Newsletter

Volume 8, No. 2, March 2007 – Special Edition

AGROCHEMICALS

Information meeting for national registration of plant protection products held at the German BVL on 28 February 2007

The regulatory world for plant protection products (PPPs) according to Directive 91/414/EEC is a rapidly changing one. To keep track of the changes, continual updates are necessary and conclusions have to be drawn as to how new requirements may impact the national registration of PPPs. The German Federal Office for Consumer Protection and Food Safety (BVL) regularly updates applicants on the developments on European and international level and how the new requirements are implemented on the national level in Germany. On 28 February 2007 they held their regular meeting at Braunschweig which was open to all applicants.

National registration in Germany – Areas of improvement for applicants

Dr. C. Landsmann (BVL)
Dr. A. Wilkening (BVL)

The registration process at the BVL starts with the pre-evaluation. This phase is split up in two parts: completeness check and plausibility check. During this first phase in 2006, 55 of the 129 submitted dossiers have already been blocked. In most cases this is due to the fact that formal requirements have not been fulfilled, e.g. incomplete registration forms or incorrect use of the new OECD format for the structure of the dossier (Doc O evaluation forms 1 to 4), deficiencies in the reference lists, incomplete application forms, missing Good Laboratory Practice (GLP) certificates, and other inconsistencies between the submitted documents. Also in light of the upcoming electronic application system "BundOnline" (which will start 1 July 2007), it is obligatory that submitted dossiers be accurate in terms of content as well as formal requirements. Otherwise the evaluation cannot go ahead and consequently the registration will be delayed.

In order to speed up the evaluation process and its internal co-ordination, Dr. Landsmann proposed that applicants inform the authority at least four weeks prior to the scheduled date of a new dossier submission.

The BVL estimates approximately one year for the finalization of the main evaluation, which follows the pre-evaluation phase. Due to the enormous workload at the authority, this deadline often cannot be met. However, the system is improving: compared to 2005, the backlog has been significantly reduced. Today, out of 104 submitted applications, only 15 are delayed.

A number of dossiers are blocked in the main evaluation, mostly due to interventions by the German Environmental Agency (UBA). Often there are open questions in the fields of (avian) toxicology and ecotoxicology (substances suspected of having endocrine disrupting potential). Open questions in this field often lead to additional higher tier studies.

For substances which need to be re-registered applicants must take into account a re-evaluation time of 2 – 3 years. As a result, the respective dossier must be submitted to BVL 2 to 3 years before the registration expires.

Forecast for 2007

On the national level, the BVL expects a reduced workload for 2007, as fewer applications will probably be submitted and only a limited number of products are scheduled for re-evaluation. The implementation of "BundOnline" will lead to a temporary increase of work. To fulfill the evaluation duties as a rapporteur member state (RMS) on the EU level, all of the BVL's resources will be used.

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Mutual recognition

Dr. D. Gottschild (BVL)

Under Directive 91/414/EEC member states (MSs) can, under specific conditions, recognize evaluation dossiers from other EU members. The implementation of this process has proven to be rather difficult among EU MSs because evaluations by other authorities were in many cases not accepted. Dr. Gottschild pointed out that in general, there is increased confidence in the evaluations made by other authorities, and the acceptance of foreign evaluations is expected to grow. As he reported, the BVL had received nine applications for mutual recognition by February 2007, five of which have been granted. The original registrations were granted by the United Kingdom, the Netherlands (2), Finland and Denmark. German registrations for PPPs are generally mutually recognized by the Czech Republic, Lithuania and Poland; in Austria, all German registrations are accepted by law. Due to organizational changes and related communication problems in the French registration authority, mutual recognition in or from France seems to be difficult at the moment.

The application time for mutual recognition in Germany is 12 months. This timeframe is often exceeded due to communication problems among the involved authorities. In order to improve the situation between the MSs, the Pesticide Safety Directorate (PSD - registration authority in the UK) and the BVL have set up the JULIA project with the purpose of bilaterally supporting the exchange of evaluation information for PPPs. A second reason for delays in the registration via mutual recognition is that uses for which products are registered often differ between the country granting the original authorization and the country in which mutual recognition is sought. If this situation occurs, it is recommended to contact the BVL directly. This is a known problem and it is under discussion among the MSs; however, no solution is foreseen at the moment.

