



SCC Newsletter

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“Nationale Pflanzenschutzmittelzulassung” (National Registration of Plant Protection Products)

Information Meeting for applicants held at the German BVL on 16 February 2005

Location:	BVL, Braunschweig
Participants from SCC:	Dr. Bernd Brielbeck Christian Beck Heike Schimmelpfennig

The German Federal office for Consumer Protection and Food Safety (BVL) held an information meeting in Braunschweig on 16 February 2005 regarding the national registration of Plant Protection Products. The participants of SCC summarize below the important aspects of this meeting.

1. Status of the pre-evaluation

Dr. Holzmann, BVL, Braunschweig

Current situation

There are 328 applications under evaluation. 50 applications have request with postponing/blocking effect and the evaluation of 23 applications in completeness check (Vollzähligkeitsprüfung) and 79 applications in plausibility check (Vollständigkeitsprüfung). The annual mean of evaluations processed by the BVL is about 10 applications per month.

Measures of BVL to accelerate the evaluation procedure:

The BVL has set the following priorities. §15 applications are evaluated r §18 application and national dossiers take priority before EU dossiers.

Application areas are fixed during the completeness check (Vollständigkeitsprüfung). In the future, phys/chem parameters and identity of the active and preparation also are to be assessed during the plausibility check.

To avoid peaks in the application submissions like in December 2003 and 2004 (27 applications) BVL asks to spread the application submissions throughout the year.

In order to speed the evaluation process the BVL offers turbo-check and ask for the submission of electronic reference lists (word, excel, caddy). Most importantly industry should provide complete and comprehensive applications and dossiers.

2. Status of the main-evaluation

Dr. Wilkening, BVL, Braunschweig

BVL acknowledges the following problems raised by industry:

- Security of planning
- Delays caused by post- submissions

Future problems to keeps BVL timelines:

- Move of BBA to Dessau in April
 - Reorganisation of BfR (also responsible for biocide evaluation)
 - Concerning §15 application:
- BBA is holding all timelines
- UfR has 20 delays in §15 (will be remedied), and problems/delays in §1
- UBA has 50 delays

Measures of BVL accelerate the evaluation procedure:

- Latest 18 weeks after start of the evaluation BVL receive preliminary information reports from BBA, BfR and UBA (on e.g. relevant metabolites etc)
 - 4 different priority lists are currently in use at the BVL:
 - National procedure
 - Activities in the EU
 - Residue MRL regulation (Rückstandshöchstmengenverordnung)
 - Plant strengtheners and additives
 - Priority setting within individual lists:
 - according to necessity of agricultural practice
 - priority to applications according to §15c, if ai is already included into Annex I
 - Companies can discuss the priority listing of their own applications with BVL (during the main evaluation)
- Concerning §15c:
 - A simplified extension/prolongation procedure after Annex I inclusion (email to BVL lawyer is sufficient)
 - Higher priority setting of application evaluation after Annex I inclusion
 - BVL initiated a legal initiative to treat the extension /prolongation of 315c like the extension procedure for §16 (2)
 - Submission of post.-submission :
 - Post.-Submission during or at the end of the main evaluation legally always causes resetting of the main evaluation to TO (the application is set to the last place of the waiting list)
 - Inter –authority agreement (exception):

Studies which are easy to evaluate are exempt of this resetting (lists of study exists internal but will not be published). The submission are to be discussed case by case with the BVL. Interruptions during the main evaluation amount to less than 10%

- Increase of planing security:
New scientific insights /information will be put on the BVL homepage
- Concerning §16 (2):
Partial extension of application areas are possible now (92 extension of registration granted and 8 negative decisions given)

Additional information:

- An organisation chart of the BVL will not be published . The contact person for national registration applications is Mr. Werner
 - In the future G18 will be reviewed more critically

3. New legal position on parallel import

Herr Uteß, BVL, Braunschweig

All Points raised in this section are made with references to: zweites Gesetz zur Änderung des Pflanzenschutzgesetzes (Drucksache 871/04), which is expected to enter into force by mid 2005.

Parallel import:

- Prior to the first import permit (Verkehrsfähigkeitsbescheinigung) must be obtained from the BVL. Exempt from this regulation are imports for own needs
- Parallel import approval is tied to the registration duration of the reference product
- If the application of the reference product is withdrawn without scientific reason by the registration holder the parallel imported product can be sold one year longer before the sell out period starts
- It is nit mandatory that the manufacture of the ai of the imported product is identical to the manufacture of the ai of the referent product. Adequate similarity of the parallel import must be proven (5 batch analysis)

Other issues addressed in the law:

- Changes in §11 (2) – imminent danger
- Recording of application amounts in professional use
- Waste management becomes mandatory

4. Mutual recognition of authorizations according § 15 PflSchG

Dr. Gottschild, BVL, Braunschweig

- Official label and instructions of use officially translated into German
Declaration Official details can be obtained from the BVL homepage.

