

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.

The zonal system provides for obligatory mutual recognition of authorisations within one zone and for voluntary mutual recognition between different zones. The procedure of mutual recognition has been streamlined and strict timelines apply. Member States, when recognising an authorisation, may modify the risk mitigation measures in order to adapt the authorisation to their own purposes; if this is not sufficient and an unacceptable risk persists, the recognition can be refused.

Other provisions of the new regulation, like comparative assessment and substitution, shall have no detrimental influence on the availability of products, if they are implemented on a scientifically and technically sound basis.

Important objectives of the proposal:

- To protect human and animal health and the environment
- To safeguard the competitiveness of agriculture
- To improve the functioning of the common market
- To speed up decision making

Key issues:

- Zonal system and obligatory mutual recognition
- Criteria for approval
- Comparative assessment and substitution principle
- Minor uses
- Scope (safeners & synergists, co-formulants)
- IPM
- Monitoring and controls
- Human testing
- Low risk/basic substances
- Information about use

Zonal Mutual Recognition:

Art 40 (also: 41, 36)

- 3 zones in general, one zone for greenhouse, post-harvest, storage rooms and seed treatment)
- Initial evaluation shall take into account the whole zone
- All Member States of a zone can participate in evaluation
- Different time periods for initial (12+6 months) and recognised authorisation (120 days)
- Obligatory Mutual Recognition within a zone
- Voluntary Mutual Recognition between zones, for candidates for substitution, for provisional authorisations, for derogations under art. 4(7)
- Mutual recognition no longer needs consent of authorisation holder in case of a prevailing public interest
- Adapting risk mitigation measures is possible in order to address the specific situation in a MS
- Possibility to refuse Mutual recognition in case of a serious risk for health or the environment

Criteria for approval:

Annex II.3

- CMR cat. 1&2, POP, PBT, vPvB, endocrine disruption
- Exemption for CR cat. 1&2 and ED if only negligible exposure to humans
- Endocrine Disruptors:
- COM to present specific scientific criteria within 4 years
- Transitional regime: CR cat. 3 shall and R cat. 3 + toxic to endocrine organs may be considered as endocrine disruptors

Art. 4(7)

- Derogation in order to control a serious danger to plant health
- Endocrine disruptors and CR cat. 2 can be approved for 5 years
- MS to report on possible phasing out
- No residues
- Burden of proof on notifier

Substitution and Comparative Assessment:

Art. 50, Annex II.4, Annex IV

- Candidates for substitution identified at EU level
- Comparative Assessment at MS level
- Criteria: high ADI/ARfD/AOEL, PB/PT/BT, non-manageable concerns (critical effect + exposure pattern), high in non-active isomers, falls under point 3.6.3-3.6.5 together with negligible exposure
- Approval period: 7 years

Conditions:

- o significantly lower risk
- o no significant economic or practical disadvantages
- o sufficient chemical diversity to minimise occurrence of resistance
- o sufficient experience
- o minor uses are taken into account

Transition:

- o One authorisation without comparative assessment of 5 years in order to gain experience
- o Compliance deadline 3 years after assessment

Minor uses:

Art. 51

- Definition in the text
- MS may take measures to facilitate or encourage applications
- Off-label extensions
- Mutual recognition of extensions possible
- "Minor uses fund" within two years after entry into force

For more information please consult our new website:

http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm

Please keep in mind: Regulation = directly applicable in MS,

Legislative framework, many technical issues to be tackled during the implementation phase (31 tasks for implementation given to COM),

Scope unchanged (also with respect to biocides),

Zonal system and comparative assessment must be seen as complementary concerning MS workload.