FUTURE AVAILABILITY OF PESTICIDES IN THE INTEGRATED PEST MANAGEMENT AGRICULTURAL PROGRAMME IN ITALY IN ACCORDANCE WITH THE APPLICATION OF THE NEW EUROPEAN REGULATION NO.1107/2009 CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET: IMPACT OF THE APPLICATION OF CUT-OFF CRITERIA AND SELECTION CRITERIA FOR SUBSTANCES THAT ARE CANDIDATE FOR SUBSTITUTION

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Riassunto

ENEA - UTAGRI-ECO (Lab. Gestione Sostenibile degli Agro-Ecosistemi), in collaborazione con il Servizio Fitosanitario della regione Emilia-Romagna ed il contributo di EUROPASS, ha realizzato uno studio al fine di individuare le criticità, a livello di disponibilità di sostanze attive fitosanitarie per la difesa delle colture, a valle dell'applicazione del Regolamento europeo n.1107/2009 sull'immissione in commercio dei prodotti fitosanitari.

Sulla base delle informazioni riportate nei report prodotti a livello comunitario e dall'EFSA, in sede di revisione europea delle sostanze fitosanitarie, sono state valutate 200 sostanze attive, individuate tra quelle di interesse prioritario nel campo della difesa agronomica.

Lo studio ha consentito, all'attuale stato di conoscenze scientifiche, l'individuazione delle sostanze attive che intercettano i criteri di "cut-off" o di "sostanze candidate alla sostituzione" ed ha permesso la stima delle possibili ricadute sulla produzione agricola.

Tra le sostanze diserbanti valutate circa il 11,4% incontrano i criteri di cut-off, mentre, per quanto riguarda i fungicidi e gli insetticidi, il 9,5% ed il 4% rispettivamente.

Un numero maggiore di sostanze incontrano i criteri che le definiscono "sostanze candidate alla sostituzione": in particolare il 24,5% degli insetticidi valutati, il 15,9% dei fungicidi ed il 8% dei diserbanti.

In generale 82 sono le sostanze attive che incontrano o potrebbero incontrare i criteri di cut-off o di candidate alla sostituzione (30 diserbanti, 27 fungicidi e 25 insetticidi).

Va, comunque, evidenziato che, al momento, permangono degli importanti margini di soggettività nella scelta dei dati da utilizzare per i parametri interessati dai criteri di cut-off e di individuazione delle sostanze candidate alla sostituzione.

Alla luce di queste importanti criticità, che potrebbero essere determinanti nel processo di valutazione delle sostanze attive sottoposte all'iter autorizzativo per l'immissione in commercio, è auspicabile che al più presto vengano definiti criteri europei e nazionali univoci per una corretta applicazione del regolamento.

Parole chiave: pesticidi, fitofarmaci, regolamento 1107/2009, cut-off criteri, candidato per i criteri di sostituzione

Abstract

ENEA – UTAGRI-ECO (Lab. Sustainable Management of the Agro-Ecosystems), with the Emilia-Romagna Phytosanitary Service and EUROPASS contributions conducted a study in order to discover the availability of active substances for defence strategy programmes once the European regulation no. 1107/2009 for the placing of plant protection products on the market has been applied.

Based on the information in the EU and EFSA reports, 200 active substances have been analyzed from those that are of priority interest in agronomical defense strategy.

Taking current scientific knowledge into account, the study has allowed us to identify the active substances that meet the cut-off criteria or are candidate for substitution and also permitted us to estimate the possible consequences on agricultural production.

Amongst the herbicides that we analyzed, about 11.4% fell into the cut-off group whilst for the fungicides and insecticides they were 9.5% and 4% respectively.

A greater number of substances meet the criteria of substances that are candidate for substitution, in particular 24.5% of the insecticides that we analyzed, 15.9% for fungicides and 8% for herbicides.

In general there were 82 active substances that will meet or probably meet the cut-off or candidate for substitution criteria (30 herbicides, 27 fungicides and 25 insecticides).

We would like to underline, however, that currently, there are significant margins of subjectivity in the choices made for using data for the cut-off and candidate for substitution parameters.

Given these important critical points that will be decisive in the evaluation process of active substances that will be subject to the authorization process before being released onto the market, we would hope that at European and national level, the criteria will be established soonest in order to see correct application of the regulations.

keywords: pesticides, plant protection product, regulation 1107/2009, cut-off criteria, candidate for substitution criteria

keywords: *pesticides, plant protection product, regulation 1107/2009, cut-off criteria, candidate for substitution criteria*

Introduction

September 14, 2009 saw the EC regulation no.1107/2009 of the European Parliament and Council concerning the placing of plant protection products on the market ***(1)*** come into effect, this repealed Council Directives 79/117/EEC (prohibiting both the placing on the market and use of plant protection products containing certain active substances) ***(2)*** and 91/414/EEC (concerning the placing of plant protection products on the market) ***(3)***. The application of the regulation is for June 14, 2011 and by that date, Annex 1 of Council Directive 91/414/EEC where authorized active substances for agricultural use are included, will be transferred to the new regulation.

Amongst the innovations that are contained in the new European regulation, there is the introduction of cut-off criteria which exclude, a priori, active substances that have been identified as dangerous to human health, animal organisms and the environment. These are listed in annex II, chapter 3, points 3.6 - 3.10 of the same regulation.

Furthermore, active substances that possess dangerous, intrinsic characteristics that arouse concerns will be identified as "candidate for substitution," and chapter 3, point 4 of Annex II of the regulation lists the criteria for defining the typology of such substances. These substances will be approved for a period of not more than 7 years with renewable approval for periods that should not exceed 7 years. The plant protection products (PPPs) that contain such active substances shall be subjected to a procedure of "comparative evaluation" that must show availability, in the market, of similar products or alternative non-chemical methods that have a toxicological and ecotoxicological profile that are more favorable. The repeal or limitation will be enacted 3 years after the decision.

This new normative overview will be integrated into legislation that, in March 2009, saw the conclusion of the European programme to revise all pesticides that were on the market in 1993, this was in accordance with the 91/414/EEC directive. The revision covered about 1,000 substances and subsequently, around 750 were excluded from trade in Europe.

It is estimated in Italy that about 200 pesticides have been repealed. Amongst these substances a relevant number were widespread (e.g. organophosphates), this particular substitution created some problems which required redefinition of defensive crop strategies**.**

However, the real impact of the European revision regarding the availability of PPPs will be evaluated only when the re-registration process of the formulates that contain the active substance included in Annex I of the 91/414 directive are completed.

In this overview, the important directions as laid down by the new regulation 1107/2009 have been inserted and concern the placing of plant protection products onto the market that could, in the future, lead to the exclusion from sale of other active substances that are currently included in

Annex I.

The process states that currently authorized substances should be re-evaluated in the light of new cut-off criteria and selection of substances that are candidate for substitution only at the moment of the deadline of their commercial authorization. Thus, only in future years will we be able to quantify the effective availability of active substances.

This uncertain situation also creates relevant critical dynamics in the planning and updating offices of the Integrated Management Norms (IMNs) at a regional level. The strategies of Integrated Pest Management are laid down in the IMNs, and the agricultural firms who adhere to the producer organizations have to abide by these. They represent the methods of production that form both the basis of promotional activity and evaluation of quality of the majority of regional fruit and vegetable production.

