



# SCC Newsletter

## Special Edition, 17 February 2006

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

## **Information Meeting for applicants held at the German BVL on 15 February 2006**

Location: BVL, Braunschweig

Participants from SCC: Dr. Bernd Brielbeck  
Dr. Christian Beck  
Dr. Jutta Görg  
Dr. Norbert Weißmann

The German Federal office for Consumer Protection and Food Safety (BVL) held an information meeting in Braunschweig on 15 February 2006 regarding the national registration of Plant Protection Products. The important aspects of this meeting are summarized below:

#### **Status of the pre-evaluation**

Dr. A. Holzmann

371 applications are at present in the evaluation (2005: 328). Thereof 106 applications are in pre-evaluation (2005: 147).

At present, 16 (15%) of the applications are delayed in the pre-evaluation phase. 53 (50%) of the applications are blocked with postponing effect already in the pre-evaluation phase.

16 (43%) of the applications in the completeness check (Vollzähligkeitsprüfung) are blocked. In 2005, requests on reference lists with deficiencies in the efficacy area were mainly responsible for blocking. Therefore, the BVL changed its requirements. 37 (54%) of the applications are blocked in the plausibility check (Vollständigkeitsprüfung).

## Status of the main-evaluation

Dr. A. Wilkening

BVL states that the evaluation time for §15 applications increased slightly when compared to 2004. On a chart it was shown that the majority of registration certificates were granted ca. 250 to 650 days after the last start of the main evaluation phase. However, the total number of evaluations increased in 2005 as well compared to 2002. The aim of 29 weeks for the main evaluation phase was very hard to meet.

The time frame between filing of the application and granting of the registration was between ca. 400 and 1800 days, with the majority of processes between ca. 700 and 1000 days.

The internal aim is to achieve a throughput of 120 §15 applications per year. In 2005 83 decisions were taken in the Scientific Advisory Committee meetings (SVA), compared to 137 applications filed in this year.

In January 2006, 29 decisions were taken and 29 products are already scheduled for the SVA in March. This shows that the backlog is being significantly reduced at present.

The delay of §18 applications is mainly due to MRL-setting (when MRL application is handed in during the main evaluation phase of the PPP). BVL intends to co-ordinate both applications and decide in one SVA. The time between receipt of application (time Z0) and granting of certificate was in most cases between 90 and 250 days.

Time extensions according to §16(2) : 106 applications in total, thereof 2 rejections.

For products with new active substances 9 preliminary registrations were extended until application was finally evaluated.

## Outcome of the action program to eliminate the evaluation backlog

Dr. H.-G. Nolting

At the beginning of 2005 there were only 49 delays (Verfristungen). This number increased until mid 2005 to ca. 80 delays. In order to eliminate the backlog an action program was started on 11 July 2005. The following aims were set:

- Elimination of evaluation backlog until 28 February 2006
- No delays in evaluation processes of approval procedures (Genehmigungsverfahren)
- Elimination of delays in EU procedures (Germany as RMS)
- Germany should again be prepared to be available as RMS for NAS

Measures e.g.:

- Priority lists
- §16(2) extensions also for §15c products
- Optimisation of preliminary evaluations
- UBA: setting of workload aims : 30 evaluations per month

Dr. Nolting pointed out that the German authorities are involved in many other important processes, e.g.:

- §11(2): since 2003 138 applications , in 2005 only 40
- §15, §15b, §15c: currently 371 applications
- §16(2) : 113 in 2005
- §18a (25% of all applications) currently 170 proceedings
- §18b since 2000 : 3300 expert statements
- Identity proofs (Identitätsbescheinigungen)
- Parallel import requests
- EU review (91/414)

- Biocides (98/8)

Current status of delays:

BBA: 26 (thereof 3 applications with delay of >3 months), BfR: 26 (2 >3 months), UBA 36 (9 > 3 months)

Total number of applications in delay: 57 (thereof 37 with only one evaluation outstanding)

Total number of decisions in 2005:

BBA 105, BfR 120, UBA 165

Applications 2005 : 137

Dr. Banasiak (BfR) stated that to get the present backlog removed, several positions in BfR were transferred short term within BfR to PPP evaluation.

After termination of the action program in April 2006, BfR will not be able to keep the high throughput due to other obligations, esp. in the EU review of biocides. Delays for PPPs are foreseen.

Due to present backlog and the new problems to come, the depth of evaluation was reduced when compared to the detailed evaluations made in the past. If a DAR exists BfR now takes evaluations from there and no longer checks uncritical studies. Established contacts with other national authorities are used and, if possible, evaluations are taken into consideration.

