Commission (Regulations 283/2013 and 284/2013) and although transitional measures as regards procedures concerning approval of active substances and authorisation of PPPs have been considered, cases have been identified which need further clarification to guarantee a consistent approach in Member States. This Guidance Document deals with the interpretation of the transitional measures regarding the new data requirements for chemical active substances and PPPs.
Applications for renewal of approval of active substances submitted under article 14 of Regulation 1107/2009 and in accordance with Regulation 844/2012	
SANCO/**10148/2014** Rev. 2 of 01.09.2014	Overview of applications received in the renewal programme under Regulation 844/2012 (notifiers and submission dates). This overview is published under the provisions of Art. 3(6) of Regulation (EU) No 844/2012: "*the Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications have been submitted by the date provided for in the first subparagraph of Article 1(1) and contain all the elements provided for in Article 2*". The document is regularly updated.
Template to be used for the List of Endpoints	
SANCO/**12483/2014** Rev. 2 of 12.12.2014 This template should be used for assessment reports prepared for active substances for which an application for (renewal of) approval was submitted as from 1 March 2015. Preferably	This template for the List of Endpoints reflects the new data requirements for active substances and plant protection products as set out in Commission Regulations 283/2013 and 284/2013 of 1 March 2013, in accordance with Regulation 1107/2009. This template should be used in conjunction with the - Template to be used for assessment reports (SANCO/12592/2012) - Template to be used for assessment reports regarding level 3 of Volume 1 (SANCO/11114/2012). It is envisaged that there will be a general review of the templates for the List of Endpoints within the next years.
these templates should also be used for assessment reports for all active substances (chemicals as well as microorganisms): • For which an application for approval has been submitted after 1 January 2014 (i.e. an application according to the data requirements as laid down in Regulations 283/2013 and No 284/2013), • covered by Regulation 844/2012 for which an application for the renewal was submitted before 01.03.2015.	
Template to notify intended zonal applications under Articles 33 and 43 of Regulation 1107	
SANCO/**12544/2014**	At least six months before the application is due to be made it is recommended that the

Rev. 0 of 12.12.2014 This template is already in use for zonal applications as it is similar to the appendix 3 of Guidance document SANCO/13169/2010.	applicant should submit to all zonal contact points in MSs in the zone a summary of the products for which authorisation will be sought, detailing in which MSs the authorisation is envisaged. In the case of application according to Article 43 this summary should preferably submitted 1 year before the indicative/estimated application of the renewal of the PPP. A common format ("notification form") has been developed which should be used by applicants (see Appendix). This will help to organise the allocation of work to MSs and speed up the process. In future, the applicant shall also feed this information into the authorisation database.
Guidance document for applicants on preparing dossiers for approval or renewal of approval of a micro-organism under Regulations 283/2013 and 284/2013	
SANCO/**12545/2014** Rev. 1 of 12.12.2014 Applications for approval or renewal of approval submitted as from 1 March 2015	This guidance document describes how the applicant should submit a dossier for the approval or the renewal of approval of an active substance which is a microorganism[1] to comply with the Table of Contents described in Part B of the Annex to Regulation (EU) No 283/2013 and Part B of the Annex to Regulation (EU) No 284/2013 This Guidance Document addresses the following aspects relating to delivering submissions for addressing Regulations 283/2013 and 284/2013: • Data points from OECD Table of Contents to revised EU Table of Contents; • Electronic Submission (CADDY) Table of Contents; • Documents to be included in the Submission Dossier.

[1] According to Article 3(15) of Regulation (EC) No 1107/2009 *'micro-organisms' means "any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material"*.

Main text of the Regulation

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [4] provides for rules governing plant protection products and the active substances contained in those products.

(2) Following the progress report presented by the Commission under Directive 91/414/EEC, the European Parliament by its Resolution of 30 May 2002 [5] and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

(3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.

(4) By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances [6].

(5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.

(7) Plant protection products can however also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used.

(8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any

[1] OJ C 175, 27.7.2007, p. 44.
[2] OJ C 146, 30.6.2007, p. 48.
[3] Opinion of the European Parliament of 23 October 2007 (OJ C 263 E, 16.10.2008, p. 181), Council Common Position of 15 September 2008 (OJ C 266 E, 21.10.2008, p. 1) and European Parliament Position of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.
[4] OJ L 230, 19.8.1991, p. 1.
[5] OJ C 187 E, 7.8.2003, p. 173.
[6] OJ L 33, 8.2.1979, p. 36

harmful effect on human or animal health or any unacceptable effects on the environment.

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

(10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

(11) The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use.

(12) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a rapporteur for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([1]) (the Authority). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active substance. Provisions should be included to ensure the transparency of the evaluation process.

(13) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.

(14) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.

(15) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. The renewal of the approval should be for a period not exceeding 15 years.

(16) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied, or where compliance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([2]) is compromised, should be provided for under certain conditions.

(17) The evaluation of an active substance may reveal that it presents considerably less of a risk than other substances. In order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to facilitate the placing on the market of plant protection products containing them. Incentives should be given for the placing on the market of low-risk plant protection products.

(18) Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such

([1]) OJ L 31, 1.2.2002, p. 1.

([2]) OJ L 327, 22.12.2000, p. 1.

substances, as far as their risks are acceptable, may also be approved for plant protection use.

(19) Some active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly examine plant protection products containing such active substances with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods.

(20) In certain Member States non-chemical control or prevention methods, which are significantly safer for human and animal health and for the environment, have been established and generally applied for certain uses. In exceptional cases Member States should also be able to apply the comparative assessment when granting authorisation for plant protection products.

(21) In addition to active substances, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.

(22) Plant protection products may also contain co-formulants. It is appropriate to provide a list of co- formulants which should not be included in plant protection products.

(23) Plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Authorisations for plant protection products should therefore be granted by Member States.

(24) The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

(25) In the interest of predictability, efficiency and consistency, criteria, procedures and conditions for the authorisation of plant protection products should be harmonised, account being taken of the general principles of protection of human and animal health and the environment.

(26) Where the decision on approval cannot be finalised within the period provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for a limited period in order to facilitate the transition to the approval procedure provided for under this Regulation. In the light of the experience gained from the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary.

(27) The active substances contained in a plant protection product can be produced by different manufacturing processes, leading to differences in specifications. Such differences may have safety implications. For efficiency reasons, a harmonised procedure at Community level should be provided for the assessment of those differences.

(28) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure.

(29) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of one or more Member States might require that, on application, Member States recognise or amend an authorisation issued by another Member State, or refuse to authorise the plant protection product in their territory, where justified as a result of specific environmental or agricultural circumstances or where the high level of protection of both human and animal health and the environment required by this Regulation cannot be achieved. It should also be possible to impose appropriate conditions having regard to the objectives laid down in the National Action Plan adopted in accordance with Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a

framework for Community action to achieve a sustainable use of pesticides [1].

(30) The economic incentive for industry to apply for an authorisation is limited for certain uses. In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses.

(31) Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products.

(32) In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level.

(33) Community seeds legislation provides for free movement of seeds within the Community but does not contain a specific provision concerning seeds treated with plant protection products. Such a provision should therefore be included in this Regulation. If treated seeds constitute a serious risk to human or animal health or to the environment, Member States should have the possibility of taking protective measures.

(34) To promote innovation, special rules should be established permitting the use of plant protection products in experiments even where they have not yet been authorised.

(35) To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non- chemical and natural alternatives wherever possible. The Council should include in the statutory management requirement referred to in Annex III to Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers [2], the principles of integrated pest management, including good plant protection practice and non-chemical methods of plant protection and pest and crop management.

(36) In addition to this Regulation and Directive 2009/128/EC, a thematic strategy on the sustainable use of pesticides was adopted. In order to achieve coherence between these instruments, the user should know from the product label where, when and under what circumstances a plant protection product may be used.

(37) A system of exchange of information should be established. Member States should make available to each other, the Commission and the Authority the particulars and scientific documentation submitted in connection with applications for authorisation of plant protection products.