The present study is, therefore, based on this context. It aims to evaluate the impact of the criteria that are laid down in the new European directive (cut-off criteria and selection of substances that will be candidate for substitution in the future) on the future availability of active substances. It also has to respond to the requests for information that come from producer organizations who feel that they will not be sufficiently well prepared to face the effects that the new European norms will demand regarding IMNs.

The results of the study can be used to the advantage of regional production in imposing production guidelines and Integrating Pest Management (IPM) in the near future. They will also be used to guide research and experiments in pesticide defense strategies.

Materials and methods

In order to evaluate the impact of the European norm (cut-off criteria and future candidate for substitution) on the availability of pesticides in IPM strategies, 200 substances as indicated by the Phytosanitary Service of the Emilia-Romagna region (Italy) were tested as priority interest for phytoiatric defense in crops. Table 1 shows the list of the 200 active substances, sub-divided by use category.

Table. 1 – List of active substances covered in the study and use areas.

Herbicides = no.88		
2,4-D	Ethoxysulfuron	Napropamide
2,4-DB	Fenoxaprop-P	Nicosulfuron
Acetochlor**	Flazasulfuron	Oxadiargyl
Aclonifen	Florasulam	Oxadiazon
Amidosulfuron	Fluazifop-p-butyl*	Oxasulfuron
Asulam*	Flufenacet	Oxyfluorfen**
Azimsulfuron	Flurochloridone	Pendimethalin
Benfluralin	Fluroxypyr	Penoxsulam
Bensulfuron	Foramsulfuron	Pethoxamid
Bentazone	Glufosinate ammonium	Phenmedipham
Bifenox	Glyphosate	Pinoxaden**
Bispyribac sodium	Imazamox	Profoxydim
Bromoxynil	Imazosulfuron	Propaquizafop
Carfentrazone-ethyl	Iodosulfuron-methyl-sodium	Propyzamide
Chloridazon	Ioxynil	Prosulfuron
Chlorotoluron	Isoproturon	Pyridate
Chlorsulfuron	Isoxaben	Quizalofop-P-ethyl
Clethodim	Isoxaflutole	Rimsulfuron
Clodinafop	Lenacil	S-Metolachlor
Clomazone	Linuron	Sulcotrione
Clopyralid	MCPA	Tepraloxydim
Cycloxydim	Mecoprop	Terbuthylazine**
Cyhalofop-butyl	Mecoprop-P	Thifensulfuron-methyl
Desmedipham	Mesosulfuron	Thiobencarb*
Dicamba	Mesotrione	Tralkoxydim
Diclofop methyl	Metamitron	Triasulfuron
Diflufenican	Metosulam	Tribenuron
Dimethachlor	Metribuzin	Triclopyr
Dimethenamid-P	Metsulfuron-methyl	
Diquat	Molinate	
Fungicides = no.63		
Benalaxyl	Fenpropidin	Penconazole
Benalaxyl-M**	Fenpropimorph	Pencycuron
Benthiavalicarb isopropyl	Fluazinam	Propamocarb
Bitertanol**	Fludioxonil	Propiconazole
Boscalid	Fluopicolide	Propineb
Bupirimate	Folpet	Proquinazid
Captan	Fosetyl alluminium	Prothioconazole
Chlorothalonil	Iprodione	Pyraclostrobin
Cyazofamid	Iprovalicarb	Pyrimethanil
Cymoxanil	Kresoxim-methyl	Quinoxyfen
Cyproconazole	Mancozeb	Spiroxamine
Cyprodinil	Mandipropamid**	Tebuconazole
Difenoconazole	Maneb	Tetraconazole
Dimethomorph	Mepanipyrim	Thiabendazole
Dithianon	Meptyldinocap**	Thiofanate-methyl
Dodine	Metalaxyl	Thiram

Epoxiconazole	Metalaxyl-M	Tolclofos-methyl
Famoxadone	Metconazole	Triadimenol
Fenamidone	Metiram	Trifloxystrobin
Fenbuconazole	Metrafenone	Ziram
Fenhexamid	Myclobutanil	Zoxamide
Insecticides/Acaricides = no.49		
Abamectin	Fenamiphos	Oxamyl
Acetamiprid	Fenazaquin	Phosmet
Acrinathrin*	Fenbutatin oxide	Pirimicarb
Alphamethrin	Fenpyroximate	Propargite**
Chlorpyrifos	Fipronil	Pymetrozine
Chlorpyrifos methyl	Flonicamid	Pyridaben
Cipermetrina	Flufenoxuron**	Pyriproxyfen
Clofentezine	Fosthiazate	Spinosad
Clothianidin	Hexythiazox	Spirodiclofen
Cyfluthrin	Imidacloprid	tau-Fluvalinate
Cyromazine	Indoxacarb	Tebufenozide
Deltamethrin	lambda-Cyhalothrin	Tebufenpyrad
Diflubenzuron	Methiocarb	Tefluthrin**
Dimethoate	Methoxyfenozide	Thiacloprid
Ethoprophos	Milbemectin	Thiamethoxam
Etofenprox	Novaluron***	zeta-Cypermethrin
Etoxazole		

*substances with voluntary withdrawal from sale (withdrawal authorization by December 2010, sale prohibition from August 2011, use prohibition from December 2011) – Commission Decision 2008/934/EC
** substance pending

The toxicological, ecotoxicological, chemical-physical and environment persistence data come from Review Reports and from Draft Assessment Reports on active substances that are to be found on the European Commission site in the section "Plant Protection Products - EU Pesticides database of "The European Commission Directorate-General for Health and Consumers (DG Sanco)." (http://ec.europa.eu/sanco_pesticides/public/index.cfm).
The information on the active substances Profoxydim, Fenhexamid and Benalaxyl-M was found on the European database PPDB-FOOTPRINT (http://sitem.herts.ac.uk/aeru/footprint/en/index.htm), whilst the data on Thiacloprid were found on the INRA database AGRITOX (http://www.dive.afssa.fr/agritox/php/fiches.php).

The references for each substance in table 1 are reported in table 2. The nomination of risk to humans that are allocated to each active substance were taken from the EU Pesticides Database and technical progress from the Directive 67/548/EEC, particularly 25° (from 1998), 26° (from 2000), 28° (from 2001), 29° (from 2004), 30° (from 2008) and 31° (from 2009) (***4-5-6-7-8-9-10-11***).
The information on Endocrine Disrupting Chemicals (EDCs) was taken from the European

Commission site in the named section, see links:

http://ec.europa.eu/environment/endocrine/documents/index_en.htm

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list

The data come from the European Commission DG ENV reports, "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption (2000)" ***(12)***, "Endocrine Disrupters- Study on gathering information on 435 substances with insufficient data (2002)" ***(13)***, "Study on enhancing the endocrine disrupting priority list with a focus on low production volume chemicals (2007)" ***(14)***.

The information on neurotoxic effects in humans was taken from a recent study review by University of Southern Denmark (DE) and Harvard School of Public Health (USA) ***(15).***

Table.2 – References for each single active substance.

