

Literature

Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

Manual of decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products - 2008

26 - Latest developments in the registration of SPP chemicals in Germany and Europe

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Abstract

Regulation of the European Parliament and of the Council (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in and on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. The review process of active substances under Directive 91/414/EEC led to a rapid decline in the number of available existing active substances on EU level. New active substances to protect stored products are missing. Consequently the number of available storage insecticides is reduced even more. The aim of Regulation 396/2005 is to harmonise the maximum residue levels (MRLs) on EU level to eliminate barriers to trade and to increase the transparency of the market. A reduction of MRLs and as a result the reduction of the number of available active substances is possible. Subsequently the number of gaps and resistance problems will increase. In the consequence all persons involved, including farmers, industry, government and administration, research and trade are requested to spare no effort to reach a long-term and effective store protection, which is save to users and consumers as well as the environment. The influence of the new Regulation on placing plant protection products on the market will depend on its arrangements on EU and national level.

Introduction

Referring to actual estimations about 20 to 25 % of the crops are damaged by stored product pests worldwide. The main management techniques in the protection of stored products are:

- hygiene,
- air circulation/ventilation and
- chemical treatment.

Due to different conditions during storage and infestation pressure, precautionary measures are often insufficient to protect the stored products. The infested stored products have to be treated, not only to ensure the necessary quality (nil tolerance) and quantity, but also because of health precautions. In many cases no alternatives to chemical treatment exist. At EU level two legislative regulations have an important impact on the availability of plant protection products:

- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.
- Regulation of the European Parliament and of the Council (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in and on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
- EU evaluation program for active substances under Council Directive 91/414/EEC.

Current situation regarding the evaluation of existing active substances. Table 1 shows the current situation regarding the evaluation of existing active substances.

Tab. 1 Current situation regarding the evaluation of existing active substances				
Stage	No. active substances	Inclusion in Annex I	Non-inclusion or withdrawal	Not yet decided
Stage 1	90	55	35	0
Stage 2	148	32	116	0
Stage 3	387	62	319	6
Stage 4	316	62	252*	2
Total	941	211	722**	8

*It was decided that 25 active substances from the original stage 4 do not fall under the scope of Directive 91/414/EEC. They were withdrawn from Reg. 2229/2004. **64 non-inclusions of active substances due to voluntary withdrawal (3rd stage: 49; 4th stage: 15). Authorised PPP can remain on the market. Possibly re-submission according to Reg. 33/2008.

The EU review of the 941 existing active substances was divided into 4 stages. Concerning stages 1 and 2 all decisions have been taken, i. e. 87 old substances are included in Annex I of Directive 91/414. Concerning stages 3 and 4 there are 124 substances which are included in Annex I.

This means in total:

- 211 existing active substances are included in Annex I,
- 722 are not included and
- 8 existing active substances have not yet been decided on.

Regarding the percentages:

- 26 % of the existing active substances are included in Annex I of Directive 91/414/EEC.
- 67 % have been withdrawn from the market. The reasons are
 - no dossier submitted,
 - dossier incomplete,
 - withdrawn by the applicant.
- 7 % are not included following the Peer Review because of no proof of safe application.

Consequently the review process of active substances under Council Directive 91/414/EEC led to a rapid decline in the number of available existing active substances at EU level. Table 2 shows the current situation regarding the evaluation of new active substances.

Tab. 2 Current situation regarding the evaluation of new active substances

	No. active substances	Inclusion in Annex I	Non-inclusion or dossier withdrawn	Not yet decided
Chemical active substances	129	74	8	47
Microorganisms	19	8	1	10
Total	148	82	9	57

In total 148 new active substances have to be evaluated, 129 chemical active substances and 19 microorganisms. 82 of these are already included in Annex I of Directive 91/414, 9 substances are not included. 57 have not yet been decided on.

Future work

The plans for the years 2009 - 2010 are:

- Peer Review for new active substances: > 53 active substances
- „Green tracks” (Peer Review following Annex I inclusion, Regulation (EC) No. 1095/2007): 68 active substances
- Re-submissions (Regulation (EC) No. 33/2008): 71 active substances
- Annex I renewals: 9 active substances
- Submission of confirmatory data: 26 active substances

Therefore 227 active substances in total have to be examined during the years 2009 and 2010. Situation regarding the evaluation of active substances for storage protection.