(38) Adjuvants may be used to increase the efficacy of a plant protection product. Their placing on the market or use should be forbidden where they contain a co-formulant which has been prohibited. The technical rules necessary for the authorisation should be established.

(39) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, tests and studies, other than those involving vertebrate animals, which will be subject to obligatory data sharing, lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary. Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.

(40) The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[3], tests on vertebrate animals must be replaced, restricted or refined. Therefore, rules should be laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. For the purpose of developing new plant protection products, there

[1] OJ L390, 24.11.2009, p. 71
[2] OJ L 270, 21.10.2003, p. 1.
[3] OJ L 358, 18.12.1986, p. 1.

should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access.

(41) As different rules are applied by Member States, the Commission and the Authority in relation to access to and confidentiality of documents, it is appropriate to clarify the provisions concerning access to information contained in the documents in the possession of these authorities and the confidentiality of these documents.

(42) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations [1] applies to the classification, packaging and labelling of plant protection products. However, to improve further the protection of users of plant protection products, of consumers of plants and plant products and of the environment, further specific rules are appropriate which take account of the specific conditions of use of plant protection products.

(43) To ensure that advertisements do not mislead users of plant protection products or the public, it is appropriate to lay down rules on the advertising of those products.

(44) Provisions on record-keeping and information about the use of plant protection products should be established in order to raise the level of protection of human and animal health and the environment by ensuring the traceability of potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality.

(45) Provisions on control and inspection arrangements with regard to the marketing and use of plant protection products should ensure correct, safe and harmonised implementation of the requirements laid down in this Regulation in order to achieve a high level of protection of both human and animal health and the environment.

(46) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [2] provides for control measures for the use of plant protection products at all stages of the production of food, including record-keeping on the use of plant protection products. Similar rules on monitoring and controls relating to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004 should be adopted by the Commission. The bureaucratic burden on farmers should be as limited as possible.

(47) The measures provided for in this Regulation should apply without prejudice to other Community legislation, in particular Directive 2009/128/EC, Directive 2000/60/EC, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [3] and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.

(48) It is necessary to establish procedures for the adoption of emergency measures in situations where an approved active substance, a safener, a synergist or a plant protection product is likely to constitute a serious risk to human or animal health or the environment.

(49) Member States should lay down rules on penalties applicable to infringements of this Regulation and should take the measures necessary to ensure that they are implemented.

(50) General civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the plant protection product on the market or using it should remain applicable.

(51) Member States should have the possibility of recovering the costs of the procedures associated with the application of this Regulation from those seeking to place, or placing, plant protection products or adjuvants on the market and from those applying for the approval of active substances, safeners or synergists.

(52) Member States should designate the necessary national competent authorities.

(53) The Commission should facilitate the application of this Regulation. Therefore, it is appropriate to provide for the necessary financial resources and the possibility of amending certain provisions of

[1] OJ L 200, 30.7.1999, p. 1.

[2] OJ L 165, 30.4.2004, p. 1.
[3] OJ L 70, 16.3.2005, p. 1.

this Regulation in the light of experience or of developing technical notes for guidance.

(54) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(55) In particular, the Commission should be empowered to adopt harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants, and maximum quantities of plant protection products to be released, and to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(56) On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a Regulation postponing the expiry of the approval period for a period sufficient to examine the application.

(57) Furthermore, it is appropriate to transfer certain current provisions set out in the Annexes to Directive 91/414/EEC into separate legal instruments to be adopted by the Commission within 18 months after the entry into force of this Regulation. Since these current provisions should be, as a first step, transferred into new legal instruments and thus be adopted without any substantial modification, the advisory procedure is the most appropriate.

(58) It is also appropriate to use the advisory procedure to adopt some purely technical measures, in particular technical guidelines in view of their non-binding character.

(59) Certain provisions of Directive 91/414/EEC should remain applicable during the transitional period,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and purpose

1. This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community.

2. This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.

3. The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

4. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

Article 2

Scope

1. This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

(c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;

[1] OJ L 184, 17.7.1999, p. 23.

(d) destroying undesired plants or parts of , except algae unless the products are applied on soil or water to protect plants;

(e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

These products are referred to as 'plant protection products'.

2. This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.

3. This Regulation shall apply to the following:

(a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as 'safeners';

(b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as 'synergists';

(c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants';

(d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'residues' means one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products;

2. 'substances' means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

3. 'preparations' means mixtures or solutions composed of two or more substances intended for use as a plant protection product or as an adjuvant;

4. 'substance of concern' means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect.

   Such substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures [1], and present in the plant protection product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC;

5. 'plants' means live plants and live parts of plants, including fresh fruit, vegetables and seeds;

6. 'plant products' means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plants;

7. 'harmful organisms' means any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products;

8. 'non-chemical methods' means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC, or physical, mechanical or biological pest control methods;

9. 'placing on the market' means the holding for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation;

10. 'authorisation of a plant protection product' means an administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory;

[1] OJ L 353, 31.12.2008, p. 1.

11. 'producer' means a person who manufactures plant protection products, active substances, safeners, synergists, co-formulants or adjuvants on his own, or who contracts this manufacturing to another party, or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;

12. 'letter of access' means an original document by which the owner of data protected under this Regulation agrees to the use of such data under the specific terms and conditions by the competent authority for the purpose of granting an authorisation of a plant protection product or an approval of an active substance, synergist or safener for the benefit of another applicant;

13. 'environment' means waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms;

14. 'vulnerable groups' means persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term;

15. 'micro-organisms' means any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;

16. 'genetically modified organisms' means organisms in which the genetic material has been altered within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [1];

17. 'zone' means a group of Member States as defined in Annex I.

    For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment the zone means all zones defined in Annex I;

18. 'good plant protection practice' means a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;

19. 'good laboratory practice' means a practice as defined in point 2.1 of Annex I to Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances [2];

20. 'good experimental practice' means a practice in accordance with the provisions of European and Mediterranean Plant Protection Organisation (EPPO) Guidelines 181 and 152;

21. 'data protection' means the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant;

22. 'rapporteur Member State' means the Member State which undertakes the task of evaluating an active substance, safener or synergist;

23. 'tests and studies' means investigations or experiments whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products;

24. 'authorisation holder' means any natural or legal person holding an authorisation of a plant protection product;

25. 'professional user' means a professional user as defined in Article 3(1) of Directive 2009/128/EC;

26. 'minor use' means use of a plant protection product in a particular Member State on plants or plant products which are:

    a. not widely grown in that Member State; or

    b. widely grown, to meet an exceptional plant protection need;

27. 'greenhouse' means a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment.

[1] OJ L 106, 17.4.2001, p. 1.

[2] OJ L 50, 20.2.2004, p. 44.

For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses;

28. 'post-harvest treatment' means treatment of plants or plant products after harvest in an isolated space where no run-off is possible, for example in a warehouse;

29. 'biodiversity' means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;

30. 'competent authority' means any authority or authorities of a Member State responsible for carrying out the tasks established under this Regulation;

31. 'advertisement' means a means of promoting the sale or use of plant protection products (to anyone other than the authorisation holder, the person placing the plant protection product on the market and their agents) by printed or electronic media;

32. 'metabolite' means any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment.

A metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures;

33. 'impurity' means any component other than the pure active substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage).

CHAPTER II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 1

Requirements and conditions for approval

Article 4

Approval criteria for active substances

1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;

(b) they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements[1]:

(a) it shall be sufficiently effective;

[1] *see* Guidance Doc. SANCO/10054/2013 Rev.3 of 11.07.2013

(b) it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;

(c) it shall not have any unacceptable effects on plants or plant products;

(d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.

4. The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in Article 29(6).

5. For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

6. In relation to human health, no data collected on humans shall be used to lower the safety margins resulting from tests or studies on animals.

7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory.

At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

Article 5

First approval

First approval shall be for a period not exceeding 10 years.