Dr. Klein (UBA) stated that the UBA is working with an almost completely new team and expects to have worked up the backlog until April 2006. Then UBA will shift capacities again on other important fields, like the simplification of application regulations (Anwendungsbestimmungen).

Dr. Zwerger (BBA) stated that the BBA can not keep the number of decisions of the previous years due to a constant reduction in the number of efficacy experts.

## **New application restriction for protection of the natural environment and groundwater**

Dr. M. Streloke

The multitude of current application regulations (Anwendungsbestimmungen) are not practical, difficult to understand and to control and therefore must be simplified and reduced in number.

It was made clear that the revision of the application regulations must not lead to withdrawal of registrations.

The transition from the old system to the new one must be very quick in order to avoid two systems in parallel. Besides the authorities (BVL, BBA, BfR and UBA) IVA and plant protection services (amtlicher Dienst) are also involved in the process. Presumably the new system shall not allow exceptions. Special regulations for special areas (Sondergebietsregelungen/hot spots) should be avoided as much as possible.

Publication in the official journal (Bundesanzeiger) is expected in late Summer 2006. This should lead to a transparent and calculable system.

Five risk categories are proposed for the PPPs: Group 1 = low risk, Group 2 to 4 = medium risk, Group 5 = high risk.

Risk mitigation measures are implemented for Group 2 to 4. For products in group 5, risk-benefit evaluations will be conducted. If the benefit outweighs the risk, PPPs will be re-grouped into Group 4.

Group-criteria:

- Buffer zones (max.: field: 3 to 10 m, high crops: 10 m)
- drift-reducing measures only 2 groups: 75 and 90 %
- all high crops are to be combined (orchards, vineyards, hops)
- low risk groups: "or"-combination of risk mitigation requirements
- high risk groups: "and"-combinations of risk mitigation requirements
- probabilistic RA will be the basis for the classification instead of realistic worst case.

The basis of the probabilistic RA will be published in Autumn 2006 in the official journal (Bundesanzeiger) and further details in a regulation (Verordnung). Topographical analysis will be taken from the ATKIS data base. Probabilistic data from BBA will be available for all applicants. Some legal aspects have to be clarified before. Probabilistic RA is intended to be used in the registration process for aquatic environment, drift, high crops. Second step will include field crops, non-target plants and groundwater. Special considerations will be made for home and garden.

The federal states requested from the BBA that the use of probabilistic risk assessments in the registration process will not lead to withdrawal of existing registrations. To ensure this, the BBA was asked to present probabilistic risk assessments for critical products. Criteria for risk – benefit analyses will not be published in detail to maintain flexible decisions.

Beginning 2007 probabilistic RA (water, horticulture, hops) will start to be used in the registration process. The development of probabilistic RA for field crops and run-off will start mid 2006.

## **New legal position on parallel import**

M. Utess

- a new law is currently under preparation (publication expected in first half of 2006)
- safety standard of 91/414 must be maintained also for parallel imported products
- Verkehrsfähigkeitsbescheinigung (import permit) will be mandatory (exception: import for private use)
- Equivalence is accepted when the same amount of a.i. with the same purity is used, and the composition (formulants) is equivalent. The same producer of the product is no longer mandatory
- Laboratory proof of equivalence can only be accepted from specially certified laboratories (vereidigter Sachverständiger)
- The names of the reference product and the parallel import product are published in the official journal (Bundesanzeiger).
- The fields of use (Anwendungsgebiete) have to be identical to the reference product.
- §18/18a is also valid for the parallel import
- Import permits remain valid one year after the reference product is withdrawn (if no reasons for withdrawal are given). Then the 2 year sell out period starts.
- The import permit can be withdrawn, if the importer does not obey the obligation of surveillance of the product.
- Transitional period of new law: old import permits are valid for 1 year after entry into force
- Second import permits for the same product will be granted via a simplified procedure
- BVL states that the new law (expected before Summer 2006) sets a legal basis for the current

practise.  
The new rules will apply 6 months after entering into force.

## **Status of the Regulation (EC) Nr. 396/2005**

Dr. K. Hohgardt

The new regulation can be downloaded from the BVL homepage including annex I.