Herbicides	Reference Data	Regulations
2,4-D	EU Review Report (2001), 7599/VI/97- final	ATP 28°
2,4-DB	EU Review Report (2002), 7601/VI/97- final	ATP28°
Acetochlor	EFSA Journal (2011)	ATP 25°
Aclonifen	EFSA Scientific Report (2008)	NoATP
Amidosulfuron	EFSA Scientific Report (2008)	NoATP
Asulam	EFSA Journal (2010)	NoATP
Azimsulfuron	EFSA Journal (2010)	ATP 30°
Benfluralin	EFSA Scientific Report (2008)	NoATP
Bensulfuron	EFSA Scientific Report (2008)	NoATP
Bentazone	EU Review Report (2000), 7585/VI/97- final	ATP 25°
Bifenox	EFSA Scientific Report (2007)	NoATP
Bispyribac sodium	EFSA Journal (2010)	NoATP
Bromoxynil	EU Review Report (2004), SANCO/4347/2000- final	ATP 29° rev
Carfentrazone-ethyl	EU Review Report (2003), 7473/VI/99- final	ATP 28°
Chloridazon	EFSA Scientific Report (2007)	ATP 26°
Chlorotoluron	EU Review Report (2005), SANCO/4329/2000- final	ATP 29° rev
Chlorsulfuron	EFSA Scientific Report (2008)	NoATP
Clethodim	EFSA Journal (2010)	NoATP
Clodinafop	EFSA Scientific Report (2005)	ATP 31°
Clomazone	EFSA Scientific Report (2007)	NoATP
Clopyralid	EFSA Scientific Report (2005)	ATP 31°
Cycloxydim	EFSA Journal (2010)	NoATP
Cyhalofop-butyl	EU Review Report (2002), 6500/VI/99- final	NoATP
Desmedipham	EU Review Report (2004), SANCO/4061/2001-final	ATP 29° rev
Dicamba	EFSA Journal (2011)	ATP 28°
Diclofop methyl	EFSA Journal (2010)	ATP 25°
Diflufenican	EFSA Scientific Report (2007)	Rec.ATP29°
Dimethachlor	EFSA Scientific Report (2008)	Rec.ATP29°
Dimethenamid-P	EU Review Report (2003), SANCO/1402/2001-final	NoATP
Diquat	EU Review Report (2001), 1688/VI/97	ATP 25°
Ethoxysulfuron	EU Review Report (2002), 7461/VI/98-final	ATP 28°

Fenoxaprop-P	EFSA Scientific Report (2007)	NoATP
Flazasulfuron	EU Review Report (2003), SANCO/3051/99-final	ATP 28°
Florasulam	EU Review Report (2002), SANCO/1406/2001-final	ATP 29° rev
Fluazifop-p-butyl	EFSA Journal (2010)	ATP 28°
Flufenacet	EU Review Report (2003), 7469/VI/98-final	ATP 30°
Flurochloridone	EFSA Journal (2010)	NoATP
Fluroxypyr	EU Review Report (1999), 6848/VI/98	ATP 26°
Foramsulfuron	EU Review Report (2002), SANCO/10324/2002-final	NoATP
Glufosinate ammonium	EFSA Scientific Report (2005), Conclusions	ATP 31°
Glyphosate	EU Review Report (2002), 6511/VI/99	ATP 28°
Imazamox	EU Review Report (2002), SANCO/4325/2000-final	ATP 29° rev
Imazosulfuron	EU Review Report (2004), 7457/VI/98- rev.6	NoATP
Iodosulfuron-methyl-sodium	EU Review Report (2003), SANCO/10166/2003-final	ATP 29° rev
Ioxynil	EU Review Report (2004), SANCO/4349/2000-final	ATP 29° rev
Isoproturon	EU Review Report (2002), SANCO/3045/99-final	ATP 29° rev
Isoxaben	EFSA Journal (2010)	NoATP
Isoxaflutole	EU Review Report (2003), SANCO/3136/99-final	ATP 28°
Lenacil	EFSA Journal (2009)	NoATP
Linuron	EU Review Report (2002), 7595/VI/97-final	ATP 29° rev
MCPA	EU Review Report (2008), SANCO/4062/2001	ATP 31°
Mecoprop	EU Review Report (2003), SANCO/3063/99-final	ATP 29° rev
Mecoprop-P	EU Review Report (2003), SANCO/3065/99-final	ATP 29° rev
Mesosulfuron	EU Review Report (2004), SANCO/10298/2003-final	NoATP
Mesotrione	EU Review Report (2003), SANCo/1416/2001-final	ATP 29° rev
Metamitron	EFSA Scientific Report (2008)	ATP 29°
Metosulam	EFSA Journal (2010)	NoATP
Metribuzin	EFSA Scientific Report (2006)	ATP 30°
Metsulfuron-methyl	EU Review Report (2000), 7593/VI/97-final	ATP 30°
Molinate	EU Review Report (2003), SANCO/3047/99-final	ATP 29° rev
Napropamide	EFSA Journal (2010)	NoATP
Nicosulfuron	EFSA Scientific Report (2007)	NoATP
Oxadiargyl	EU Review Report (2002), SANCO/3053/99-final	ATP 30°
Oxadiazon	EFSA Journal (2010)	NoATP
Oxasulfuron	EU Review Report (2002), SANCO/4323/2000-final	ATP 29° rev
Oxyfluorfen	EFSA Journal (2010)	NoATP
Pendimethalin	EU Review Report (2003), 7477/VI/98	ATP 28°
Penoxsulam	EFSA Scientific Report (2009)	NoATP
Pethoxamid	EU Review Report (2006), SANCO/10396/2002-final	ATP 30°
Phenmedipham	EU Review Report (2004), SANCO/4060/2001-final	ATP 29° rev
Pinoxaden	Draft Assessment Report (2006)	NoATP
Profoxydim	FOOTPRINT – EU database	ATP 30°
Propaquizafop	EFSA Scientific Report (2008)	NoATP
Propyzamide	EU Review Report (2007), 6502/VI/99	ATP28°
Prosulfuron	EU Review Report (2002), SANCO/3055/99-final	ATP30°
Pyridate	EU Review Report (2001), 7576/VI/97-final	ATP28°
Quizalofop-P-ethyl	EFSA Scientific Report (2008)	NoATP
Rimsulfuron	EFSA Scientific Report (2005)	NoATP

S-Metolachlor	EU Review Report (2004), SANCO/1426/2001- rev.3	ATP 29° rev
Sulcotrione	EFSA Scientific Report (2008)	NoATP
Tepraloxydim	EU Review Report (2004), SANCO/10388/2002-rev.4	ATP30°
Terbuthylazine	EFSA Journal (2011)	NoATP
Thifensulfuron-methyl	EU Review Report (2001), SANCO/7577/VI/97-final	ATP 29° rev
Thiobencarb	Draft Assessment Report (2006)	Rec.ATP 29°
Tralkoxydim	EFSA Scientific Report (2008)	NoATP
Triasulfuron	EU Review Report (2000), 7589/VI/97-final	ATP 26°
Tribenuron	EFSA Scientific Report (2004)	ATP 30°
Triclopyr	EFSA Scientific Report (2005)	NoATP