Prerequisite for mutual recognition:

- Registration in one Member state (MS) in the EU
- Conditions of use in the MS must be comparable to Germany
- Annex I inclusion under observance of 91/414EEC Annex VI

- Risk assessment will not be conducted again but has to be comprehensible

Required documents from the applicant are:

- Copy of the registration certificate of the MS (with official translation)
- of the MS on Annex I inclusion of ai according to 91/414 Annex VI
- Identity of the product must be submitted
- Comparability of application conditions must be shown
- Adequate applications from must be submitted (specimen on BVL homepage)

Additionally required documents are (normally obtained by the registration authorities; to speed up the process the applicants can ask for the information directly):

- Registration report (in English)
- Complete Annex III
- Analytical method for residues determination
- Analytical method for determination of active and impurities in the technical material and of the active ingredient in the product

Currently occurring problems:

- Missing registration reports
- Registration not according to 91/414 Annex VI
- Language barriers

Additional information:

- 15 applications are under evaluation, but no decision has been made until now.
- The duration of the procedure is estimated to be 6 to 12 months
- There is one twin project (= Julia project), evaluating a project is parallel with PDS (work share), ongoing
- The registration in Germany is considered to be an independent registration . However, the registration period is tied to the original registration granted in the other MS. Both registration expire together
- The BVL can modify the application areas to suit national requirements
- If an ai listing was approved according to old guidance documents, Germany can still grant registration according to §15b but can modify application areas according to the national needs
- The BVL currently writes registration reports routinely in German but this will be adapted to English in the future. The application can ask for the registration report if mutual recognition is intended
- To simplify the comparability of the application areas. The EU Commission is intending to introduce a guideline within 2 to 3 months containing a zonal concept

5. Electronic reference lists

Dr. Holzmann, BVL, Braunschweig

The submission of the electronic reference lists is going to reduce the evaluation time needed by the BVL. If applied for in the cover letter and the application form, a 2% reduction of fees is granted, if the reference lists are submitted electronically.

Current situation:

- 50% of the references lists are submitted electronically
- 20% are submitted in excel-format
- 30% are submitted as CAADY

6. Information on the status of the EU MRL regulation

Dr. Hohgardt, BVL, Braunschweig

All points raised in this section are made with reference to KOM (2003) 117, which is estimated to be published by mid March 2005 and expected to enter into force 20 days later:

- March 2005: Member States to report their national MRLs to ESFA
 - Plus three month: appendix I is to be published
 - Plus 12 month: appendices II, III, IV to be published
- September 2006: enforcement of the directive (chapters II, III, V)
- National MRL regulation will stay in force until EU MRL regulation enters into force

No registration without MRL (except micro-organisms, ornamentals, etc.)

- MRLs a priori set to 0-01mg/kg
- 91/414 4(1)f (preliminary MRLs) will become obsolete
- MRLs must be applied for (in MS together with registration application) or as import tolerances from the EU Commission
- EFSA to develop methods for synergistic and cumulative actions of ai
- MRL exceedances can be published (name and shame policy)

The BVL plans an applicants conferences after the publication.

7. Project 'electronic registration application' within the scope of BundOnline

Dr. Lunde, BVL, Braunschweig

Expected time frame:

- The pilot phase is expected to start 31 October 2005 (BVL is asking for participants, applications should be submitted by May 2005)
- The expected starting date for the electronic work of BVL is in January 2007

Information on implementation / extend:

- Initial implementation planned for §15 application only
- Electronic submission will be less expensive than paper submission
- Dossier submission initially by CD ROMs, later via BVL homepage; however, until certified electronic signatures are introduced, the application forms must be submitted in paper form signed by the application
- If an electronic submission was initially chosen, the post submission during pre-evaluation has to be made in electronic form, also
- Post submission during the main evaluation can be done in any form (including paper)

8. Final Discussion

The BVL has no intention to implement a procedure for a date protection information system outside the application

Application for Home and Garden products will not be negatively influenced by prioritisation.

Lunde, states that upon implementation, OECD format will take precedence over EU format in all areas. In this context EU 7600/VI/95 was also discussed. BVL is currently clarifying the implications.

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