Insecticides and Acaricides: Table 3 shows the current situation regarding the evaluation program for active substances at EU level and authorisation status in Germany for insecticides and acaricides.

Tab. 3 Situation regarding the evaluation program for active substances (EU) and authorisation (Germany) – insecticides/acaricides

Substance	RMS	Status under Regulation 91/414/EEC	Status under the German Plant Protection Act	Problem area
Aluminium phosphide	DE	Included expiry: 31/08/2019	+	consumer, operator, worker and bystander exposure
Bifenthrin	FR	Pending (non-inclusion proposed)	+ (outdoor)	consumer, operator, worker and bystander exposure; contamination groundwater, protection of aquatic organisms, earth-worms and non-target arthropods
Carbon dioxide	UK	Included expiry: 31/08/2019	+	no areas of concern
Chlorpyrifos-methyl	ES	Included expiry: 30/06/2016	-	risks to birds, mammals, aquatic organisms, bees and non-target arthropods
Cypermethrin	BE	Included expiry: 28/02/2016	+ (outdoor)	operator exposure; protection of aquatic organisms, bees and non-target arthropods
Deltamethrin	SE	included expiry: 31/10/2013	-	operator and consumer

Substance	RMS	Status under Regulation 91/414/EEC	Status under the German Plant Protection Act	Problem area
Dichlorvos	IT	not included withdrawal of authorisation: 06/12/2007 period of grace: 6/12/2008 (2007/387/EC)	-	exposure operator, worker, bystander exposure
Endosulfan	ES	not included withdrawal of authorisation: 02/06/2006 period of grace: 30/06/2007 (2005/864/EC)	-	environmental fate and behaviour, operator exposure (indoor)
Fenitrothion	UK	not included withdrawal of authorisation: 25/11/2007 period of grace: 25/11/2008 (2007/379/EC)	-	risks to operator, worker, and consumer unclear
Kieselguhr	EL	Included expiry: 31/08/2019	+	operator and consumer exposure, protection of aquatic organisms, bees and non-target arthropods
Lambda-Cyhalothrin	SE	Included expiry: 31/12/2011	+	
Magnesium phosphide	DE	included expiry: 31/08/2019	+	consumer, operator, worker and bystander exposure risks to operator, worker, bystander and consumer unclear
Malathion	FI/ UK	not included withdrawal of authorisation: 06/12/2007 period of grace: 06/12/2008 (2007/389/EC) re-submission!	-	
Methyl bromide	UK	not included withdrawal of authorisation: 18/03/2009 period of grace: 18/03/2010 (2008/753/EC)	-	insufficient data; bystander and consumer exposure; acute, short and long term risks to birds and mammals; toxicity to non-target arthropods and earthworms; ozone depletion (Montreal Protocol)
Nitrogen	-	not included (2004/129/EC)	-	insufficient data or not notified
Permethrin	IE	not included (2000/817/EC)	-	insufficient data or not notified
Phoxim	FI	not included (2007/442/EC)	-	insufficient data or not notified
Phosphane	DE	pending (dossier complete)	+	operator exposure, MRLs piperonyl butoxide (synergist)
Pirimiphos-methyl	UK	Included expiry: 30/09/2017	+	
Pyrethrins	IT	Included expiry: 31/08/2019	+	
Sulfuryl fluoride	UK	pending (dossier complete)	+	

Rodenticides: Table 4 shows the current situation regarding the evaluation program for active substances at EU level and authorisation status in Germany for rodenticides.