Fungicides	Reference Data	Regulations
Benalaxyl	EU Review Report (2004), SANCO/4351/2000	ATP 29° rev
Benalaxyl-M	BD-FOOTPRINT	NoATP
Benthiavalicarb isopropyl	EFSA Scientific Report (2007), Conclusions	NoATP
Bitertanol	EFSA Journal (2010)	NoATP
Boscalid	EU Review Report (2008), SANCO/3919/2007	NoATP
Bupirimate	EFSA Journal (2010)	NoATP
Captan	EFSA Journal (2009)	ATP 30°
Chlorothalonil	EU Review Report (2006), SANCO/4343/2000-final	ATP 30°
Cyazofamid	EU Review Report (2002), SANCO/10379/2002	NoATP
Cymoxanil	EFSA Scientific Report (2008), Conclusions	NoATP
Cyproconazole	EFSA Journal (2010)	ATP 26°
Cyprodinil	EFSA Scientific Report (2005), Conclusions	ATP 31°
Difenoconazole	EFSA Journal (2011)	NoATP
Dimethomorph	EFSA Scientific Report (2006), Conclusions	NoATP
Dithianon	EFSA Journal (2010)	ATP 25°
Dodine	EFSA Journal (2010)	Rec. ATP29°
Epoxiconazole	EFSA Scientific Report (2008)	ATP29° rev
Famoxadone	EU Review Report (2002), 6505/VI/99	ATP29° rev
Fenamidone	EU Review Report (2003), SANCO/1404/2001	ATP29° rev
Fenbuconazole	EFSA Journal (2010)	NoATP
Fenhexamid	EU Review Report (2000), 6497/VI/99 + BD-FOOTPRINT	ATP29° rev
Fenpropidin	EFSA Scientific Report (2007)	NoATP
Fenpropimorph	EFSA Scientific Report (2008)	ATP29° rev
Fluazinam	EFSA Scientific Report (2008), Conclusions	NoATP
Fludioxonil	EFSA Scientific Report (2007), Conclusions	NoATP
Fluopicolide	EFSA Scientific Report (2009), Conclusions	NoATP
Folpet	EFSA Scientific Report (2009), Conclusions	ATP 30°
Fosetyl alluminium	EFSA Scientific Report (2005), Conclusions	ATP 30°
Iprodione	EU Review Report (2002), 5036/VI/98	ATP 28°
Iprovalicarb	EU Review Report (2002), SANCO/2034/2000	NoATP
Kresoxim-methyl	EFSA Journal (2010)	ATP 28°
Mancozeb	EU Review Report (2005), SANCO/4058/2001	ATP 31°
Mandipropamid	Draft Assessment Report (2008)	NoATP

Maneb	EU Review Report (2005), SANCO/4057/2001-rev.3.3	ATP 31°
Mepanipyrim	EU Review Report (2004), SANCO/1412/2001	ATP 30°
Meptyldinocap	Draft Assessment Report (2008)	NoATP
Metalaxyl	EU Review Report (2010), SANCO/10476/2010- rev.1	ATP 29° rev
Metalaxyl-M	EU Review Report (2002), SANCO/3037/99-final	ATP 28°
Metconazole	EFSA Scientific Report (2006)	ATP 31°
Metiram	EU Review Report (2005), SANCO/4059/2001	NoATP
Metrafenone	EFSA Scientific Report (2006), Conclusions	NoATP
Myclobutanil	EFSA Journal (2010)	ATP 26°
Penconazole	EFSA Scientific Report (2008), Conclusions	NoATP
Pencycuron	EFSA Journal (2010)	NoATP
Propamocarb	EFSA Scientific Report (2006), Conclusions	NoATP
Propiconazole	EU Review Report (2003), SANCO/3049/99	ATP 29° rev
Propineb	EU Review Report (2003), SANCO/7574/VI/97	ATP 30°
Proquinazid	EFSA Journal (2009), Conclusions	NoATP
Prothioconazole	EFSA Scientific Report (2007)	NoATP
Pyraclostrobin	EU Review Report (2004), SANCO/1420/2001	ATP 30°
Pyrimethanil	EFSA Scientific Report (2006), Conclusions	ATP 31°
Quinoxyfen	EU Review Report (2003), 6781/VI/97	NoATP
Spiroxamine	EFSA Journal (2010)	ATP 25°
Tebuconazole	EFSA Scientific Report (2008), Conclusions	ATP 29°
Tetraconazole	EFSA Scientific Report (2008)	ATP 30°
Thiabendazole	EU Review Report (2001), 7603/VI/97-final	ATP 28°
Thiofanate-methyl	EU Review Report (2005), 5030/VI/98	ATP 28°
Thiram	EU Review Report (2003), 6507/VI/99	ATP 29° rev
Tolclofos-methyl	EFSA Scientific Report (2005)	ATP 30°
Triadimenol	EFSA Scientific Report (2008), Conclusions	NoATP
Trifloxystrobin	EU Review Report (2003), SANCO/4339/2000	ATP 29° rev
Ziram	EU Review Report (2004), 6508/VI/99	ATP 29° rev
Zoxamide	EU Review Report (2004), SANCO/10297/2003-final	ATP 30°

Insecticides and Acaricides	Reference Data	Regulations
Abamectin	EFSA Scientific Report (2008), Conclusions	NoATP
Acetamiprid	EU Review Report (2004), SANCO/1392/2001	ATP 30°
Acrinathrin	EFSA Journal (2010)	NoATP
Alphamethrin	EU Review Report (2004), SANCO/4335/2000	ATP 30°
Chlorpyrifos	EU Review Report (2005), SANCO/3059/99	ATP 29° rev
Chlorpyrifos-methyl	EU Review Report (2005), SANCO/3061/99	ATP 29° rev
Cipermetrina	EU Review Report (2005); SANCO/4333/2000	ATP 29° rev
Clofentezine	EFSA Scientific Report (2009), Conclusions	NoATP
Clothianidin	EU Review Report (2005), SANCO/10533/05	ATP 31°
Cyfluthrin	EU Review Report (2002), 6843/VI/97	ATP 30°
Cyromazine	EFSA Scientific Report (2008)	NoATP
Deltamethrin	EU Review Report (2002), 6504/VI/99	ATP 30°
Diflubenzuron	EFSA Scientific Report (2009), Conclusions	NoATP
Dimethoate	EFSA Scientific Report (2006), Conclusions	Rec.ATP 29°