- Current status: MSs have submitted national MRLs and Commission has forwarded the values to EFSA in June 2005. The values have been put on the internet of DG-SANCO (and BVL home page) in December 2005 (the compilation contains mistakes: group and single values MRLs are mixed).
- Currently MS are post-submitting ADI and ARFD values. The date for submission has expired. Data from some MS are still missing. The new deadline for submission is unclear.
- Until April 2006 the MRLs for new cultures must be submitted
- On 6 Feb 2006 EFSA has addressed a question to the scientific panel on the correct consumption data to be used (France: highest wine consumption, Greece: highest olive consumption, UK: highest black current consumption).
- Currently new MRLs have to be transferred into national law. The date for entering into force of the new directive cannot be given yet.
- The funding by official fees is being discussed at present (see probably §6 of BVL-law).
- Germany still has MRLs for safeners and synergists while these are not yet foreseen in the EU, therefore RHMV will be in force after Regulation (EC) No. 396/2005 enters into force.

## **Mutual recognition of authorisations according to § 15b PflSchG**

Dr. D. Gottschild

Up to now no application for mutual recognition has passed the German system. It was stated that most files did not match basic requirements, e.g. the A-I-listing of the active ingredient. Applications that meet the requirements as published on the BVL website are welcome.

Mutual recognition registrations would be in Germany full registrations.

- Distribution extensions (Vertrieberweiterung) could be granted on the basis of these registrations.
- Supplement applications (Ergänzungsanträge) in Germany can only be granted if they are also supported in the original MS.
- Indications of vacancies (Lückenindikationen) are to be decided case by case depending on the data available (Datenlage) in the original member state
- Home and garden registrations can only be granted if they have been explicitly named and granted in the original member state.

Comparability of EU conditions for efficacy and residues (BVL opinion not unified with BBA)

- Efficacy:
  - protection of stored crops: no zoning (world-wide, if conditions of ware-houses are comparable)
  - glass house: two zones (north and south Europe, same as currently used in residues)
  - field: three zone model (COM) versus 4 zone model of EPPO

- Residues
  - protections of stored goods: no zoning (world-wide)
  - glass house: no zones
  - field: two zones

Eight applications on mutual recognition for products with EAS and 5 with NAS (from Spain, France, Belgium, The Netherlands, UK and Finland) have been filed to BVL so far.

- Rejection: 3
- Expected rejection: 1
- Withdrawal: 1
- Repose after Scientific Advisory Committee meeting (SVA): 1
- Next Scientific Advisory Committee evaluation: 1 (positive decision expected)
- In main evaluation: 3
- In completeness check: 2
- In preliminary evaluation: 1

#### Mutual recognition from Germany to other MS

- Information from BVL directly to registration holder if he is the same as the applicant for the mutual recognition.
- Registration report can be requested from BVL directly after Scientific Advisory Committee (SVA) meeting
- If the German registration holder is not the same as the applicant of the mutual recognition, BVL gives information only directly to target MS.
- § 18 a: approval reports (Genehmigungsberichte) can only be requested from BVL if the approval holder is the same as the applicant of the mutual recognition, if not: case by case decision.

#### General issues:

- According to Dr. Lundehn, the COM has declared the failure of the mutual recognition system. COM is currently checking and seems to be prepared to abandon mutual recognition in favour of zonal registrations.
- In Belgium 15 applications for mutual recognitions are under evaluation and 15 mutual recognitions have already been granted.
- Up to now no applications for mutual recognition were filed in the NL.
- Companies are encouraged by BVL to submit applications for mutual recognition. Information on this process are provided on the BVL homepage.

## Project 'electronic registration application' within the scope of BundOnline

Dr. J.-R. Lundeohn

BundOnline started 2002 and the German PPP-registration authorities joined from the beginning. Recently ten applications were filed by 9 companies to start the pilot phase of the project. Still not all functions required are working, but implementation is ongoing.

- Acceptable format: CADDY or XML. A CADDY-XML-converter will be available.
- Due to quantity of data, studies should be submitted via CADDY. The application form can be filled in via a BVL internet portal. Also post-submissions can be done electronically
- Starting 2007 it can be expected that BVL will accept e-applications without any paper. Electronic data submission will not be mandatory, but extra fees will be charged for those companies that do not submit electronic files.
- Starting 2007 BVL is planning to work only with electronic files. In order to do so BVL will scan all documents of ongoing processes and destroy the paper versions.
- All applicants will be able to use the electronic interface (web information manager, password-protected) in order to be able to follow up online 24 h a day the status of their applications.
- BfR prefers to receive XML formats, especially for structured data like residues. This is preferred over pdfs because manual re-entry of data can be avoided.
- The electronic procedures above will be extended, e.g. to §18.

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