

Pesticides and Biotechnical Products
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Interpretation in Sweden of the impact of the “cut-off” criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)

The European Council adopted recently its common position after having reached a political agreement in June this year of a Regulation concerning the placing of plant protection products (PPP) on the market. The new Regulation, in contrary with the present Directive 91/414/EEC, contains a proposal for “cut-off” criteria for the approval of active substances, safeners and synergists based on hazard properties of the substance.

The aim of this document is mainly to present a preliminary assessment of the impact on the number of approved active substances by applying the adopted “cut-off” criteria. Some of the criteria are not as yet precisely defined within the EU and therefore we present herein our own view, in particular with regard to the criteria in Annex II 3.6.5 related to endocrine disruption. We also briefly discuss the criteria for selecting candidates for substitution. However, we have not made a detailed impact assessment with regards to the adopted candidate criteria. Our general view is that, regardless of the candidate criteria, the adopted text on comparative assessment and substitution of PPPs is sufficiently flexible and does even include a prerequisite that prevents economic or practical disadvantages to the agriculture including risks for development of resistance.

The European Parliament opinion on the approval criteria is not assessed in this document. In our opinion, the European Parliament criteria are stricter than the Council criteria. We consider that the approval criteria adopted by the Council are stringent enough to reach a satisfactory level of protection of human health and the environment. In our view, the Parliament’s opinion of a single approval period for the substances approved as candidates for substitution will probably have a considerable negative impact on the European agriculture. This view is shared by PSD (UK)¹.

We present below the:

1. Summary of the criteria in the Regulation adopted by the Council
2. Interpretation of the “cut-off” criteria in Annex II 3.6-3.7
3. Selection of active substances included in the assessment and methodology
4. Substitution
5. Results and Discussion
6. Table 1: List of active substances examined
7. Table 2: List of active substances preliminary identified in Sweden that may not be approved according to the “cut-off” criteria adopted by the Council

¹ Assessment of the impact on crop protection in the UK of the “cut-off criteria” and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of the plant protection products in the market by PSD- Pesticides Safety Directorate, May 2008

1. Summary of the criteria in the new Regulation adopted by the Council

A summary of the “cut-off” criteria based on the hazard properties of the active substances (Annex II 3.6-3.7) and the criteria for candidate for substitution (Annex II 4) is presented below:

“Cut-off”

- Mutagen category 1 or 2
- Carcinogen or toxic for reproduction category 1 or 2, unless the exposure to human is negligible
- Endocrine disruptors (ED) causing adverse effect in humans, unless the exposure to human is negligible
- POPs (persistent organic pollutant)
- PBT (persistent bioaccumulating and toxic)
- vPvB (very persistent and very bioaccumulating)

Candidate for substitution

- ADI, ARfD or AOEL is significantly lower
- Two of the PBT criteria are met
- Developmental neurotoxic or immunotoxic effects, high potential risk for groundwater
- A significant proportion of non-active isomers
- Carcinogen or toxic for reproduction category 1 or 2 and ED with negligible exposure

2. Interpretation of the “cut-off” criteria on Annex II 3.6-3.7 and methodology

There are (as yet) no guidelines for the interpretation of the new Regulation’s criteria related to identification of active substances in PPP as ED, PBT/vPvB or POP. However based on the formerly applied national criteria and principles we have interpreted the criteria in the following way:

CMR – Carcinogenic, mutagenic and toxic for reproduction based on agreed classification at ECB or included in Annex I of Directive 67/548/EEC and may be expected to not have negligible exposure.