Ethoprophos	EFSA Scientific Report (2006)	ATP 29° rev
Etofenprox	EFSA Scientific Report (2008), Conclusions	NoATP
Etoxazole	EU Review Report (2004), SANCO/4054/2001	ATP 29° rev
Fenamiphos	EFSA Scientific Report (2006)	ATP 29° rev
Fenazaquin	EFSA Journal (2010)	NoATP
Fenbutatin oxide	EFSA Journal (2010)	NoATP
Fenpyroximate	EFSA Scientific Report (2008)	NoATP
Fipronil	EFSA Scientific Report (2006)	ATP 30°
Flonicamid	EFSA Journal (2010)	NoATP
Flufenoxuron	EFSA Journal (2011)	NoATP
Fosthiazate	EU Review Report (2003), SANCO/10199/2003-final	ATP 28°
Hexythiazox	EFSA Journal (2010)	Rec.ATP 29°
Imidacloprid	EFSA Scientific Report (2008), Conclusions	ATP 31°
Indoxacarb	EU Review Report (2005), SANCO/1408/2001	NoATP
lambda-Cyhalothrin	EU Review Report (2001), 7572/VI/97	ATP 30°
Methiocarb	EFSA Scientific Report (2006)	ATP 26°
Methoxyfenozide	EU Review Report (2004), SANCO/10384/2002	NoATP
Milbemectin	EU Review Report (2005), SANCO/10386/2002	ATP 31°
Novaluron	Draft Assessment Report (2008)	NoATP
Oxamyl	EFSA Scientific Report (2005)	NoATP
Phosmet	EFSA Scientific Report (2006), Conclusions	ATP 29° rev
Pirimicarb	EFSA Scientific Report (2005), Conclusions	ATP 25°
Propargite	EFSA Journal (2011)	ATP 29°
Pymetrozine	EU Review Report (2002), 7455/VI/98	ATP 29° rev
Pyridaben	EFSA Journal (2010)	NoATP
Pyriproxyfen	EFSA Scientific Report (2009), Conclusions	ATP 31°
Spinosad	EU Review Report (2006), SANCO/1428/2001	ATP 30°
Spirodiclofen	EFSA Scientific Report (2009), Conclusions	NoATP
tau - Fluvalinate	EFSA Journal (2010)	Rec.ATP 29°
Tebufenozide	EFSA Journal (2010)	ATP 28°
Tebufenpyrad	EFSA Scientific Report (2008), Conclusions	NoATP
Tefluthrin	EFSA Journal (2010)	NoATP
Thiacloprid	EU Review Report (2004), SANCO/4347/2000 + BD-AGRITOX	NoATP
Thiamethoxam	EU Review Report (2006), SANCO/10390/2002	ATP 30°
zeta-Cypermethrin	EFSA Scientific Report (2008), Conclusions	ATP 29° rev

N.B.
ATP = Adaptation to Technical Progress of the Council Directive 67/548/EEC
No ATP – Classification of the active substance present in non of the law provisions
For ATP 25° see point (4) in the reference, for ATP 26° point (5), for ATP 28° point (6), for ATP 29° point (7), for ATP 29 rev point (8), for Rec ATP 29° point (9), for ATP 30° point (10) and for ATP 31° point (11).

Adopted criteria

Each active substance was examined in accordance with the criteria as reported in annex II of Reg.EC no.1107/2009. Based on such criteria, it was established to see if an active substance could be authorized, if it had to be excluded from sale or if it could be defined as candidate for substitution.

The criteria that were used for the evaluation of the substances being tested are reported below.

Cut-off criteria

Impact on human health

An active substance shall only be approved if:

- it is not or has not to be classified as mutagen category 1A or 1B in accordance with the provisions of Regulation (EC) n.1272/2008 (previously Cat.1 and Cat.2 mutagenesis);
- it is not or has not to be classified as carcinogen category 1A or 1B in accordance with the provisions of Regulation (EC) n.1272/2008 (previously Cat.1 and Cat.2 carcinogenesis);
- it is not or has not to be classified as toxic for reproduction category 1A or 1B in accordance with the provisions of Regulation (EC) n.1272/2008 (previously Cat.1 and Cat.2 teratogenesis and fertility);
- it is not considered to have endocrine disrupting properties that may cause adverse effects in humans. By 14 December 2013, the Commission shall present, to the Standing Committee on the Food Chain and Animal Health, a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure in the Regulation (EC) n.1107/2009. Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) n.1272/2008, as carcinogenic category 2 (previously risk phrase R40: "Limited evidence of a carcinogenic effect") and toxic for reproduction category 2 (previously risk phrases R62: "Possible risk of impaired fertility" and R63: "Possible risk of harm to the unborn child"), 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) n.1272/2008, as toxic for reproduction category 2 (previously risk phrases R62 and R63) and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

Fate and behaviour in the environment

► An active substance 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:

- Persistence

  An active substance fulfils the persistence criterion where:

  - there is evidence that the time it takes for a degradation of 50% (DT_{50}) in water is greater than 2 months, or

  - that its DT_{50} in soil is greater than 6 months, or

  - that its DT_{50} in sediment is greater than 6 months.

- Bioaccumulation

  An active substance fulfils the bioaccumulation criterion where there is:

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

    or

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

- Potential for long-range environmental transport:

  An active substance fulfils the potential for long-range environmental transport criterion where:

  - measured levels of the active substance 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 with the potential for transfer to a receiving environmental, may have occurred via air, water or migratory species, or

  - environmental fate properties and/or model results demonstrate that the active substance 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 that migrates significantly through the air, its DT_{50} in air is to be greater than 2 days.

► An active substance 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:

- Persistence

  An active substance fulfils the persistence criterion where:

  - the half-life in marine water is higher than 60 days, or
  - the half-life in fresh or estaurine water is higher than 40 days, or
  - the half-life in marine sediments higher than 180 days, or
  - the half-life in fresh or estaurine water sediments higher than 120 days, or
  - the half-life in soil is higher than 120 days.

- Bioaccumulation

  An active substance fulfils the bioaccumulation criterion where:

  - the bioconcentration factor (BCF) 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.

- Toxicity

  An active substance fulfils the toxicity criterion where:

  - the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0,01 mg/l, or
  - the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A, 1B or 2), or
  - there is other evidence of chronic toxicity, as identified by the classification STOT RE 1 (phrase H372 - previously risk phrases R48/23, R48/24, R48/25) or STOT RE 2 (phrase H373 - previously risk phrases R48/20, R48/21, R48/22 e R33) pursuant to Regulation (EC) n. 1272/2008.

► An active substance shall only be approved if it is not considered to be a **very Persistent,** and **very Bioaccumulative** (vPvB) substance. A substance that fulfils both of the criteria of the points below is a **vPvB** substance:

- Persistence

  An active substance fulfils the “very persistent” criterion where:

  - the half-life in marine, fresh- or estaurine water is higher than 60 days, or
  - the half-life in marine, fresh- or estaurine water sediment is higher than 180 days, or
  - the half-life in soil is higher than 180 days.

- Bioaccumulation

  An active substance fulfils the "very bioaccumulative" criterion where the bioconcentration factor (BCF) is greater than 5,000.

In absence of persistence in sediment data ($DT50_{sed}$), the persistence of water system/sediment data ($DT50_{water/sed}$) was used, such data if compared to that of persistence in water and soil may provide indications of the capacity for the degrading of the substance in sediment. When the $DT50_{water/sed}$ exceeded the threshold value level for $DT50_{sed}$, that are reported in the criteria which indicate a PTB or vPvB substance, the substance was indicated as being persistent in sediments. Such substances are reported in table 6.

Criteria for defining substances as candidate for substitution

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

1. its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,
2. it meets two of the criteria to be considered as a PBT (Persistent, Bioccamulative, Toxic) substance,
3. 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),
4. it contains a significant proportion of non-active isomers,
5. 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. of the Regulation (EC) No. 1107/2009,
6. 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. of the Regulation (EC) No. 1107/2009,
7. 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. of the Regulation (EC) No. 1107/2009.

Regarding criterion **3**, those substances that show to have neurotoxic effects on development were highlighted by a credible review study (5). It must be remembered that eventual inclusion of such substances on the list of "candidate for substitution" will be strongly influenced by specific use conditions that are relative to any commercial product that contains them (e.g. usage dose, number of treatments) and not only by the characteristics of the active substance itself.