Article 6

Conditions and restrictions

Approval may be subject to conditions and restrictions including:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and al, including climatic, conditions in question;

(d) type of preparation;

(e) manner and conditions of application;

(f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge[1];

(g) designation of categories of users, such as professional and non-professional;

[1] *see* Guidance doc. SANCO/5634/2009 Rev. 6.1 of 12.2013.

(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;

(i) the need to impose risk mitigation measures and monitoring after use;

(j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.

Subsection 2

Approval procedure

Article 7

Application

1. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2) or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.

2. Assessment of an application may be performed by a number of Member States together under a co-rapporteur system.

3. When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Member States shall assess the confidentiality requests. Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

4. When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2) and a list of any claims for data protection pursuant to Article 59.

5. When assessing the application the rapporteur Member State may at any time consult the Authority.

Article 8

Dossiers[1]

1. The summary dossier shall include the following:

(a) information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met; where the information submitted does not cover all zones or concern a crop which is not widely grown, justification for this approach;

(b) for each point of the data requirements for the active substance, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

(c) for each point of the data requirements for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

(d) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

(e) a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

(f) the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

(g) where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(h) an assessment of all information submitted.

2. The complete dossier shall contain the full text of the individual test and study reports concerning all the

[1] *see* Guidance Doc. SANCO/11244/2011 Rev. 5 of 14.03.2011
Guidance Doc. SANCO/10181/2013 Rev. 3 of 13.05.2013
Guidance Doc. SANCO/12545/2014 Rev.1 12.12.2014

information referred to in points (b) and (c) of paragraph 1. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

3. The format of the summary dossier and the complete dossier shall be established in accordance with the advisory procedure referred to in Article 79(2).

4. The data requirements referred to in paragraphs 1 and 2 shall contain the requirements for active substances and plant protection products as set out in Annexes II and III to Directive 91/414/EEC and laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(b).

5. Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Article 9

Admissibility of the application

1. Within 45 days of receiving the application, the rapporteur Member State shall send the applicant a written acknowledgement, stating the date of receipt, and check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in point (c) of Article 8(1). It shall also check the requests for confidentiality referred to in Article 7(3) and the complete lists of tests and studies submitted pursuant to Article 8(2).

2. Where one or more of the elements provided for in Article 8 are missing, the rapporteur Member State shall inform the applicant, setting a period for their submission. Such period shall be a maximum of 3 months.

Where at the end of that period, the applicant has not submitted the missing elements, the rapporteur Member State shall inform the applicant, the other Member States and the Commission that the application is inadmissible.

A new application for the same substance may be submitted at any time.

3. Where the dossiers submitted with the application contain all the elements provided for in Article 8, the rapporteur Member State shall notify the applicant, the other Member States, the Commission and the Authority of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant shall immediately forward the dossiers as provided for in Article 8 to the other Member States, the Commission and the Authority, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 7(3).

Article 10

Access to the summary dossier

The Authority shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Article 11

Draft assessment report

1. Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2. The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3. Where the rapporteur Member State needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the rapporteur Member State. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the rapporteur Member State. It shall inform the Commission and the Authority accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the rapporteur Member State shall inform the applicant, the Commission and the Authority and shall state the missing elements in the assessment included in the draft assessment report.

4. The format of the draft assessment report[1] shall be established in accordance with the advisory procedure referred to in Article 79(2).

Article 12

Conclusion by the Authority

1. The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States at the latest 30 days after its receipt. It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and the Authority.

The Authority shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

The Authority shall allow a period of 60 days for the submission of written comments.

2. The Authority, where appropriate shall organise a consultation of experts, including experts from the rapporteur Member State.

Within 120 days of the end of the period provided for the submission of written comments, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. In the event of a consultation as provided for in this paragraph, the 120-day period shall be extended by 30 days.

Where appropriate, the Authority shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3. Where the Authority needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within 60 days after receipt of the additional information. In that case the 120-day period provided for in paragraph 2 shall be extended by a period which shall cease at the moment when the additional assessment is received by the Authority.

The Authority may ask the Commission to consult a Community reference laboratory, designated pursuant to Regulation (EC) No 882/2004 for the purposes of verifying whether the analytical method[2] for the determination of the residues proposed by the applicant is satisfactory and meets the requirements in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the Community reference laboratory, provide samples and analytical standards.

4. The conclusion of the Authority shall include details concerning the evaluation procedure and the properties of the active substance concerned.

5. The Authority shall establish the format for its conclusion which shall include details concerning the evaluation procedure and the properties of the active substance concerned.

6. The time limits for the Authority's opinion on applications concerning maximum residue levels set out in Article 11 and for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

7. Where the conclusion of the Authority is adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Article 11 of Regulation (EC) No 396/2005 shall not apply and the provisions of Article 14 of that Regulation shall apply without delay.

8. Where the conclusion of the Authority is not adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Articles 11 and 14 of Regulation (EC) No 396/2005 shall apply without delay.

Article 13

Approval Regulation

1. Within six months of receiving the conclusion from the Authority, the Commission shall present a report, referred to as 'the review report', and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of the Authority.

The applicant shall be given the possibility to submit comments on the review report.

2. On the basis of the review report, other factors legitimate to the matter under consideration and the

[1] *see* Guidance Doc. SANCO/11114/2012 Rev. 0 of 01.06.2012
Guidance Doc. SANCO/12592/2012 Rev.0 of 20.11.2012
Guidance Doc. SANCO/10180/2013 Rev. 1 of 15.03.2013
Guidance Doc. SANCO/12483/2014 Rev. 2 of 12.12.2014

[2] See Guidance Doc. SANCO/825/00 rev.8.1

precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, a Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

(a) an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate;

(b) an active substance is not approved; or

(c) the conditions of the approval are amended.

3. Where the approval provides for the submission of further confirmatory information as referred to in Article 6(f), the Regulation shall provide the time limit to submit the information to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit its assessment to the other Member States, the Commission and the Authority without delay and at the latest six months after the receipt of the additional information.

4. Approved active substances shall be included in the Regulation referred to in Article 78(3) containing the list of active substances already approved. The Commission shall maintain a list of approved active substances electronically available to the public.

Subsection 3

Renewal and review[1]

Article 14

Renewal of approval

1. On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.

2. The renewal of the approval shall be for a period not exceeding 15 years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.

Article 15

Application for renewal

1. The application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than three years before the expiry of the approval.

2. When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval. The applicant shall at the same time submit a timetable of any new and ongoing studies.

The applicant shall identify, giving reasons, the parts of the information submitted that he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

Article 16

Access to the information for renewal

The Authority shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Article 17

Extension of approval period for the duration of the procedure

Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.

A Regulation postponing the expiry for a period sufficient to examine the application shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(5) where an applicant could not give the three years' notice required under Article 15(1) because the active substance was included in Annex I to Directive 91/414/EEC for a duration which expired before 14 June 2014.

The length of that period shall be established on the basis of the following:

[1] *see* Guidance Doc. SANCO/2012/11251 Rev. 4 of 12.12.2014

(a) the time needed to provide the information requested;

(b) the time needed to complete the procedure;

(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

Article 18

Work programme[1]

The Commission may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties[2] to submit all the necessary data to the Member States, the Commission and the Authority within a period provided for in the programme.

The programme shall include the following:

(a) the procedures concerning the submission and assessment of applications for renewal of approvals;

(b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done among Member States acting as rapporteurs.

Article 19

Implementing measures

A Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided for in Article 18.

Article 20

Renewal Regulation

1. A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

(a) the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or

(b) the approval of an active substance is not renewed.

2. Where the reasons for not renewing the approval do not concern the protection of health or the environment, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding six months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. The grace period for the sale and distribution shall take into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months.

In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

3. Article 13(4) shall apply.

Article 21

Review of approval[3]

1. The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where, after the review of the authorisations pursuant to Article 44(1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC is compromised.

Where, in the light of new scientific and technical knowledge it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or further information required in accordance with Article 6(f) has not been provided, it shall inform the Member States, the Authority and the producer of the active substance, setting a period for the producer to submit its comments.