ED – The EU Commission has defined endocrine disruptors ED as: “Endocrine disruptors are exogenous substances that alter function(s) of the endocrine system and consequently cause adverse health effects in an intact organism, or its progeny, or (sub)populations.”²

From the perspective of human health our interpretation of this definition and the criteria in Annex II 3.6.5 is that an ED is a substance which induces severe effects such as cancer or is toxic for reproduction, causes effects on fertility or development, and there are indications of an endocrine disrupting mechanism behind the effects. These substances are classified or have to be classified as toxic for reproduction (category 2 or 3) and carcinogenicity (category 3) or are classified or has to be classified as toxic for reproduction (category 2 or 3) and have toxic effects on the endocrine organs. For these substances we believe that the effects are likely to be of relevance for

² COM’s website: http://ec.europa.eu/environment/endocrine/definitions/endodis_en.htm

humans. As for CMR the criteria is applied only for substances which may be expected to not have negligible exposure.

PBT/vPvB/POP – These criteria are meant to identify substances which clearly can be defined as PBT/vPvB/POP substances. In the assessments we have used all available data (phys/chem properties, simulation studies on degradation in various environmental compartments, field dissipation studies, monitoring data etc.) and used a weight of evidence approach. The parameter DT_{50} should reflect degradation, not only dissipation from a particular environmental compartment. Substances may occasionally be identified as PBT/vPvB/POP even in the case one individual criterion (P or B etc.) is marginally not exceeded or in the case there is substantial uncertainty since the criteria are assessed in combination.

3. Selection of active substances included in the assessment and methodology

Only active substances have been examined, no safener or synergists. The following active substances have been included in the study:

- Substances included in Annex I to Directive 91/414/EEC
- Substances from stage 3 pending a decision

The pending new substances and the substances from stage 4 not yet included in Annex I were not examined because they are in the assessment process and there may still be remaining uncertainties in the identification of endpoints.

Substances withdrawn voluntarily under Commission Regulation 1095/2007 but remaining on the market until 2010 are not included in this assessment. We expect that several of them will be included in Annex I, however they have not been peer reviewed and there are still data gaps, which in our opinion could change the results of an assessment in relation to the proposed criteria.

A total number of 271 active substances have been examined (see Table 1).

The assessment of ED, PBT/vPvB and POP was based on endpoints concluded in the “review report” and the EFSA conclusion from the substances on stage 2 and 3 (and, in case review reports or EFSA conclusions were not available the assessment was based on the list of endpoints presented in the DAR). However, for the substances from stage 1 it is not clear if the data provided in the list of endpoints is comparable with the data from the later stages, therefore it is possible that a revision of the list of endpoint would have an impact on the results of the present assessment.

4. Substitution

The proposal for a new Regulation includes also criteria for selecting candidates for substitution. The substances that fulfil these criteria will be approved and put on a “list of candidate for substitution”. A comparative assessment will be done at MS level for the PPP. Products containing candidates may not be approved only if the conditions for comparative assessment in Annex IV are met. As these criteria take sufficient considerations to the risk for occurrence of resistance and other significant economic or

practical disadvantages, we do not expect that substitution when applied as intended will have a substantial negative impact on the European agriculture.

5. Result and Discussion

The results are shown in Table 2. In total 23 substances (8 herbicides, 11 fungicides, 3 insecticides and 1 plant growth regulator) were identified to meet the “cut-off” criteria in Annex II 3.6-3.7 adopted by the Council and may therefore not be approved. These 23 substances constitute approx. 8 % of the 271 substances being assessed in Sweden (substance in Annex I of 91/414/EEC and pending on stage 3).

Out of these 23 substances, 7 substances were identified as CMR (category 1 or 2), 11 were recognized as ED using our interpretation of the criteria in Annex II 3.6.5 and 4 substances were identified as PBT/vPvB or POP.

The criteria for approval of active substances adopted by the Council are in general agreement with the Commission proposal as amended in March 2008.

The main advantage of using these “cut-off” is to accelerate the peer review process of the active substances and at the same time achieve a satisfactory level of protection of human and animal health and of the environment.