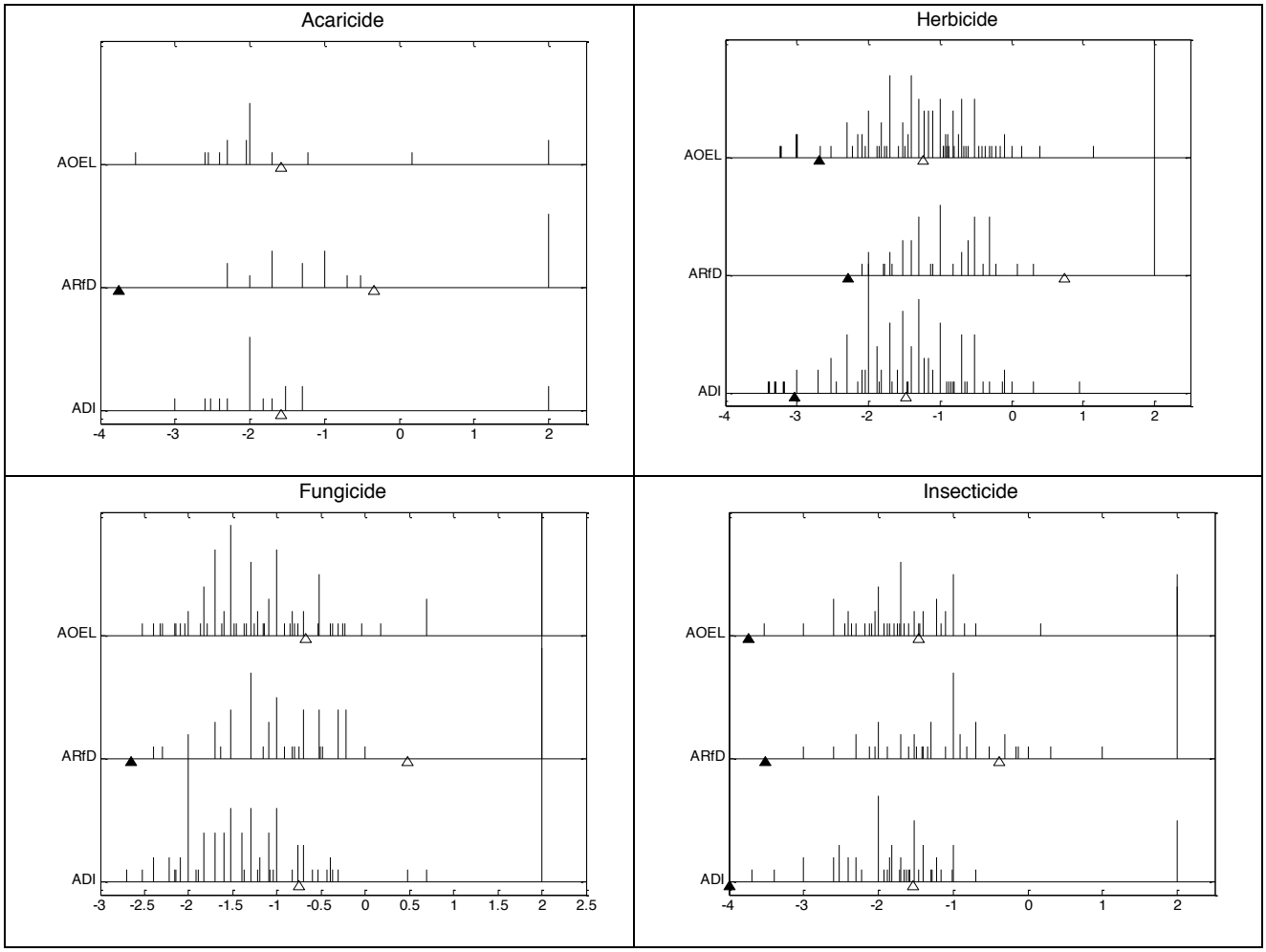
Criterion **1.** defines a substance as "candidate for substitution" if its ADI, its ARfD or its AOEL are significantly less than those of the majority of active substances that have been approved in the field of group of substances/use category." It was taken into account as follows:
The value of ADI, AOEL and ARfD of each active substance currently authorized (i.e. present in Annex I, including the natural pesticide substances), were divided by use category (insecticides, fungicides, acaricides, herbicides).

The thresholds for ADI, AOEL e ARfD, that identify a substance as "candidate for substitution", were defined by starting from the assumption that the ADI, AOEL and ARfD values placed at 2 standard deviations from the means, may be considered “significantly less than those of the majority of active substances that have been approved in the field of group of use category" (Fig.1).
For calculating the means, a standard value of 100 mg/kg of p.c. was assigned to all those substances for which the calculation of ADI, AOEL or ARfD was not applicable due to reduced toxicity.

Based on these criteria, the thresholds for ADI, AOEL and ARfD were the following for any use category:

Use category	*ADI threshold mg/kg p.c.*	*ARfD threshold mg/kg p.c.*	*AOEL threshold mg/kg p.c.*
Herbicide	≤ 9.34E10-4	≤ 5.11E10-3	≤ 2.07E10-3
Fungicide	≤ 2.19E10-4	≤ 2.25E10-3	≤ 4.08E10-4
Insecticide	≤ 1.02E10-4	≤ 3.09E10-4	≤ 1.85E10-4
Acaricide	≤ 5.65E10-5	≤ 1.79E10-4	≤ 2.75E10-5

Fig 1 –Threshold for ADI, AOEL and ARfD of the four use categories (logarithms). White triangles are the distribution means, black triangles indicate the threshold values (two standard deviations).



Results

"CUT-OFF" substances

The substances in table 4 meet the cut-off criteria, therefore, there is a strong possibility of their being eliminated upon re-examination at the authorization expiry deadline time. The times of expiry authorization for each active substance are also given in the table as is the inclusion in Annex I of Directive 91/414/EEC. The cut-off criteria which are met are shown beside the active substances.

Table.4 - List of the **18** active substances that could be eliminated from Annex I, following the application of ***cut-off criteria***.

	A.S.	Cut-off criteria	Inclusion expiry
HER	Aclonifen	PBT	2019
	Chlorotoluron	EDCs (R40 + R63) and (2PBT)	2016
	Flurochloridone	Cat.2 Rep. R61*	2021
	Glufosinate ammonium	Cat.2 Rep. R60	2017
	Ioxynil	EDCs (R63 + cat.1 EDCs)	2015
	Linuron	Cat.2 Rep. R61 and Cat.1 EDCs	2013
	Molinate	EDCs (R40 + R62)	2014
	Pendimethalin	vPvB e PBT	2013
	Tepraloxydim	EDCs (R40 + R63 + R62) and (2PBT)	2015
	Tralkoxydim	EDCs (R40* +R63* +R62*) and (2PBT)	2018
FUN	Bitertanol	Cat.2 Rep. R61*	pending
	Cyproconazolo	Cat.2 Rep. R61* or EDCs (R40*+ R63)	2021
	Epoxiconazole	EDCs (R40 + R63 + R62)	2018
	Mancozeb	EDCs (R63 + cat.1 EDCs)	2016
	Maneb	EDCs (R63 + cat.1 EDCs)	2016
	Quinoxyfen	vPvB	2014
INS	Novaluron	PBT	pending
	Propargite	EDCs (R40 + R63*) and (2PBT)	pending

* the toxicity classification has been presented by EFSA but it has not yet been incorporated by an official act

Risk phrases: R40 (Limited evidence of a carcinogenic effect); R60 (May impair fertility); R61 (May cause harm to the unborn child); R62 (Possible risk of impaired fertility); R63 (Possible risk of harm to the unborn child)

Candidate for substitution substances

In **table 5** there are the **29** substances, amongst those examined in the study that, at the moment of re-examination at the inclusion expiry, could be defined as "candidate for substitution substances" in so much that they conform to the criteria in Annex II, chapter 4 of the regulation. Beside each active substance, the criteria which define it as candidate for substitution are specified. In the same table, the times of authorization expiry for each active substance and inclusion in Annex I of directive 91/414/EEC are indicated.

