Newsletter

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SPECIAL EDITION

AGROCHEMICALS

Proposal for the revised 91/414/EEC adopted by European Parliament

On 13 January 2009 the European Parliament (EP) adopted in the second reading the proposed regulation for the revision of Directive 91/414 (the proposed new Regulation). In the next step, the new legislation will be formally adopted by the Council. A specific date for this step has not yet been announced. After publication in the Official Journal, the new legislation will enter into force this year with a foreseen implementation during the second half of 2010.

The following summarizes a number of important issues which impact the plant protection industry.

Approval criteria

As published by the EP, no substances will be banned immediately. Approvals of active substances made under the existing legislation (current Directive 91/414/EEC) for the standard 10-year period will remain in effect until the end of that period. The evaluation criteria (i.e. "the cut-offs") from the new Regulation will only be applied when these substances come up for re-approval.

According to the EP's proposal of 13 January 2009, actives which are to be classified in one of the following categories will not be approved:

- Mutagen (M) category 1 or 2
- Carcinogen (C) category 1 or 2, unless exposure to humans is negligible
- Toxic to reproduction (R) category 1 or 2, unless exposure to humans is negligible
- Endocrine disruptors (EDs) causing adverse effect on humans, unless exposure to humans is negligible
- Endocrine disruptors causing adverse effect on non-target organisms, unless exposure is negligible
- Persistent Organic Pollutants (POPs)
- Persistent Bioaccumulating and Toxic (PBT) substances
- very Persistent and very Bioaccumulating (vPvB) substances.

In addition to the above-mentioned aspects, a special paragraph on the protection of honeybees was introduced to the new Regulation (see 3.8.3.):

> "an active substance … shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance…:
>
> - will result in a negligible exposure of honeybees, or
> - there are no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior."

With the revision of Directive 91/414/EEC, the issue of endocrine disruption was introduced as an approval criterion for substances as well. According to the EU Commission (COM), "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."

At this point it must be emphasized that based on SCC's knowledge, there are no approved guidelines (international or EU) available on how substances with possible endocrine disrupting properties are defined or assessed. For this reason, it is unclear how EDs will be taken into account by the responsible EU institution. Consequently it is unknown which actives used in plant protection products (PPPs) will finally be identified as ED. The Commission must present scientific criteria for the determination of endocrine disrupting properties four years after entry into force of the proposed new regulation at the latest. As long as such criteria are not adopted, substances that are classified as carcinogen category 3 and toxic for reproduction category 3 "shall be considered to have endocrine disrupting properties".

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Based on these definitions for "the cut-offs", KEMI, the Swedish regulatory authority concluded that approximately 22 substances (out of the substances which have been included to Annex I until September 2008) will not be re-approved after the expiration of their regular registration period under the current 91/414/EEC.

This list is not part of the law but, according to our information, it is regarded as a realistic assessment by EU institutions.

For further information please refer to http://www.kemi.se/upload/Bekampningsmedel/Docs_eng/SE_positionpapper_annenII_sep08.pdf.

The proposed new Regulation offers the possibility for substances which do not comply with approval criteria but are necessary to control certain pests, to be approved for up to five years. During this time, alternative methods for the control of the respective pest must be developed.

Candidates for substitution

The proposed new Regulation introduces the "approval category" candidate for substitution. Substances which fall under this group will receive approval "for a period not exceeding seven years". Renewal of the approval is possible.

Four years after entry into force of the new Regulation (foreseen for 2013), COM must compile a list of all substances classified as candidates for substitution. If PPPs to be authorized contain substances approved as candidates for substitution, Member States are obliged, in addition to other activities, to carry out a comparative risk assessment. If candidate substances do not fulfill certain safety criteria (refer to Annex IV of the proposed new regulation), PPPs containing these actives may not be authorized or their use can be restricted.

The goal of this new approval category is to replace candidates for substitution with safer alternatives that are already on the market. Substances are categorized as candidates for substitution if they fulfill one of the following criteria (criteria for the low risk substances are not included):

- ADI, ARfD or AOEL is significantly lower than those of the majority of the approved actives
- Two of the PBT criteria are met
- There are critical effects for example such as developmental neurotoxic or immunotoxic effects or a high potential risk for groundwater
- A significant proportion of non-active isomers is contained in the substance
- Carcinogen category 1 or 2 (in case the substance has not been excluded in accordance with the criteria laid down in point 3.6.3 "Impact on human health" of the EP proposal ("cut-off criterion" carcinogenicity))
- Toxic for reproduction category 1 or 2 (in case the substance has not been excluded in accordance with the criteria laid down in point 3.6.4, "Impact on human health" of the EP proposal ("cut-off criterion" toxic for reproduction))
- Considered to have endocrine disrupting properties which have adverse effects in humans in case the substance has not been excluded in accordance with the criteria laid down in point 3.6.5 "Impact on human health" of the EP proposal ("cut-off criterion" ED properties).

Mutual recognition

For the purpose of mutual recognition of authorizations for plant protection products, the EU territory was divided into three zones:

- Zone A North: DK, EE, LV, LT, FI, SE
- Zone B Centre: BE, CZ, DE, IE, LU, HU, NL, AT, PL, RO, SI, SK, UK
- Zone C South: BG, EL, ES, FR, IT, CY, MT, PT.

In each of them agricultural, plant health and environmental conditions are comparable. Holder of authorizations for PPPs may apply for mutual recognition of authorizations of the same product for the same use in another member state if the Member State belongs to the same zone. Under certain restrictions, mutual recognition of authorizations between Member States in two different zones (for example Italy and Sweden) is possible as well.

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Data protection

According to the resolution, test and study reports on a defined plant protection product are protected for a period of 10 years (13 years for PPPs based on low risk substances) starting at the date of first authorization in one Member State. Studies necessary for the renewal or review of authorizations are data protected for an additional period of 2.5 years.

All animal testing involving vertebrate animals must be justified; duplicative testing on vertebrate animals must especially be avoided. Applicants and holders of authorizations must therefore take all efforts to share existing tests and studies involving vertebrate animals. If the prospective applicant and the holder of the relevant authorization fail to reach agreement on the sharing of data, the competent authority can use the tests and study reports for the evaluation of the new application.

Parallel Trade

Parallel trade of plant protection products is possible as long as they are considered identical to the reference product in the member state of introduction. The term “identical” is among others defined as manufactured by the same company, identical specification and equivalent or same co-formulants.

If you would like to know what these new provisions mean for the approval of your active substances, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.

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