7. Table1. List of active substances examined

Active substance	Status Annex I 91/414/	Stage	#
<i>Herbicides</i>			
2,4-D	Annex I	1	1
2,4-DB	Annex I	1	2
Aclonifen	pending	3	3
Amidosulfuron	Annex I	3	4
Amitrole (aminotriazole)	Annex I	1	5
Azimsulfuron	Annex I	New	6
Beflubutamid	Annex I	New	7
Benfluralin	pending	3	8
Bensulfuron	pending	3	9
Bentazone	Annex I	1	10
Bifenox	Annex I	3	11
Bromoxynil	Annex I	1	12
Carfentrazone-ethyl	Annex I	New	13
Chloridazon (aka pyrazone)	Annex I	3	14
Chlorotoluron	Annex I	1	15
Chlorpropham	Annex I	1	16
Chlorsulfuron	pending	3	17
Chlorthal-dimethyl	pending	3	18
Cinidon ethyl	Annex I	New	19
Clodinafop	Annex I	2	20
Clomazone	Annex I	3	21
Clopyralid	Annex I	2	22
Cyhalofop-butyl	Annex I	New	23
Desmedipham	Annex I	1	24
Dicamba	Annex I	3	25
Dichlorprop-P	Annex I	2	26
Diflufenican	Annex I	3	27
Dimethachlor	pending	3	28
Dimethenamid – P	Annex I	New	29
Diquat (dibromide)	Annex I	1	30
Diuron	Annex I	2	31
Ethofumesate	Annex I	1	32
Ethoxysulfuron	Annex I	New	33
Fenoxaprop-P	Annex I	3	34
Flazasulfuron	Annex I	New	35
Florasulam	Annex I	New	36
Flufenacet (formerly fluthiamide)	Annex I	New	37
Flumioxazin	Annex I	New	38

Active substance	Status Annex I 91/414/	Stage	#
Flupyr-sulfuron methyl	Annex I	New	39
Fluroxypyr	Annex I	1	40
Flurtamone	Annex I	New	41
Foramsulfuron	Annex I	New	42
Glufosinate	Annex I	2	43
Glyphosate (incl trimesium aka sulfosate)	Annex I	1	44
Imazamox	Annex I	New	45
Imazosulfuron	Annex I	New	46
Iodosulfuron-methyl-sodium	Annex I	New	47
Ioxynil	Annex I	1	48
Isoproturon	Annex I	1	49
Isoxaflutole	Annex I	New	50
Lenacil	Annex I	3	51
Linuron	Annex I	1	52
MCPA	Annex I	1	53
MCPB	Annex I	1	54
Mecoprop	Annex I	1	55
Mecoprop-P	Annex I	1	56
Mesosulfuron	Annex I	New	57
Mesotrione	Annex I	New	58
Metam (incl. -potassium and -sodium)	pending	3	59
Metamitron	pending	3	60
Metazachlor	pending	3	61
Metribuzin	Annex I	2	62
Metsulfuron	Annex I	1	63
Molinate	Annex I	1	64
Nicosulfuron	Annex I	3	65
Oxadiargyl	Annex I	New	66
Oxadiazon	Annex I	3	67
Oxasulfuron	Annex I	New	68
Pendimethalin	Annex I	1	69
Pethoxamid	Annex I	New	70
Phenmedipham	Annex I	1	71
Picloram	Annex I	3	72
Picolinafen	Annex I	New	73
Propaquizafop	pending	3	74
Propoxycarbazone	Annex I	New	75
Propyzamide	Annex I	1	76
Prosulfocarb	Annex I	3	77
Prosulfuron	Annex I	New	78
Pyraflufen-ethyl	Annex I	New	79