To increase transparency, the BVL has published a guidance document on mutual recognition. The document can be found under http://www.bvl.bund.de.

National process following Annex I inclusion of actives under 91/414/EEC

J. Kunze (BVL)

The EU harmonized procedure on the national level after Annex I inclusion of an active substance is as follows:

Six months after the Annex I inclusion has entered into force, the approval holders have to demonstrate access to a dossier satisfying the requirements of Annex II and to demonstrate compliance of the active substance with the relevant conditions of the Annex I inclusion.

In a period of four years the Annex I inclusion has entered into force, national authorities have to ensure that PPPs containing this active substance have been evaluated in accordance with Annex VI (the uniform principles for product evaluation) of Directive 91/414/EEC. This evaluation has to be done on the basis of a dossier satisfying the requirements of Annex III (product specific) data.

In Germany, submission of an Annex III dossier is part of the registration process of PPPs, evaluated according to uniform principles. Therefore, it is not necessary for notifiers to provide further submissions (as described above) to the BVL after inclusion of the active substance into Annex I of Directive 91/414/EEC. The BVL reviews the registration based on the respective directive and will ask for post-submissions accordingly.

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Groundwater metabolites

Dr. M. Streloke (BVL)

There are two opinions as to when metabolites in groundwater become relevant. One opinion is that values of more than 10 µg/l in drinking water are still tolerable (guidance document SANCO/221/2000). Another opinion, which the German drinking water commission follows, says that metabolites above 0.1 µg/l are already relevant, and can lead to closure of drinking water sources, for example.

In the case of the authorized substance Tolylfluanid (the active ingredient in the PPP Euparen), the metabolite Dimethylsulfamide was detected in November 2006. This is a problem because the metabolite may be converted during the ozonisation process for drinking water into a nitrosamine which can be harmful for health.

The registration holder informed the German authorities immediately. Until a wide-ranging management solution is found, outdoor uses of Euparen and products containing Tolylfluanid have been temporarily suspended in Germany.

For PPPs based on Chloridazon, an unspecified metabolite was detected that exceeded 10 µg/l in drinking water. Due to the fact that the metabolite is not relevant, no immediate action was necessary.

In both cases, communication between the notifiers and the German authorities (the German Ministry of Health - BMG, the Federal Environment Ministry - BMU, and Federal Ministry of Food, Agriculture and Consumer Protection - BMELV) has been cooperative and very fruitful.

The German authorities are aware of the problem and are in the process of developing management plans on how to deal with this issue in general. It is assumed that metabolites will occur for 20% of the active substances. Therefore, this issue will lead to further discussions in the future and might have a negative influence on public opinion on PPPs.

Data requirements for residues and setting of MRLs

Dr. K. Hohgardt (BVL)

Setting of maximum residue limits (MRLs) according to European regulation 396/2005: please refer to SCC Newsletter Vol. 7, No.1 from January 2007 for further details on this subject.

Regulation 396/2005/EC on maximum levels of pesticides in or on food and feed of plant and animal origin has seven Annexes. Annex III to the regulation, listing the temporary MRLs, is currently under development.

Status of Annex III

EU member states submitted national MRLs from their respective countries to the European Commission (the Commission), which were forwarded to the European Food Safety Authority (EFSA) in June 2005 with the request for an official opinion. However, the compilation received contained numerous errors, e.g. group and single value MRLs were mixed.

Integral part of the discussion on MRLs:

- When and on which basis were the different reference values (ADI and ARfD) deduced?
- Different diets in different countries have been taken into account.

Further actions:

- Proposal by EFSA on the temporary MRLs and identification of those MRLS which are not safe was expected by end of February.
- When the EFSA proposal is available, the MSs will get a period of 10 to 12 working days to comment on the proposal.
- Draft MRLs will be revised by EFSA (scheduled for March 2007)
- Draft will be discussed with COM in mid-2007. Annex III of the Directive could then enter into force in 2008.
- WTO will be involved prior to entering into force.