[1] *see* Guidance doc. SANCO/11284/2012 Rev.14 of 12.2014
[2] *see* Guidance doc. SANCO/10148/2014 Rev.2 of 01.09.2014
[3] *see* Guidance Doc. SANCO/10328/2004 Rev.8 of 24.01.2012

2. The Commission may ask the Member States and the Authority for an opinion, or for scientific or technical assistance. The Member States may provide their comments to the Commission within three months from the date of the request. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

3. Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, or the further information required in accordance with Article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 13(4) and Article 20(2) shall apply.

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]

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.

[1] *see:* Guidance Doc. SANCO/10363/2012 Rev.9, 21.03.2014
see: Guidance Doc. SANCO/10069/2013 Rev.3 of 03.06.2014

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).

SECTION 2

Safeners and synergists

Article 25

Approval of safeners and synergists

1. A safener or synergist shall be approved, where it complies with Article 4.

2. Articles 5 to 21 shall apply.

3. Similar data requirements to those referred to in Article 8(4) shall be defined for safeners and synergists in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 26

Safeners and synergists already on the market

By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.

SECTION 3

Unacceptable co-formulants

Article 27

Co-formulants

1. A co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

(a) its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or

(b) its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.

2. Co-formulants which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included in Annex III in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

3. The Commission may review co-formulants at any time. It may take into account relevant information provided by Member States.

4. Article 81(2) shall apply.

5. Detailed rules for the implementation of this Article may be established in accordance with the regulatory procedure referred to in Article 79(3).

CHAPTER III

PLANT PROTECTION PRODUCTS

SECTION 1

Authorisation

SUBSECTION 1

Requirements and contents

Article 28

Authorisation for placing on the market and use

1. A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.

2. By way of derogation from paragraph 1, no authorisation shall be required in the following cases:

(a) use of products containing exclusively one or more basic substances;

(b) placing on the market and use of plant protection products for research or development purposes in accordance with Article 54;

(c) production, storage or movement of a plant protection product intended for use in another Member State, provided that the product is authorised in that Member State and that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory;

(d) production, storage or movement of a plant protection product intended for use in a third country provided that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is exported from its territory;

(e) placing on the market and use of plant protection products for which a parallel trade permit has been granted in accordance with Article 52.

Article 29

Requirements for the authorisation for placing on the market

1. Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements:

(a) its active substances, safeners and synergists have been approved;

(b) where its active substance, safener or synergist is produced by a different source, or by the same source with a change in the manufacturing process and/or manufacturing location:

(i) the specification, pursuant to Article 38, does not deviate significantly [1] from the specification included in the Regulation approving that substance, safener or synergist; and

(ii) the active substance, safener or synergist has no more harmful effects within the meaning of Article 4(2) and (3) due to its impurities than if it had been produced in accordance with the manufacturing process specified in the dossier that supported the approval;

(c) its co-formulants are not included in Annex III;

(d) its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

(e) in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

(f) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or ally relevant impurities and co-formulants can be determined by appropriate methods;

(g) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in all Member States, with appropriate limits of determination on relevant samples;

(h) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

(i) for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.

2. The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3. Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the zone where the product is intended to be used.

4. With respect to point (f) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5. Article 81 shall apply.

6. Uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(c).

[1] Guidance Doc. SANCO/10597/2003 Rev. 10.1 of 13.07.2012

Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.

Article 30

Provisional authorisations

1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:

(a) the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and

(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and

(c) the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and

(d) maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2. In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3. The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 31

Contents of authorisations

1. The authorisation shall define plants or plant products and non-agricultural areas (for example railways, public areas, storage rooms) on which and the purposes for which the plant protection product may be used.

2. The authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall as a minimum include the conditions of use necessary to comply with the conditions and requirements provided for in the Regulation approving the active substances, safeners and synergists.

The authorisation shall include a classification of the plant protection product for the purpose of Directive 1999/45/EC. Member States may provide that authorisation holders shall classify or update the label without undue delay following any change to the classification and labelling of the plant protection product in accordance with Directive 1999/45/EC. In such cases, they shall immediately inform the competent authority thereof.

3. The requirements referred to in paragraph 2 shall also include where applicable:

(a) the maximum dose per hectare in each application;

(b) the period between the last application and harvest;

(c) the maximum number of applications per year.

4. The requirements referred to in paragraph 2 may include the following:

(a) a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, residents, consumers or workers concerned or the environment, taking into consideration requirements imposed by other Community provisions; such restriction shall be indicated on the label;

(b) the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed;

(c) indications for proper use according to the principles of Integrated Pest Management referred to in Article 14 of and Annex III to Directive 2009/128/EC;

(d) designation of categories of users, such as professional and non-professional;

(e) the approved label;

(f) the interval between applications;

(g) the period between the last application and consumption of the plant product where applicable;

(h) the re-entry interval;

(i) the packaging size and material.

Article 32

Duration

1. The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the

active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.

This period shall allow the examination as provided for in Article 43 to be carried out.

2. Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.

Subsection 2

Procedure[1]

Article 33

Application for authorisation or amendment of an authorisation[2]

1. An applicant who wishes to place a plant protection product on the market shall apply for an authorisation or amendment of an authorisation himself, or through a representative, to each Member State where the plant protection product is intended to be placed on the market.

2. The application shall include[3] the following:

(a) a list of intended uses in each zone as indicated in Annex I and the Member States where the applicant has made or intends to make an application;

(b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post- harvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;

(c) where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

(d) where relevant, a copy of any conclusion of the Member State assessing equivalence[4] as referred to in Article 38(2).

3. The application shall be accompanied by the following:

(a) for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

(b) for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

(d) the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

(e) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(f) where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

(g) a draft label.

4. When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the Member State examining the application shall decide what information is to be kept confidential.

5. Where requested by the Member State the applicant shall submit his application in the national or official languages of that Member State or one of those languages.

6. On request, the applicant shall provide the Member State with samples of the plant protection product and analytical standards of its ingredients.

[1] *see* Guidance Doc. SANCO/13169/2010 Rev.9 of 11.07.2014
[2] *see* Guidance Doc. SANCO/12544/2014 Rev.0 of 12.12.2014
[3] *see* Guidance Doc. SANCO/10055/2013 Rev.4 of 03.10.2013
[4] *see* Guidance Doc. SANCO/10597/2003 Rev.10.1 of 13.07.2012

Article 34

Exemption from the submission of studies

1. Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired.

2. However, applicants to whom paragraph 1 applies shall provide the following information:

(a) all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used;

(b) the information needed to identify the active substance, safener or synergist, where they have been approved, and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;

(c) on the request of the concerned Member State, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

Article 35

Member State examining the application

The application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine it. The Member State which will examine the application shall inform the applicant.

At the request of the Member State examining the application, the other Member States in the same zone to which an application has been submitted shall cooperate to ensure a fair division of the workload.

The other Member States within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application.

Where an application has been made in more than one zone, Member States evaluating the application shall agree on the evaluation of data which are not related to the environmental and agricultural conditions.

Article 36

Examination for authorisation

1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report[1] shall be established in accordance with the advisory procedure referred to in Article 79(2).

2. The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32.

3. By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed[2] with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefor.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.

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[1] *see* Guidance Doc. SANCO/6895/2009 Rev 1 of 02.10.2009
[2] *see* Guidance Doc. SANCO/10532/2013/ rev.0

Article 37

Period for examination

1. The Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a period for the applicant to supply it. In that case, the 12- month period shall be extended by the additional period granted by the Member State. That additional period shall be a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

2. The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3. For an application for authorisation of a plant protection product containing an active substance not yet approved, the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report referred to in Article 12(1). In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the Member State shall decide on the application at the latest within six months of the active substance being approved.

4. The other Member States concerned shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).

Article 38

Assessment of equivalence under point (b) of Article 29(1)[12],

1. Where it is necessary to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process and/or manufacturing location complies with point (b) of Article 29(1), this shall be assessed by the Member State which acted as rapporteur for the active substance, safener or synergist as referred to in Article 7(1) unless the Member State examining the application as referred to in Article 35 agrees to assess the equivalence. The applicant shall submit all necessary data to the Member State assessing equivalence.