Active substance	Status Annex I 91/414/	Stage	#
Pyridate	Annex I	1	80
Quinoclamine	Annex I	3	81
Quizalofop-P	pending	3	82
Rimsulfuron (aka renniduron)	Annex I	2	83
S-Metolachlor	Annex I	New	84
Sulcotrione	pending	3	85
Sulfosulfuron	Annex I	New	86
Tepraloxydim	Annex I	New	87
Thifensulfuron (aka thiameturon)	Annex I	1	88
Tralkoxydim	Annex I	3	89
Tri-allate	pending	3	90
Triasulfuron	Annex I	1	91
Tribenuron (aka metometuron)	Annex I	2	92
Triclopyr	Annex I	2	93
Triflusulfuron	pending	3	94
Tritosulfuron	Annex I	New	95
<i>Fungicides</i>			
(Calcium) copper oxychloride	Pending	3	96
(Calcium) copper sulfate (Bordeaux mix)	Pending	3	97
<i>Ampelomyces quisqualis</i> strain AQ10	Annex I	New	98
Azoxystrobin	Annex I	New	99
<i>Bacillus subtilis</i> str. QST 713	Annex I	New	100
Benalaxyl	Annex I	1	101
Benthiavalicarb	Annex I	New	102
Benzoic acid	Annex I	New	103
Boscalid	Annex I	New	104
Burgundy mixture	Pending	3	105
Captan	Annex I	2	106
Carbendazim	Annex I	1	107
Chlorothalonil	Annex I	1	108
<i>Coniothyrium minitans</i>	Annex I	New	109
Copper acetate	Pending	3	110
Copper ammonium carbonate	Pending	3	111
Copper carbonate basic	Pending	3	112
Copper hydroxide	Pending	3	113
Copper octanoate	Pending	3	114
Copper oxychloride	Pending	3	115
Copper salts of fatty and rosin acids	Pending	3	116
Copper sulfate	Pending	3	117
Copper sulfate, tri-basic	Pending	3	118

Active substance	Status Annex I 91/414/	Stage	#
Cuprammonium	Pending	3	119
Cuprous oxide	Pending	3	120
Cyazofamid	Annex I	New	121
Cymoxanil	Pending	3	122
Cyprodinil	Annex I	2	123
Dichlorobenzoic acid methylester	Pending	3	124
Difenoconazole	Annex I	3	125
Dimethomorph	Annex I	2	126
Dimoxystrobin	Annex I	New	127
Dinocap	Annex I	1	128
Dodemorph	Pending	3	129
Epoxiconazole	Annex I	3	130
Famoxadone	Annex I	New	131
Fenamidone	Annex I	New	132
Fenhexamid	Annex I	New	133
Fenpropidin	Annex I	3	134
Fenpropimorph	Annex I	3	135
Fluazinam	Annex I	3	136
Fludioxonil	Annex I	3	137
Fluoxastrobin	Annex I	New	138
Flusilazole	Annex I	1	139
Flutolanil	Annex I	3	140
Folpet	Annex I	2	141
Fosetyl	Annex I	2	142
Fuberidazole	Annex I	3	143
<i>Gliocladium catenulatum strain J1446</i>	Annex I	New	144
Imazalil (aka enilconazole)	Annex I	1	145
Iprodione	Annex I	1	146
Iprovalicarb	Annex I	New	147
Kresoxim-methyl	Annex I	New	148
Mancozeb	Annex I	1	149
Maneb	Annex I	1	150
Mepanipyrim	Annex I	New	151
Metalaxyl-M	Annex I	New	152
Metconazole	Annex I	2	153
Metiram	Annex I	1	154
Metrafenone	Annex I	New	155
<i>Paecilomyces fumosoroseus Apopka strain 97</i>	Annex I	New	156
<i>Paecilomyces lilacinus</i>	Annex I	New	157
Penconazole	Pending	3	158
<i>Phlebiopsis gigantea</i>	Annex I	4	159