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Obstacles to directive: WTO agreement and discussion in Parliament.

Concerns:

The procedure might lead to the loss of uses for many active substances. National registrations will have to be adapted after entry into force. Uses and applications are expected to be subject to change.

OECD test guidelines adapted to European regulatory frame

A number of OECD test guidelines on metabolism and residues in livestock, crops and rotational crops (test guidelines 501 – 505) were adapted at the beginning of January 2007. The content of the OECD guidelines is broader than those under the scope of plant protection in the EU. For example, EU requirements do not cover hygiene in animal houses and dermal treatment of animals. EU guidelines will be adapted soon (not scheduled yet). Metabolism studies carried out according to either current EU guidelines or new OECD guidelines will be accepted in Germany.

A new guidance document on analytical methods of residues is scheduled for autumn 2007.

REACH and Classification and Labelling of Chemicals

S. Scherf (BVL)

REACH will enter into force on 1June 2007 and will replace all existing legislation from that date onwards pertaining the notification and registration of chemicals, such as Directive 91/155/EEC on Safety Data Sheets (SDSs). Along with REACH, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) will be implemented as well. For further information on the relation between GHS and REACH, please see SCC Newsletter Vol. 7, No. 1 from January 2007.

The content of the SDSs has to be adapted according to REACH. From 1 June 2007 onwards, the new Safety Data Sheet will have to provide at a minimum:

- Registration numbers
- Most important uses, and uses advised against
- Authorization information (as listed in REACH Title VII)
- Restrictions (as imposed under REACH Title VII).

For substances subject to Chemical Safety Assessment (CSA) or Chemical Safety Report (CSR) under REACH, a further elaboration of the SDS is needed. From 1 June 2008 onwards an extended SDS (extSDS) is required for the following substances:

- Substances classified as dangerous
- PBT/vPvB substances
- Substances produced or imported at or above 10 t/yr

On 14 March 2007 the BVL's expert round met to discuss how to manage the implementation of the new SDSs and the starting date for when the news SDSs have to be provided.

With the implementation of GHS, new risk pictograms, risk and safety (R&S) phrases, and risk keywords will be added to labels. In addition, trigger values for the classification of chemicals will change (most likely lowered). No timeline was provided with regard to the implementation date.

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E-Application: Training sessions scheduled for applicants

Dr. A. Wilkening (BVL)

Since 2002, the BVL has been in the process of testing its electronic application system "BundOnline". During this period, 9 out of the originally scheduled 10 applications were introduced to the system. Out of the 9 dossiers, 3 have reached the main evaluation. One dossier will have finished the main evaluation in May 2007. Two applications were not complete, three are in the completeness check, and one is blocked.

So far, a number of technical problems have occurred, such as the program closing down before work was finished, long download times, accessibility of code lists, and missing instructions; however, according to the BVL, these problems have been solved .

Starting 1 July 2007, BundOnline will be available for all notifiers. Applications made on paper will be scanned by the BVL and introduced in the new system. All applicants will be able to access BundOnline via a password-protected website. They will be able to follow the status of their application online which will improve transparency for the applicants. Also for studies submitted via Computer Aided Dossier and Data Supply (CADDY), applications were blocked due to technical errors: missing or incorrect labelling of the CDs, missing conformity test, wrong number of submitted copies of CADDY dossier (4!), separate CDs for Annex II and III data, and incomplete or wrong Index files. Post submission for dossiers already handed in can be sent via CADDY but must be filed separately.

Internally, the BVL expects the following improvements with the electronic application system: less paper work (better handling, reduced storage facilities necessary), possibility of working in parallel, and improved internal co-ordination.

A training session for all applicants is planned for May/June 2007. BVL will set up a help desk. Contact persons will be C. Landsmann and A. Spinti. Additional information will be published as soon as it is available.

For further details regarding this meeting, please contact
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