2. After giving the applicant the opportunity to submit comments, which the applicant shall also communicate to the rapporteur Member State or the Member State examining the application as the case may be, the Member State assessing equivalence shall prepare a report on equivalence within 60 days from receiving the application and shall communicate the report to the Commission, the other Member States and the applicant.

3. In the case of a positive conclusion on equivalence and where no objection to this conclusion has been raised, point (b) of Article 29(1) shall be considered to be complied with. However, where a Member State examining the application does not agree with the conclusion of the rapporteur Member State or vice versa, it shall inform the applicant, the other Member States and the Commission stating its reasons.

The Member States concerned shall try to reach agreement on whether point (b) of Article 29(1) is complied with. They shall provide the applicant with an opportunity to submit comments.

4. Where the Member States concerned do not reach agreement within 45 days, the Member State assessing equivalence shall submit the matter to the Commission. A decision on whether the conditions referred to in point (b) of Article 29(1) are complied with shall be adopted in accordance with the regulatory procedure referred to in Article 79(3). The 45-day period begins on the date on which the Member State examining the application for authorisation informed the rapporteur Member State or vice versa that it does not agree with the conclusion of the latter, in accordance with paragraph 3.

Before such a decision is adopted, the Commission may ask the Authority for an opinion, or for scientific or technical assistance which shall be provided within 3 months of the request.

5. Detailed rules and procedures for the implementation of paragraphs 1 to 4 may be established in accordance with the regulatory procedure referred to in Article 79(3), after consultation of the Authority.

Article 39

Reporting and exchange of information on applications for authorisation

1. Member States shall compile a file on each application. Each file shall contain the following:

(a) a copy of the application;

(b) a report containing information on the evaluation of and decision on the plant protection product; the format of the report shall be established in accordance with the advisory procedure referred to in Article 79(2);

[2] *see* Guidance Doc. SANCO/10597/2003 rev.10.1: 13.07.2012
Guidance Doc. SANCO/6075/2009 Rev.3 of 07.2009
Guidance Doc. SANCO/12823/2012 Rev.4 of 12.12.2014

(c) a record of the administrative decisions taken by the Member State concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;

(d) the approved label, where applicable.

2. On request, Member States shall, without delay, make available to the other Member States, the Commission and the Authority a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3. On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to Member States, the Commission and the Authority.

4. Detailed rules for the implementation of paragraphs 2 and 3 may be established in accordance with the regulatory procedure referred to in Article 79(3).

Subsection 3

Mutual recognition of authorisations

Article 40

Mutual recognition

1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone;

(b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone;

(c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

2. Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction.

Where the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.

Article 41

Authorisation

1. The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies.

2. By way of derogation from paragraph 1, the Member State may authorise the plant protection product where:

(a) an authorisation under point (b) of Article 40(1) was applied for;

(b) it contains a candidate of substitution;

(c) Article 30 has been applied; or

(d) it contains a substance approved in accordance with Article 4(7).

Article 42

Procedure

1. The application shall be accompanied by the following:

(a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;

(b) a formal statement that the plant protection product is identical to that authorised by the reference Member State;

(c) a complete or summary dossier as required in Article 33(3) when requested by the Member State;

(d) an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product.

2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days.

3. Where requested by the Member State, the applicant shall submit the application in the national or official languages of that Member State or one of those languages.

Subsection 4

Renewal, withdrawal and amendment[1]

Article 43

Renewal of authorisation

1. An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2. Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:

(a) a copy of the authorisation of the plant protection product;

(b) any new information required as a result of amendments in data requirements or criteria;

(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;

(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;

(e) a report on the monitoring information, where the authorisation was subject to monitoring.

3. Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation renewing the approval under Article 20.

The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.

4. Guidelines on the organisation of compliance checks may be established in accordance with the advisory procedure referred to in Article 79(2).

5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6. Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Member State in question shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

Article 44

Withdrawal or amendment of an authorisation

1. Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

A Member State shall review an authorisation where it concludes that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.

2. Where a Member State intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3. The Member State shall withdraw or amend the authorisation, as appropriate, where:

(a) the requirements referred to in Article 29 are not or are no longer satisfied;

(b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

(c) a condition included in the authorisation has not been met;

(d) on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or

(e) the authorisation holder fails to comply with the obligations resulting from this Regulation.

4. Where a Member State withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation, the other Member States, the Commission and the Authority. The other Member States belonging to the same zone shall withdraw or amend the authorisation accordingly taking into account national conditions and risk mitigation measures except for cases where the

[1] *see* Guidance Doc. SANCO/2010/13170 Rev. 9 of 12.12.2014

second, third or fourth subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

Article 45

Withdrawal or amendment of an authorisation at the request of the authorisation holder

1. An authorisation may be withdrawn or amended[1] at the request of the holder of the authorisation, who shall state the reasons for his request.

2. Amendments may only be granted where it is established that the requirements referred to in Article 29 continue to be met.

3. Article 46 shall apply where appropriate.

Article 46

Grace period

Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Subsection 5

Special cases

Article 47

Placing on the market of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low- risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

(a) the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;

(b) it does not contain a substance of concern;

(c) it is sufficiently effective;

(d) it does not cause unnecessary pain and suffering to vertebrates to be controlled;

(e) it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as 'low-risk plant protection products'.

2. An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product.

3. The Member State shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product.

Where the Member State needs additional information, it shall set a time limit for the applicant to supply it. In that case, the period specified shall be extended by the additional time limit granted by the Member State.

The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

4. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 48

Placing on the market and use of plant protection products containing a genetically modified organism

1. A plant protection product which contains an organism falling within the scope of Directive 2001/18/EC shall be examined in respect of the genetic modification in accordance with that Directive, in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent, as referred to in Article 19 of Directive 2001/18/EC, has been granted for it.

2. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

[1] *e.g.* for formulation changes: Guidance Doc. SANCO/12638/2011 rev.2, 20.11.2012

Article 49

Placing on the market of treated seeds

1. Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State.

2. Where there are substantial concerns that treated seeds as referred to in paragraph 1 are likely to constitute a serious risk to human or animal health or to the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, measures to restrict or prohibit the use and/or sale of such treated seeds shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3). Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

3. Articles 70 and 71 shall apply.

4. Without prejudice to other Community legislation concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Directive 1999/45/EC and risk mitigation measures set out in the authorisation for that product where appropriate.

Article 50

Comparative assessment of plant protection products containing candidates for substitution

1. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

(a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;

(b) the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;

(c) the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and

(d) the consequences on minor use authorisations are taken into account.

2. By way of derogation from Article 36(2) Member States may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State.

3. By way of derogation from paragraph 1, a plant protection product containing a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.

Such authorisations shall be granted once for a period not exceeding five years.

4. For plant protection products containing a candidate for substitution Member States shall perform the comparative assessment[1] provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, Member States shall maintain, withdraw or amend the authorisation.

5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect 3 years after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.

6. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 51

Extension of authorisations for minor uses

1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

[1] *see* Guidance Doc. SANCO/11507/2013 Rev. 12 of 10.10.2014

2. Member States shall extend the authorisation provided that:

(a) the intended use is minor in nature;

(b) the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;

(c) the extension is in the public interest; and

(d) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3. Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4. The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, in accordance with the administrative procedures of the Member State concerned.

5. When Member States grant an extension of authorisation for a minor use, they shall inform if necessary the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6. Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7. The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1) provided that a plant protection product concerned is authorised in that Member State. Member States shall authorise such uses in accordance with the provisions of Article 41 provided that those uses are also considered minor in the Member States of application.

8. Member States shall establish and regularly update a list of minor uses.

9. By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

10. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 52

Parallel trade[1]

1. A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.

2. From receiving a complete application, a parallel trade permit shall be granted in a simplified procedure within 45 working days if the plant protection product to be introduced is identical in terms of paragraph 3. Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request. The procedure for granting a parallel trade permit is interrupted from the day the request for information is sent to the competent authority of the Member State of origin until the complete information required is delivered to the competent authority of the Member State of introduction.