Tab. 4 Situation regarding the evaluation program for active substances (EU) and authorisation (Germany) - rodenticides

Substance	RMS	Status under Regulation 91/414/EEC	Status under the German Plant Protection Act	Problem area
Brodifacoum	-	not included (2007/442/EC)	+ essential use; expiry: 31/12/2010)	insufficient data or not notified
Bromadiolone	SE	not included (voluntary) withdrawal of authorisation: 31/12/2010; period of grace: 31/12/2011 (2008/941/EC) re-submission?	+	
Calciferol	-	not included (2004/129/EC)	-	insufficient data or not notified
Chloralose	-	not included (2007/442/EC)	-	insufficient data or not notified
Chlorphaci-none	PT	not included (2007/442/EC)	+ (outdoor) essential use; expiry: 31/12/2010)	insufficient data or not notified
Coumatetralyl	-	not included (2004/129/EC)	-	insufficient data or not notified
Difenacoum	FI	Included; expiry: 30/12/2019 only uses in the form of pre-prepared baits placed in specially constructed, tamper resistant and secured bait boxes are authorised, the nominal concentration of the	+	further information on methods for the determination of residues in body fluid and on the specification is needed

Substance	RMS	Status under Regulation 91/414/EEC	Status under the German Plant Protection Act	Problem area
Difethialone	PL	active substance in the products shall not exceed 50 mg/kg not included (2004/129/EC)	-	insufficient data or not notified
Diphacinone	-	not included (2004/129/EC)	-	insufficient data or not notified
Flocoumafen	PL	not included (2004/129/EC)	-	insufficient data or not notified
Hydrogen cyanide	-	not included (2004/129/EC)	-	insufficient data or not notified
Phosphane	DE	pending (dossier complete)	+	
Warfarin	IE	Included expiry: 30/09/2013	+ (outdoor)	only uses in the form of prepared bait if appropriate, placed in specially constructed hoppers; protection of operators, birds and non-target mammals
Zinc phosphide	DE	not included (voluntary) withdrawal of authorisation: 31/12/2010 period of grace: 31/12/2011 (2008/941/EC) re-submission?	+	

Regulation (EC) No 396/2005: The aim of Regulation 396/2005 is to harmonise the maximum residue levels (MRLs) at EU level to eliminate barriers to trade and to increase the transparency of the market. A reduction of MRLs and as a result the reduction of the number of available active substances is possible and subsequently an increase in the number of use gaps and resistance problems as well as misuse.

Authorisation situation for storage protection in Germany - Insecticides and Acaricides: Table 5 shows the authorisation situation for storage protection in Germany regarding insecticides and acaricides.

Tab. 5 Authorisation situation for storage protection in Germany – insecticides/ acaricides

Active substance	Number of authorised plant protection products*	Applications
Aluminium phosphide	5	rooms, silo units, sacks; stored cereals, cereal products, starch, expeller, dried fruit, dried vegetables, pulses, cocoa, tea, coffee, spices
Carbon dioxide	2	stored cereals, cereal products, fatty seeds, tobacco, tea, spices, medicinal plants, dried fruit
Kieselguhr	1	rooms; stored cereals (conveyor belt)
lambda-Cyhalothrin	1	hardwood/softwood (consignments)
Magnesium phosphide	3	rooms; stored cereals, cereal products, dried fruit, dried vegetables, tobacco, cocoa, tea, coffee, spices, oil seed, nut fruits, medicinal plants, hay
Phosphane	1	stored cereals, fatty seeds, dried fruit, coffee, cocoa
Pirimiphos-methyl	1	rooms; stored cereals (conveyor belt)
Pyrethrins	1	rooms
Sulfuryl fluoride	1	rooms; dried fruit, nut fruits, hardwood/softwood (consignments)

*not including transfers of authorisation

Rodenticides: Table 6 shows the authorisation situation for storage protection in Germany regarding rodenticides.

Tab. 6 Authorisation situation for storage protection in Germany - rodenticides

Active substance	Number of authorised plant protection products*	Applications
Brodifacoum	2	common rat, domestic mouse
Bromadiolone**	2	common rat, domestic mouse
Difenacoum	2	black rat, common rat, domestic mouse
Zinc phosphide**	1	domestic mouse

*not including transfers of authorisation; ** re-submission?

Selected examples

Dichlorvos: Control of storage pests (moths and beetles) in the presence of stored goods and taking a relatively short exposure time into consideration. Non-inclusion in Annex I of Directive 91/414/EEC and withdrawal of authorisations by 6 December 2007 (deadline for selling stocks 6 December 2008). Evidence that estimated operator, worker and bystander exposure is acceptable could not be provided.