Active substance	Status Annex I 91/414/	Stage	#
Picoxystrobin	Annex I	New	160
Propamocarb	Annex I	2	161
Propiconazole	Annex I	1	162
Propineb	Annex I	1	163
Prothioconazole	Annex I	New	164
Pyraclostrobin	Annex I	New	165
Pyrimethanil	Annex I	2	166
<i>Pythium oligandrum</i> (M1)	Annex I	4	167
Quinoxifen	Annex I	New	168
Silthiofam	Annex I	New	169
Spiroxamine	Annex I	New	170
<i>Spodoptera exigua nuclear polyhedrosis virus</i>	Annex I	New	171
<i>Streptomyces griseoviridis</i> (K61)	Annex I	4	172
Tebuconazole	Pending	3	173
Tetraconazole	Pending	3	174
Thiabendazole	Annex I	1	175
Thiophanate-methyl	Annex I	1	176
Thiram	Annex I	1	177
Tolclofos-methyl	Annex I	2	178
Tolyfluanid	Annex I	2	179
Triadimenol	Pending	3	180
Triazoxide	Pending	3	181
<i>Trichoderma atroviride</i> (IMI 206040) (T 11) (former <i>Trichoderma harzianum</i>)	Annex I	4	182
<i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) (ICC080)	Annex I	4	183
<i>Trichoderma polysporum</i> (IMI 206039)	Annex I	4	183
Trifloxystrobin	Annex I	New	184
Triticonazole	Annex I	2	185
<i>Verticillium dahliae alboatrum</i> (WCS850) (formerly <i>Verticillium dahliae</i>)	Annex I	4	186
Ziram	Annex I	1	187
Zoxamide	Annex I	New	188
<i>Insecticides</i>			
Abamectin (aka avermectin)	Annex I	3	189
Acetamiprid	Annex I	New	190
Alpha-Cypermethrin (aka alphamethrin)	Annex I	1	191
Aluminium phosphide	Pending	3	192
<i>Beauveria bassiana</i> (ATCC	Pending	4	193

Active substance	Status Annex I 91/414/	Stage	#
74040 and GHA)			
Beta-Cyfluthrin	Annex I	1	194
Bifenthrin	Pending	3	195
Chlorpyrifos	Annex I	1	196
Chlorpyrifos-methyl	Annex I	1	197
Clothianidin	Annex I	New	198
Cubiet	Pending	3	199
<i>Cydia pomonella granulosis virus</i> (CpGV)	Pending	4	200
Cyfluthrin	Annex I	1	201
Cypermethrin	Annex I	1	202
Cyromazine	Pending	3	203
Deltamethrin	Annex I	1	204
Diflubenzuron	Annex I	3	205
Dimethoate	Annex I	2	206
Esfenvalerate	Annex I	1	207
Ethoprophos	Annex I	2	208
Etofenprox	Pending	3	209
Etoazole	Annex I	New	210
Fipronil	Annex I	2	211
Formetanate	Annex I	2	212
Imidacloprid	Pending	3	213
Indoxacarb	Annex I	New	214
lambda-Cyhalothrin	Annex I	1	215
<i>Lecanicillimu muscarium</i> (Ve6) (former <i>Verticillium lecanii</i>)	Pending	4	216
Lufenuron	Pending	3	217
Magnesium phosphide	Pending	3	218
<i>Metarhizium anisopliae</i> (BIPESCO 5F/52)	Pending	4	219
Methiocarb (aka mercaptodimethur)	Annex I	2	220
Methoxyfenozide	Annex I	New	221
Milbemectin	Annex I	New	222
Oxamyl	Annex I	2	223
Phosmet	Annex I	2	224
Pirimicarb	Annex I	2	225
Pirimiphos-methyl	Annex I	2	226
<i>Pseudomonas chlororaphis</i> strain MA342	Annex I	New	227
Pymetrozine	Annex I	New	228
Pyriproxyfen	Annex I	3	229
Spinosad	Annex I	New	230