3. Plant protection products shall be considered as identical to the reference products if:

(a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;

(b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and

(c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

4. The application for a parallel trade permit shall include the following information:

[1] *see* Guidance Doc. SANCO/10524/2012 Rev.4 of 31.05.2012

(a) the name and registration number of the plant protection product in the Member State of origin;

(b) the Member State of origin;

(c) the name and address of the authorisation holder in the Member State of origin;

(d) the original label and instructions for use with which the plant protection product to be introduced is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction. This competent authority may require a translation of the relevant parts of the original instructions for use;

(e) the name and address of the applicant;

(f) the name to be given to the plant protection product to be distributed in the Member State of introduction;

(g) a draft label for the product intended to be placed on the market;

(h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(i) the name and registration number of the reference product.

The information requirements may be amended or completed and further details and specific requirements shall be established in cases of application for a plant protection product for which a parallel trade permit has already been granted and in cases of an application for a plant protection product for a personal use in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5. A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product. To facilitate monitoring and controls the Commission shall set out specific control requirements for the product to be introduced in a Regulation referred to in Article 68.

6. The parallel trade permit shall be valid for the duration of authorisation of the reference product. If the authorisation holder of the reference product applies for a withdrawal of authorisation in accordance with Article 45(1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit shall expire by the date on which the authorisation of the reference product would normally have expired.

7. Without prejudice to specific provisions of this Article, Articles 44, 45, 46, and 55 and Article 56(4) and Chapters VI to X shall apply to parallel traded plant protection products correspondingly.

8. Without prejudice to Article 44, a parallel trade permit may be withdrawn if the authorisation of the introduced plant protection product is withdrawn in the Member State of origin because of safety or efficacy reasons.

9. Where the product is not identical, in terms of paragraph 3, to the reference product, the Member State of introduction may only grant the authorisation required for placing on the market and use in accordance with Article 29.

10. The provisions of this Article shall not apply to plant protection products which are authorised in the Member State of origin in accordance with Article 53 or 54.

11. Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits.

Subsection 6

Derogations

Article 53

Emergency situations in plant protection[1]

1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

2. The Commission may 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 1 month of the date of the request.

3. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

[1] *see* Guidance Doc. SANCO/10087/2013 Rev. 0 of 01.02.2013

(a) may or may not extend the duration of the measure or repeat it; or

(b) shall withdraw or amend its measure.

4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

Article 54

Research and development

1. By way of derogation from Article 28, experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product or involving unauthorised use of a plant protection product may be carried out if the Member State in whose territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes. The permit may limit the quantities to be used and the areas to be treated and may impose further conditions to prevent any harmful effects on human or animal health or any unacceptable adverse effect on the environment, such as the need to prevent entry into the food chain of feed and food containing residues unless a relevant provision has already been established under Regulation (EC) No 396/2005.

The Member State may authorise a programme of experiments or tests in advance or require a permit for each experiment or test.

2. An application shall be submitted to the Member State in whose territory the experiment or test is to be conducted, together with a dossier containing all the available data to permit an assessment of possible effects on human or animal health or the possible impact on the environment.

3. A permit for trial purposes shall not be granted for experiments or tests involving the release into the environment of a genetically modified organism unless such release has been accepted under Directive 2001/18/EC.

4. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

5. Detailed rules for the implementation of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

SECTION 2

USE AND INFORMATION

Article 55

Use of plant protection products

Plant protection products shall be used properly.

Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive, which shall apply at the latest by 1 January 2014.

Article 56

Information on potentially harmful or unacceptable effects

1. The holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in third countries.

2. The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3. Without prejudice to the right of Member States to adopt interim protective measures, the Member State which first granted an authorisation within each zone shall evaluate the information received and inform the other Member States, belonging to the same zone, where it decides to withdraw or amend the authorisation under Article 44.

That Member State shall inform the other Member States and the Commission where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled or whether in the case of a co-formulant it has been considered unacceptable and propose that the approval be withdrawn or the conditions amended.

4. The holder of an authorisation for a plant protection product shall report annually to the competent authorities of the Member States which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Article 57

Obligation to keep information available

1. Member States shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

(a) the name or business name of the holder of the authorisation and the authorisation number;

(b) the trade name of the product;

(c) the type of preparation;

(d) the name and amount of each active substance, safener or synergist which it contains;

(e) the classification, risk and safety phrases in accordance to Directive 1999/45/EC and to the Regulation referred to in Article 65;

(f) the use or uses for which it is authorised;

(g) the reasons for withdrawal of an authorisation if they are related to safety concerns;

(h) the list of minor uses referred to in Article 51(8).

2. The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

3. In accordance with the regulatory procedure referred to in Article 79(3), an authorisation information system may be set up to facilitate the application of paragraphs 1 and 2 of this Article.

CHAPTER IV

ADJUVANTS

Article 58

Placing on the market and use of adjuvants

1. An adjuvant shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with the conditions established in the Regulation referred to in paragraph 2.

2. Detailed rules for the authorisation of adjuvants, including data requirements, notification, evaluation, assessment and decision making procedures shall be set out in a Regulation to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

3. Article 81(3) shall apply.

CHAPTER V

DATA PROTECTION AND DATA SHARING[1]

Article 59

Data protection

1. Test and study reports shall benefit from data protection under the conditions laid down in this Article.

The protection shall apply to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were:

(a) necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and

(b) certified as compliant with the principles of good laboratory practice or of good experimental practice.

Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80.

[1] *see* Guidance Doc. SANCO/12576/2012 Rev. 1.1 of 01.02.2013

The period of data protection is 10 years starting at the date of first authorisation in that Member State, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47.

Those periods shall be extended by 3 months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years.

The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).

A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*.

2. Paragraph 1 shall not apply:

(a) to test and study reports for which the applicant has submitted a letter of access; or

(b) where any period of data protection granted for the test and study reports concerned in relation to another plant protection product has expired.

3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired.

Article 60

List of test and study reports[1]

1. For each active substance, safener and synergist and adjuvant, rapporteur Member States shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the Member States and the Commission.

2. For each plant protection product which they authorise, Member States shall keep and make available to any interested party upon request:

(a) a list of the test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation; and

(b) a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.

3. The lists provided for in paragraphs 1 and 2 shall include information on whether those test and study reports were certified as compliant with the principles of good laboratory practice or of good experimental practice.

Article 61

General rules on avoidance of duplicative testing

1. In order to avoid duplicative testing, any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, consult the information referred to in Article 57 to ascertain if and to whom an authorisation has already been granted for a plant protection product containing the same active substance, safener or synergist or for an adjuvant. The competent authority shall on request from the prospective applicant provide him with the list of test and study reports prepared in accordance with Article 60 for that product.

The prospective applicant shall submit all data regarding the identity and impurities of the active substance he proposes to use. The enquiry shall be supported by evidence that the prospective applicant intends to apply for an authorisation.

2. The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, or the renewal or review thereof, shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.

3. The prospective applicant for the authorisation, or the renewal or review thereof, and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 59, in a fair, transparent and non- discriminatory way.

[1] *see* Guidance Doc. SANCO/12580/2012 Rev. 3.1 of 17.05.2013

Article 62

Sharing of tests and studies involving vertebrate animals

1. Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.

2. Member States shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods described in Annex II to Directive 1999/45/EC could reasonably have been used, in support of applications for authorisations. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

3. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

4. Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist, or of adjuvants cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the prospective applicant shall inform the competent authority of the Member State referred to in Article 61(1).

The failure to reach agreement, as provided in paragraph 3, shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.

5. By 14 December 2016, the Commission shall report on the effects of the provisions in this Regulation concerning data protection of tests and studies involving vertebrate animals. The Commission shall submit this report to the European Parliament and the Council accompanied, if necessary, by an appropriate legislative proposal.

6. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The competent authority of the Member State may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law. Otherwise the parties may resolve the matter through litigation in the courts of the Member States. Awards from arbitration or litigation shall have regard to the principles determined in paragraph 3 and shall be enforceable in the courts of the Member States.