Tab.5 - List of the **29** active substances that could be defined as **"*candidate for substitution*"** following application of criteria that are present in Annex II chapt.4 of EU directive no.1107/2009

	A.S.	Candidate for substitution criteria	Inclusion expiry
INS	Cipermetrina ***	2PBT	2016
	Clofentezine	2PBT	2018
	Etofenprox	2PBT	2019
	Etoxazole	2PBT	2015
	Fipronil	2PBT	2017
	Flufenoxuron	2PBT	pending
	lambda-Cyhalothrin***	2PBT	2011
	Pirimicarb	2PBT	2017
	Pyridaben	2PBT	2021
	Tebufenozide	2PBT	2021
	Tebufenpyrad	2PBT	2019
	Tefluthrin	2PBT	pending
FUN	Difenoconazole	2PBT	2018
	Famoxadone	2PBT	2012
	Fludioxonil	2PBT	2018
	Metconazole***	2PBT	2017
	Penconazole ***	2PBT	2019
	Proquinazid	2PBT	2020
	Spiroxamine	2PBT	2011
	Tebuconazole ***	2PBT	2019
	Tetraconazole ***	2PBT *	2019
	Triadimenol ***	2PBT	2019

HER	Acetochlor ***	2PBT	pending
	Diquat	2PBT + AOEL	2011
	Flufenacet	2PBT	2013
	Metribuzin***	2PBT *	2017
	Oxadiazon	2PBT	2018
	Oxyfluorfen	2PBT	pending
	Sulcotrione	ADI + AOEL	2019

*** substances that in the future could also meet **cut-off criteria** if certain toxicological characteristics are confirmed (see table7).
* the toxicity classification has been proposed by EFSA but it has not yet been incorporated by an official act

Table.6 - List of the **17** active substances "***likely to be candidate for substitution***" using 2PBT criteria

	A.S.	**Criteria**	**Authorisation expiry**
INS	Fenazaquin	2PBT *	2021
	Fenbutatin oxyde	2PBT *	2021
	Imidacloprid	2PBT **	2019
	Spinosad	2PBT *	2017
FUN	Cyprodinil	2PBT *	2017
	Fenbuconazole ***	2PBT *	2021
	Myclobutanil ***	2PBT *	2021
HER	Amidosulfuron	2PBT **	2018
	Azimsulfuron	2PBT **	2011
	Chlorsulfuron	2PBT **	2019
	Diflufenican	2PBT **	2018
	Imazosulfuron	2PBT **	2015
	Mesosulfuron	2PBT **	2014
	Metsulfuron methyl	2PBT **	2011
	Nicosulfuron	2PBT **	2018
	Prosulfuron	2PBT **	2012
	Triasulfuron	2PBT **	2011

*Persistent criterion fulfilled by the DT50 value in the water/sediment system as indicative for the evaluation of the DT50 sediment.
** Toxicity criterion fulfilled by the screening PBT criteria (EC50<0,1 mg/l for algae and aquatic plant)
*** substances that in the future could also meet cut-off criteria if certain toxicological characteristics are confirmed (see table7).

It has not been possible to provide a certain classification of some substances because of insufficient data or not definitive data (e.g. "R63*" suggested but still not confirmed or EDCs that have still not been classified). These substances have been listed in **tables 7** and **8** where the probable or possible future classification and currently suspended critical data will be placed.

Table.7 – Substances with currently non-definitive data in order to be able to place them with certainty in either the CUT-OFF substance or the candidate for substitution (CS) category, but *likely to be classified* as EDCs or neurotoxic substances.

	A.S.	**Criteria**		**Inclusion expiry**
FUN	Benthiavalicarb isopropyl	Cut-off CS	EDCs (R40 + R63*)	2018
	Folpet	Cut-off CS	EDCs (R40 + R63*)	2017
	Iprodione	Cut-off CS	Cat.2 EDCs	2013
	Maneb ***	CS	Neurotoxic effects on development(**)	2016
	Metiram	Cut-off CS	Cat.1 EDCs Neurotoxic effects on development(**)	2016
	Tetraconazole ***	Cut-off	EDCs (R40* + R63* + R62*)	2019
	Thiram	Cut-off CS	Cat.1 EDCs Neurotoxic effects on development(**)	2014
	Triadimenol ***	Cut-off CS	R63* + Cat.2 EDCs	2019
	Ziram	Cut-off CS	Cat.2 EDCs Neurotoxic effects on development(**)	2014
INS	Abamectin	Cut-off CS	Cat.2 Rep. R61*	2018
	Cipermetrina ***	Cut-off CS	Cat.2 EDCs	2016
	Chlorpyrifos	CS	Neurotoxic effects on development(**)	2016
	Chlorpyrifos methyl	CS	Neurotoxic effects on development(**)	2016
	Deltamethrin	Cut-off CS	Cat.1 EDCs	2013
	Dimethoate	Cut-off CS	Cat.2 EDCs	2017
	tau-Fluvalinate	Cut-off CS	Cat.2 EDCs	2021
	lambda-Cyhalothrin ***	Cut-off CS	Cat.1 EDCs	2011

DIS	2,4-D	Cut-off CS	Cat.2 EDC Neurotoxic effects on development(**)	2012
	2,4-DB	Cut-off CS	Cat.1 EDCs	2013
	Acetochlor***	Cut-off CS	Cat.1 EDCs	pending
	Bromoxynil	Cut-off CS	R63 + Cat.2 EDCs	2015
	Metribuzin***	Cut-off CS	R63* + Cat.1 EDCs	2017

EDCs**:** probable Endocrine Disrupting Chemical but still not "classified" as such, see point 12 – 13 – 14 in the references

* the toxicity classification is still being reviewed by EFSA

**Substances with possible neurotoxic effects on development, resulting from a new study review, see point 15 in the references.