Phosphor-methyl: Significance for safe cereal protection for post-harvest treatment, concerning both the decontamination of empty rooms and pest control in cereals and equipment. Inclusion in Annex I of Directive 91/414/EEC. Only applications using automatic systems in empty rooms are permissible unless the Member States pay special attention to operator safety and observing maximum residue limits for other authorisations. Alternatives are highly toxic fumigation products (PH3) which can often not be used due to constructional reasons. During the process of evaluation at Community level, toxicological threshold values (ADI, AOEL) were reduced, but can still be complied with. However, consumer protection is being discussed at EU level (exhausting the ADI). It is therefore uncertain whether the maximum residue limits will apply in the long term.

Sulfurylfluoride: The procedure for inclusion in Annex I of Directive 91/414/EEC is not yet completed. In the context of the harmonisation of maximum residue limits according to Regulation (EC) No. 396/2005, fluoride was considered as a metabolite which occurs during application. The admissible maximum limit for cereals was set at the level of the analytical limit of determination of 2.0 mg/kg. Because the product was not listed in Annex I of Regulation (EC) No. 396/2005, no maximum limit was determined for dried fruit. It must be clarified legally whether the standard value of 0.01 mg/kg is valid. Consequently, it is not assured that the maximum limits for applications in rooms in the presence of cereals and dried fruit which are valid as from 1 September 2008 can be complied with. Authorisations were amended by restrictions so that the co-treatment of cereals was excluded.

Summary and perspectives: The limited range of active substances/plant protection products for storage protection is alarming (gaps, resistance, misuse). Preventative measures are becoming more and more important, but are still not adequate. The different kinds of storage goods, pests, local conditions, etc. require different active substances, formulations and application techniques. Many non-chemical measures are not yet ready to be put into practice or are problematic as far as food legislation is concerned. Regulations should not compete with one another but should complement one another (plant protection products, biocides). All those persons involved, including farmers, industry, government and administration, research and trade, are requested to spare no effort to find solutions for adequate storage protection which is safe both for operators and consumers as well as for the environment. Effects of the revision of Directive 91/414/EEC (for example cut-off criteria, zonal authorisation, mutual recognition) on the availability of storage protection products are open. The influence of the revision on placing plant protection products on the market will depend on its arrangements at EU and national level.

27- The new Regulation on placing plant protection products on the market – possible impacts on stored products protection

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Abstract

On 13th January 2009, the European Parliament accepted in second reading a compromise text on a new Regulation on placing plant protection products on the market. The proposal still needs to be formally adopted by the Council before publication and entry into force. The new Regulation provides for important improvements in the framework of assessment and approval of active substances. Although the scope of the new Regulation will not change, and also the borderline to biocides legislation will stay the same, some provisions in the new Regulation might also have an impact on stored products protection. The new Regulation provides for clear criteria for approval of active substances: substances which are considered as persistent organic pollutant (POP), as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) under the REACH Regulation or which are classified as mutagenic (cat. 1 or 2) will not be approved under the new system. The same applies to substances which are classified as carcinogenic or toxic to reproduction (cat. 1 or 2) or which are considered as endocrine disruptors, unless the exposition of humans is negligible under realistic proposed conditions of use. However, active substances classified as carcinogenic cat. 2 with threshold, toxic to reproduction (cat. 1 or 2) or which are considered as endocrine disruptors can be approved under restricted conditions if they are necessary to control a serious danger to plant health.

It can be expected that the approval criteria will speed up decision-making and increase the legal certainty for notifiers, but will also lead to a decrease in the number of active substances available. The number of products available to users is, however, not expected to decrease to a significant extent, because the measure described above is counterbalanced by some other measures increasing availability of products to users, like the improved framework for minor uses or the enhanced mutual recognition within the zonal system. Under this system, the EU is divided into three evaluation zones (North, Center, South). For some uses (e. g. empty storage premises, post-harvest treatments) the whole EU is considered as one zone.