CHAPTER VI

PUBLIC ACCESS TO INFORMATION

Article 63

Confidentiality

1. A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

(a) the method of manufacture;

(b) the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or ally relevant;

(c) results of production batches of the active substance including impurities;

(d) methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or ally relevant;

(e) links between a producer or importer and the applicant or the authorisation holder;

(f) information on the complete composition of a plant protection product;

(g) names and addresses of persons involved in testing on vertebrate animals.

3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information [1].

[1] OJ L 41, 14.2.2003, p. 26.

CHAPTER VII

PACKAGING, LABELLING AND ADVERTISING OF PLANT PROTECTION PRODUCTS AND ADJUVANTS

Article 64

Packaging and presentation

1. Plant protection products and adjuvants that may be mistaken for food, drink or feed shall be packaged in such a way as to minimise the likelihood of such a mistake being made.

2. Plant protection products and adjuvants available to the general public that may be mistaken for food, drink or feed shall contain components to discourage or prevent their consumption.

3. Article 9 of Directive 1999/45/EC shall also apply to plant protection products and adjuvants not covered by that Directive.

Article 65

Labelling

1. The labelling of plant protection products shall include the classification, labelling and packaging requirements of Directive 1999/45/EC and shall comply with the requirements set out in a Regulation adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

That Regulation shall also contain standard phrases for special risks and safety precautions which supplement the phrases provided for by Directive 1999/45/EC. It shall incorporate the text of Article 16 of and the text of the Annexes IV and V to Directive 91/414/EEC with any necessary modifications.

2. Member States may require samples or mock-ups of the packaging and drafts of labels and leaflets to be submitted before the authorisation is granted.

3. Where a Member State considers that additional phrases are necessary to protect human or animal health or the environment, it shall notify the other Member States and the Commission forthwith and shall forward the additional phrase or phrases and the reasons for these requirements.

Such phrases shall be considered for inclusion in the Regulation referred to in paragraph 1.

Pending that inclusion, the Member State may require the use of the additional phrase or phrases.

Article 66

Advertising

1. Plant protection products which are not authorised shall not be advertised. Every advertisement for a plant protection product shall be accompanied by the sentences 'Use plant protection products safely. Always read the label and product information before use'. These sentences shall be easily legible and clearly distinguishable in relation to the whole advertisement. The words 'plant protection products' may be replaced by a more precise description of the product-type, such as fungicide, insecticide or herbicide.

2. The advertisement shall not include information in text or graphic form which could be misleading as regards possible risks to human or animal health or to the environment, such as the terms 'low risk', 'non-toxic' or 'harmless'.

Only in the case of low-risk plant protection products shall the term 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009' be allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product.

3. Member States may prohibit or restrict the advertising of plant protection products in certain media, subject to Community law.

4. All statements used in advertising shall be technically justifiable.

5. Advertisements shall not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, nor any use near food or use by or in the vicinity of children.

6. Advertising or promotional material shall draw attention to the appropriate warning phrases and symbols as laid down in the labelling.

CHAPTER VIII

CONTROLS

Article 67

Record-keeping

1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application,

the area and the crop where the plant protection product was used.

They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the competent authority.

The competent authorities shall provide access to such information in accordance with applicable national or Community law.

By 14 December 2012, the Commission shall present a report to the European Parliament and the Council on the costs and benefits of the traceability of information from users to retailers concerning the applications of plant protection products on agricultural products, accompanied, if necessary, by appropriate legislative proposals.

2. Producers of plant protection products shall undertake post-authorisation monitoring on the request of the competent authorities. They shall notify the competent authorities of the relevant results.

3. Authorisation holders shall provide the competent authorities of the Member States with all data relating to the volume of sales of plant protection products in accordance with Community legislation concerning statistics on plant protection products.

4. Implementing measures to ensure the uniform application of paragraphs 1, 2 and 3 may be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 68

Monitoring and controls[1]

Current text (to be deleted):

Member States shall carry out official controls in order to enforce compliance with this Regulation. They shall finalise and transmit to the Commission a report on the scope and the results of these controls within six months of the end of the year to which the reports relate.

Commission experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States.

A Regulation [2], adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4), shall set out provisions for the controls, in particular on the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products. It shall also contain provisions concerning the collection of information and reporting on suspected poisonings.

Proposed new text:

Member States shall finalise and submit to the Commission by 30 June each year a report on the scope and the results of the official controls performed in order to verify compliance with this Regulation.

CHAPTER IX

EMERGENCIES

Article 69

Emergency measures

Where it is clear that an approved active substance, safener, synergist or co-formulant or a plant protection product which has been authorised in accordance with this Regulation is likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, measures to restrict or prohibit the use and/or sale of that substance or product shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3), either at the own initiative of the Commission or at the request of a Member State. Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

Article 70

Emergency measures in cases of extreme urgency

By way of derogation from Article 69, the Commission may in cases of extreme urgency provisionally adopt emergency measures after consulting the Member State or Member States concerned and informing the other Member States.

As soon as possible, and at the latest after 10 working days, those measures shall be confirmed, amended, revoked or extended in accordance with the regulatory procedure referred to in Article 79(3).

[1] EDITOR's NOTE: A Commission proposal for a new Regulation (COM) 2013 265 is currently going through the co-decision process. This package of measures, the "Official Controls Regulation", intends to "*provide a modernised and simplified, more risk-based approach to the protection of health and more efficient control tools to ensure the effective application of the rules guiding the operation of the food chain.*" and covers a wide range of EU laws, including 1107.

[2] The proposed new Official Controls Regulation (OCR) allows for the creation of specific implementing measures, such as the Regulation mentioned here. However, the OCR may in itself provide sufficient measures and may not necessitate an additional Regulation specific to pesticides.

Article 71

Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and no action has been taken in accordance with Article 69 or 70, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 30 working days, the Commission shall put the matter before the Committee referred to in Article 79(1) in accordance with the regulatory procedure referred to in Article 79(3) with a view to the extension, amendment or repeal of the national interim protective measure.

3. The Member State may maintain its national interim protective measures until Community measures have been adopted.

CHAPTER X

ADMINISTRATIVE AND FINANCIAL PROVISIONS

Article 72

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall notify those rules and any subsequent amendment to the Commission without delay.

Article 73

Civil and criminal liability

The granting of authorisation and any other measures in conformity with this Regulation shall be without prejudice to general civil and criminal liability in the Member States of the producer and, where applicable, of the person responsible for placing the plant protection product on the market or using it.

Article 74

Fees and charges

1. Member States may recover the costs associated with any work they carry out within the scope of this Regulation, by means of fees or charges.

2. Member States shall ensure that the fees or charges referred to in paragraph 1:

(a) are established in a transparent manner; and

(b) correspond to the actual total cost of the work involved except if it is in public interest to lower the fees or charges.

The fees or charges may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

Article 75

Competent authority

1. Each Member State shall designate a competent authority or authorities to carry out the obligations of the Member States laid down in this Regulation.

2. Each Member State shall designate a coordinating national authority to coordinate and ensure all the necessary contacts with applicants, other Member States, the Commission and the Authority.

3. Member States shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively.

4. Each Member State shall give the details concerning its national competent authority or authorities to the Commission, the Authority and the coordinating national authorities of the other Member States and inform them of any modifications thereof.

5. The Commission shall publish and keep updated on its website a list of the authorities referred to in paragraphs 1 and 2.

Article 76

Expenditure by the Commission

[This article is deleted through Art. 53 of Regulation (EU) 652/2014 of the European Parliament and of the Council of 15 May 2014, laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material (…)[1]]

Article 77

Guidance documents

The Commission may, in accordance with the advisory procedure referred to in Article 79(2), adopt or amend technical and other guidance documents such as explanatory notes or guidance documents on the content

[1] OJ L 189, 27.6.2014, p.1

of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.