***Substances already identified as cut-off or candidate for substitution category

Risk phrases: R40 (Limited evidence of a carcinogenic effect); R61 (May cause harm to the unborn child); R62 (Possible risk of impaired fertility); R63 (Possible risk of harm to the unborn child)

Table.8 – Active substances with *possible* endocrine activity

	A.S.	**Criteria**		**Inclusion expiry**
FUN	Fenbuconazole ***	Cut-off CS	R63 + EDC?	2021
	Metconazole***	Cut-off CS	R63 + EDC?	2017
	Myclobutanil ***	Cut-off CS	R63* + EDC?	2021
	Penconazole ***	Cut-off CS	R63* + EDC?	2019
	Propiconazole	Cut-off CS	R63* + EDC?	2014
	Prothioconazole	Cut-off CS	R63 + EDC?	2018
	Tebuconazole ***	Cut-off CS	R63* + EDC?	2019
	Tetraconazole ***	Cut-off CS	R63* R62* + EDC?	2019
INS	Thiacloprid	Cut-off CS	EDC?	2014

* the toxicity classification is still being reviewed by EFSA

***Substances already identified as cut-off or candidate for substitution category

Evaluated substances that do not enter into either the cut-off or the candidate for substitution criteria

The **117** active substances listed in table 9 don't have toxicological, chemical-physical and ecotoxicological characteristics and are not persistent in the environment so they have a strong likelihood of renewal authorization at the end of the current period of commercial authorization.
Evaluation of **Profoxydim** was not possible due to insufficient currently available data.

Table.9 – Substances that do not enter into the cut-off criteria or selection for the substance candidate for substitution criteria.

	A.S.	Inclusion expiry		A.S.	Inclusion expiry
HER	Asulam	not included*	HER	Isoproturon	2012
	Benfluralin	2018		Isoxaben	2021
	Bensulfuron	2019		Isoxaflutole	2013
	Bentazone	2011		Lenacil	2018
	Bifenox	2018		MCPA	2016
	Byspyribac-sodium	2021		Mecoprop	2014
	Carfentrazone-ethyl	2013		Mecoprop – P	2014
	Chloridazon	2018		Mesotrione	2013
	Clethodim	2021		Metamitron	2019
	Clodinafop	2017		Metosulam	2021
	Clomazone	2018		Napropamide	2020
	Clopyralid	2017		Oxadiargyl	2013
	Cycloxydim	2021		Oxasulfuron	2013
	Cyhalofop-butyl	2012		Penoxsulam	2020
	Desmedifam	2015		Pethoxamid	2016
	Dicamba	2018		Phenmedipham	2015
	Diclofop methyl	2021		Pinoxaden	pending
	Dimethachlor	2019		Propaquizafop	2019
	Dimethenamid - P	2013		Propyzamide	2014
	Ethoxysulfuron	2013		Pyridate	2011
	Fenoxaprop-P	2018		Quizalofop - P - ethyl	2019
	Flazasulfuron	2014		Rimsulfuron	2017
	Florasulam	2012		S-Metolachlor	2015
	Fluazifop-P-butyl	not included*		Terbuthylazine	pending
	Fluroxypyr	2011		Thifensulfuron-methyl	2012
	Foramsulfuron	2013		Thiobencarb	not included*
	Glyphosate	2012		Tribenuron	2016
	Imazamox	2013		Triclopyr	2017
	Iodosulfuron methyl sodium	2013			

INS	Acetamiprid	2014	**INS**	Hexythiazox	2021
	Acrinathrin	pending		Indoxacarb	2016
	Alphamethrin	2015		Methiocarb	2017
	Clothianidin	2016		Methoxyfenozide	2015
	Cyfluthrin	2013		Milbemectin	2015
	Cyromazine	2019		Oxamyl	2016
	Diflubenzuron	2018		Phosmet	2017
	Ethoprophos	2017		Pymetrozine	2011
	Fenamiphos	2017		Pyriproxyfen	2018
	Fenpyroximate	2018		Spirodiclofen	2020
	Flonicamid	2020		Thiamethoxam	2017
	Fosthiazate	2013		zeta Cypermethrin	2019
FUN	Benalaxyl	2015	**FUN**	Iprovalicarb	2012
	Benalaxyl - M	pending		Kresoxim-methyl	2011
	Boscalid	2018		Propamocarb	2017
	Bupirimate	2021		Propineb	2014
	Captan	2017		Pyraclostrobin	2014
	Chlorothalonil	2016		Pyrimethanil	2017
	Cyazofamid	2013		Mandipropamid	pending
	Cymoxanil	2019		Mepanipyrim	2014
	Dimethomorph	2017		Meptyldinocap	pending
	Dithianon	2021		Metalaxyl	2020
	Dodine	2021		Metalaxyl - M	2012
	Fenamidone	2013		Metrafenone	2017
	Fenhexamid	2011		Pencycuron	2021
	Fenpropidin	2018		Thiabendazole	2011
	Fenpropimorph	2018		Thiofanate-methyl	2016
	Fluazinam	2018		Tolclofos methyl	2017
	Fluopicolide	2020		Trifloxystrobin	2013
	Fosetyl alluminium	2017		Zoxamide	2014

*substances with voluntary withdrawal from sale (withdrawal authorization by December 2010, sale prohibition from August 2011, use prohibition from December 2011) – Commission Decision 2008/934/EC

Conclusions

Based on the information reported in the EU and EFSA reports, 200 active substances were analyzed.

Given the current level of scientific knowledge, the study permitted us to identify active substances that fall into the cut-off or candidate for substitution criteria.

In total there were 82 active substances that will meet or probably meet the cut-off or candidate for substitution criteria (30 herbicides, 27 fungicides and 25 insecticides).

In particular, from 9% to 18.5% of the total analyzed substances fell into the cut-off criteria and from 14.5% to 24.5% into the candidate for substitution criteria.

Amongst the herbicides that we analyzed, about 11.4% fell into the cut-off group whilst for the fungicides and insecticides they were 9.5% and 4% respectively.

A greater number of substances meet the criteria of substances that are candidate for substitution, in particular 24.5% of the insecticides that we analyzed, 15.9% for fungicides and 8% for herbicides.

Another 9.5% of substances could meet the cut-off criteria if some toxicological data (in particular endocrine disrupting effects) are confirmed.

In addition another 10% of substances could fall into the candidate for substitution PBT-criteria if some specific data regarding persistence in sediment or toxicity for aquatic organisms are produced.

We would like to underline, however, that currently, there are significant margins of subjectivity in the choices made for using data for the cut-off and candidate for substitution parameters. In particular:

- it is difficult to apply the criteria regarding the singling out of the substances that are candidate for substitution by using their ADI, AOEL, and ARfD. The wording "ADI, AOEL, ARfD…that are significantly lower than those of the majority of the active substances that have been approved in the area of the group of substances/use category" does not allow us to define a threshold and it is thus highly subjective. Furthermore, the threshold has to be set each time as it depends on how many substances are authorized, on the type of use, on the moment of criteria application and the number of substances that are present for each order of size of the ADI, AOEL and ARfD.
- The criteria that define a PTB substance or vPvB are not easily applicable as the data that could be used in the comparison with the proposed thresholds are not always evident (e.g. if the DT50 value is missing in the sediment but there is an high value of DT50 in soil, is it enough to use the DT50 value water/sediment

because, potentially, such value is mainly determined by the sediment component? etc.).

Given these important critical points that will be decisive in the evaluation process of active substances that will be subject to the authorization process before being released onto the market, we would hope that at European and national level, the criteria will be established soonest in order to see correct application of the regulations.

The results of our study have allowed us to identify those substances whose banning from the market in the future might cause problems for agricultural defense strategies. Knowing what these substances are now could allow alternative protection programmes to be activated in advance.

****Authors' note: the work is correct as at June 30, 2011**

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