Active substance	Status Annex I 91/414/	Stage	#
Teflubenzuron	Pending	3	231
Thiacloprid	Annex I	New	232
Thiamethoxam	Annex I	New	233
Triflumuron	Pending	3	234
zeta-Cypermethrin	Pending	3	235
Others			
1-Methyl-cyclopropene	Annex I	New	236
Acibenzolar-S-methyl (benzothiadiazole)	Annex I	New	237
<i>Bacillus thuringiensis subsp. Aizawai</i> (ABTS-1857 and GC-91)	Annex I	4	238
<i>Bacillus thuringiensis subsp. Israelensis</i> (AM65-52)	Annex I	4	239
<i>Bacillus thuringiensis subsp. Kurstaki</i> (ABTS 351, PB 54, SA 11, SA12 and EG 2348)	Annex I	4	240
<i>Bacillus thuringiensis subsp. Tenebrionis</i> (NB 176)	Annex I	4	241
Bifenazate	Annex I	New	242
Calcium phosphide	Pending	3	243
Carvone	Annex I	New	244
Chlormequat (chloride)	Pending	3	245
Clofentezine	Annex I	3	246
Copper chloride	Pending	3	247
Copper naphthenate	Pending	3	248
Cyclanilide	Annex I	New	249
Daminozide	Annex I	1	250
Diphenylamine	Pending	3	251
Ethephon	Annex I	2	252
Fenamiphos (aka phenamiphos)	Annex I	2	253
Ferric phosphate	Annex I	New	254
Flurprimidol	Pending	3	255
Flurprimidol	Pending	3	256
Forchlorfenuron	Annex I	New	257
Fosthiazate	Annex I	New	258
Imazaquin	Annex I	3	259
Laminarin	Annex I	New	260
Maleic hydrazide	Annex I	1	261
Mepiquat	Annex I	3	262
Prohexadione-calcium	Annex I	New	263
Sodium 5-nitroguaiacolate	Pending	3	264
Sodium o-nitrophenolate	Pending	3	265
Sodium p-nitrophenolate	Pending	3	266

Active substance	Status Annex I 91/414/	Stage	#
Tebufenpyrad	Pending	3	267
<i>Trichoderma harzianum</i> Rifai (T-22)	Annex I	4	268
Trinexapac (aka cimetarycarb ethyl)	Annex I	2	269
Warfarin	Annex I	1	271

8. Table 2. List of active substances identified in Sweden to meet the “cut-off” criteria in Annex II 3.6-3.7 adopted by the Council and may therefore not be approved

Active substance	Status Annex I 91/414/	Stage	“cut-off criteria” CMR/ED/PBT/vPvB without a “negligible exposure”	#
<i>Herbicides</i>				
Amitrol	Annex I	1	ED	1
Ioxynil	Annex I	1	ED	2
Glufosinate	Annex I	2	CMR	3
Linuron	Annex I	1	CMR/ED	4
Molinate	Annex I	1	ED	5
Pendimethalin	Annex I	1	PBT	6
Tepraloxydim	Annex I	New	ED	7
Tralkoxydim	Annex I	3	ED	8
<i>Fungicides</i>				
Carbendazim	Annex I	1	CMR	9
Dinocap	Annex I	1	CMR	10
Epoxiconazole	Annex I	3	ED	11
Flumioxazin	Annex I	New	CMR	12
Flusilazole	Annex I	1	CMR/ED	13
Iprodion	Annex I	1	ED	14
Mancozeb	Annex I	1	ED	15
Maneb	Annex I	1	ED	16
Metconazole	Annex I	3	ED	17
Quinoxifen	Annex I	New	vPvB/POP?	18
Tebuconazole	Pending	3	ED	19
<i>Insecticides</i>				
Bifenthrin	Pending	3	PBT/POP?	20
Lufenuron	Pending	3	PBT/vPvB	21
Thiacloprid	Annex I	New	ED	22
<i>Others</i>				
Flurprimidol (PG)	Pending	3	CMR?/ED	23

Total number of substances assessed	271
Divided in substances:	
on Annex I originating from stage 1	55
on Annex I originating from stage 2	31
on Annex I originating from stage 3	29
still pending on stage 3	58
on Annex I originating from stage 4	16
on Annex I as new active substances	82

Out of these 271 substances 23 (8 percent) were identified by Sweden to meet the “cut-off” criteria in Annex II 3.6-3.7 adopted by the Council and may therefore not be approved.