Article 78

Amendments and implementing measures

1. The following measures designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4):

(a) amendments to the Annexes, taking into account current scientific and technical knowledge;

(b) amendments to the Regulations on data requirements for active substances and for plant protection products, as referred to in points (b) and (c) of Article 8(1), taking into account current scientific and technical knowledge;

(c) amendments to the Regulation on uniform principles for evaluation and authorisation of plant protection products, as referred to in Article 29(6), taking into account current scientific and technical knowledge;

(d) a Regulation postponing the expiry of the approval period referred to in the second subparagraph of Article 17;

(e) a Regulation on data requirements for safeners and synergists referred to in Article 25(3);

(f) a Regulation establishing a work programme for safeners and synergists referred to in Article 26;

(g) adoption of the harmonised methods referred to in Article 29(4);

(h) inclusion of co-formulants in Annex III, as referred to in Article 27(2);

(i) extension of the date of application of this Regulation to provisional authorisations, as referred to in Article 30(3);

(j) information requirements for parallel trade, as referred to in Article 52(4);

(k) rules for the application of Article 54, in particular the maximum quantities of plant protection products to be released;

(l) detailed rules for adjuvants, as referred to in Article 58(2);

(m) a Regulation containing the requirements of the labelling of plant protection products, as referred to in Article 65(1);

(n) a Regulation on controls, as referred to in the third subparagraph of Article 68.

2. Any further measures necessary for the implementation of this Regulation may be adopted in accordance with the regulatory procedure referred to in Article 79(3).

3. In accordance with the advisory procedure referred to in Article 79(2), a Regulation shall be adopted containing the list of active substances included in Annex I to Directive 91/414/EEC. Those substances shall be deemed to have been approved under this Regulation.

Article 79

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health[1], as established by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits laid down in Article 5a(3)(c) and (4)(b) and (c) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

[1] Now: Standing Committee on Plants, Animals, Food and Feed (PAFF Committee)

CHAPTER XI

TRANSITIONAL AND FINAL PROVISIONS

Article 80

Transitional measures

1. Directive 91/414/EEC shall continue to apply, with respect to the procedure and the conditions for approval[1]:

(a) to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011;

(b) to active substances listed in Annex I to Regulation (EC) No 737/2007 [2];

(c) to active substances for which completeness has been established in accordance with Article 16 of Regulation (EC) No 33/2008 [3];

(d) to active substances for which completeness has been established in accordance with Article 6 of Regulation (EC) No 33/2008 before 14 June 2011.

On the basis of the examination carried out under Directive 91/414/EEC, a Regulation on the approval of such a substance shall be adopted in accordance with Article 13(2) of this Regulation. For active substances referred to in point (b) of this paragraph that approval shall not be considered as the renewal of approval referred to in Article 14 of this Regulation.

2. Article 13(1) to (4) and Annexes II and III to Directive 91/414/EEC shall continue to apply with respect to active substances included in Annex I to that Directive and to active substances approved in accordance with paragraph 1 of this Article:

(a) for a period of five years from the date of their inclusion or approval, for active substances covered by Article 8(2) of Directive 91/414/EEC[4];

(b) for a period of 10 years from the date of their inclusion or approval, for active substances which were not on the market on 26 July 1993;

(c) for a period of five years from the date of the renewal of the inclusion or renewal of the approval, for active substances whose inclusion in Annex I to Directive 91/414/EEC expires by 24 November 2011. This provision shall only apply to data necessary for the renewal of the approval and which were certified as compliant with the principles of good laboratory practice by that date.

3. Where Article 13 of Directive 91/414/EEC applies by virtue of paragraph 1 or paragraph 2 of this Article, it shall be subject to any special rules concerning Directive 91/414/EEC laid down in the Act of Accession by which a Member State joined the Community.

4. For active substances for which the first approval expires by 14 December 2012[5], the application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than two years before the expiry of the first approval.

5. Applications for authorisations of plant protection products:[6]

(a) under Article 4 of Directive 91/414/EEC which are pending in the Member States; or

(b) which are due to be amended or withdrawn following an inclusion in Annex I to Directive 91/414/EEC or following an approval in accordance with paragraph 1 of this Article;

on 14 June 2011 shall be decided on the basis of national law in force before that date.[7]

After that decision, this Regulation shall apply.

6. Products labelled in accordance with Article 16 of Directive 91/414/EEC may continue to be placed on the market until 14 June 2015.

7. By 14 December 2013, the Commission shall establish a list of substances included in Annex I to Directive 91/414/EEC which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply.

Article 81

Derogation for safeners and synergists, co-formulants and adjuvants

1. By way of derogation from Article 28(1), a Member State may, for a period of 5 years following the adoption of the programme referred to in Article 26, authorise the placing on the market in its territory of plant protection products containing safeners and synergists, which have not been approved, where they are included in that programme.

[1] *See* Guidance doc. SANCO/11509/2013 Rev.3 of 12.12.2014
[2] OJ L 169, 29.6.2007, p. 10.
[3] OJ L 15, 18.1.2008, p. 5.
[4] so-called "existing substances"
[5] *see* Guidance Doc. SANCO/10387/2010 Rev.8 of 28.10.2010
[6] *see* Guidance Doc. SANCO/10796/2003 Rev.12.2 15 July 2011
[7] *see* Guidance Doc. SANCO/6896/2009 Rev.1 of 2.10.2009

2. By way of derogation from Article 27 and without prejudice to Community law, Member States may apply national provisions for co-formulants not included in Annex III until 14 June 2016.

Where, after 14 June 2016, a Member State has serious grounds for considering that a co-formulant not included in Annex III is likely to constitute a serious risk to human or animal health or the environment, it may temporarily prohibit or restrict the application of a co-formulant in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision. Article 71 shall apply.

3. By way of derogation from Article 58(1) Member States may apply national provisions for authorisation of adjuvants until the adoption of detailed rules referred to in Article 58(2).

Article 82

Review clause

By 14 December 2014, the Commission shall present a report[1] to the European Parliament and the Council on the functioning of mutual recognition of authorisations and in particular on the application by the Member States of the provisions referred to in Article 36(3) and Article 50(2), the division of the Community into three zones and on the application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

Article 83

Repeal

Without prejudice to Article 80, Directives 79/117/EEC and 91/414/EEC, as amended by the acts listed in Annex V, are repealed with effect from 14 June 2011, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in that Annex.

References to the repealed Directives shall be construed as references to this Regulation. In particular, references in other Community legislation, such as Regulation (EC) No 1782/2003, to Article 3 of Directive 91/414/EEC shall be construed as references to Article 55 of this Regulation.

Article 84

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

By 14 June 2011, the Commission shall adopt the following:

(a) a Regulation containing the list of the active substances already approved at the moment of adoption of that Regulation;

(b) a Regulation on data requirements for active substances, as referred to in Article 8(1)(b);

(c) a Regulation on data requirements for plant protection products, as referred to in Article 8(1)(c);

(d) a Regulation on uniform principles for risk assessment for plant protection products, as referred to in Article 36;

(e) a Regulation containing the requirements of the labelling of plant protection products, as referred to in Article 65(1).

This Regulation shall apply from 14 June 2011.

[1] Editor's note: publication of this report is postponed. Presentation is expected in 2016.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 21 October 2009

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	C. MALMSTRÖM

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, Croatia[1], Italy, Cyprus, Malta, Portugal

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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

[1] "Croatia" was added by Council Regulation (EU) No 518/2013 of 13 May 2013, L 158, 10.6.2013, p. 72.

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)[1] and Acute Reference Dose[2] (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;

[1] *See* Guidance Document SANCO 7531 Rev.10
[2] *See* Guidance Document 7199/VI/99 rev.5

(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[1] and ARfD[2] 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.

[1] *See* Guidance Document SANCO 7531 Rev.10
[2] *See* Guidance Document 7199/VI/99 rev.5

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[1], 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.

[1] Editor's note: the drafting of these measures is delayed. At time of press (March 2015) no draft is presented yet.

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
- al 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.

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ANNEX III

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

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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 12
Directive 2007/21/EC	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	—

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