



German BVL Applicants' Conference: A Review of Presentations

The German Federal Office of Consumer Protection and Food Safety held a conference for applicants, highlighting procedures and experiences under Regulation 1107/2009. Dr. Bernd Brielbeck, Senior Regulatory Manager, and Dr. Norbert Weißmann, Senior Regulatory Manager – Efficacy, attended this informative meeting and have summarized it for this special edition Newsletter.

For more information, please contact Dr. Bernd Brielbeck (bernd.brielbeck@scg-gmbh.de) or Dr. Norbert Weißmann (norbert.weissmann@scg-gmbh.de).

The zonal approach: Procedures for handling applications for zonal registrations in Germany and experiences with the applications

Dr. Axel Wilkening BVL

Basis for the zonal procedure is Regulation (EC) 1107/2009 from 14 June 2011 and the German plant protection law from 6 February 2012. The BVL has already implemented the new procedures to accommodate the new deadline. Work on updating the electronic documents on the BVL homepage and the electronic applicants' portal could only be started after the German PPP law was implemented and is therefore not yet finished.

The application types described below are stipulated by Regulation 1107/2009 articles 33 to 39, 45, 30, 43 and 40 to 42. The BVL has implemented them into the following six national procedures:

- **ZV1:** zonal registration, Germany as zRMS, first application
- **ZV2:** zonal registration, Germany as Zonal Rapporteur Member State, re-registration
- **ZV3:** zonal registration, Germany as cMS, first application
- **ZV4:** zonal registration, Germany as concerned MS, re-registration
- **ZV5:** no involvement of Germany
- **ZVU:** mutual recognition

Detailed description ZV1 (zonal procedure, Germany as zRMS, first application) – Current Situation: 50 applications are under evaluation. No application is beyond evaluation phase 2. Only one application for registration extension has been evaluated without stop of the clock after the pre-evaluation (see Table page 2).

Detailed description ZV3 (zonal procedure, Germany as cMS, first application) – Current Situation: 39 applications under evaluation (see Table page 5).

Information on ZV5 (no involvement of Germany) – Germany might comment the dRR, but not as a rule. Germany will always assess and comment the dRR, if BVL was informed that a mutual recognition is intended later.

Information on ZVU (mutual recognition) – as a rule, Germany only accepts MR applications if the original registration was granted after a zonal procedure according to Regulation 1107/2009. Current situation: one application from the voluntary zonal evaluation prior to 14 June 2011 under evaluation.

In case the application is rejected, the notifier will be given a period for a possibility to comment before it takes effect. In this case, the prescribed 120 days will not be kept.

Experiences with the new procedure:

- Prior to the 50 applications according to ZV1 procedure, only 15 pre-meetings were held.
- It was emphasized that the exact GAPS (application areas) should be pre-discussed (possible also by email) or at least be checked carefully in the respective interim report.
- Missing data should always be sent in one batch only.
- In the commenting phase, no post submission of data is possible.
- The BVL offers a turbo completeness check.
- Main difficulty in keeping the deadlines for the BVL is due to workload from old applications.
- Communication with the BVL is always possible, even during evaluation. Department 203 should be contacted.

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Table for detailed description ZV1 (Germany as ZRMS)

Action	Time frame	Comment
Pre-meeting	6 month prior to submission of dossier	Strongly recommended, but voluntary.
Application reception by BVL	Start	-
Initial completeness check; confirmation of reception to applicant	1 week	-
Pre-evaluation by the BVL; first interim report to applicant	5 weeks	During the pre-evaluation, missing information is requested by the BVL (often reference lists are missing or there are problems with CADDY). Stopping of the clock is possible and the time needed for post-submission will be deducted from the overall 6-month budget. If significant documents are missing, and the application is not fit for distribution to the evaluating authorities, the application will be rejected in the future, even though no rejection of applications was foreseen during pre-evaluation in the original procedure description. The applicant is also informed about the GAP as it is appropriate for Germany. When checking the BVL reply, the applicant should pay particular attention to the German GAP description.
Distribution of evaluation documents to UBA, BfR and JKI	-	-
Evaluation by UBA, BfR and JKI	15 weeks	At the end of the evaluation phase the applicant can get access to the evaluations of the involved authorities either online (electronic applications) or by asking for inspection of records. However, the data requirements of BfR, UBA and JKI should be read with care as the BVL might modify them. Legally binding is the letter from the BVL. One letter (second interim report) will be issued which summarizes all requirements.

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Action	Time frame	Comment
Second interim report to applicant	2 weeks (if needed stop of clock; max. 6 months)	<p>The stop of the clock is issued for 6 months (or whatever time might be remaining). When the applicant has the requested information ready for submission, it must be sent in only one delivery. The applicant must clearly state that no further deliveries are intended, asking BVL to continue their evaluation. This can be made before the period indicated by BVL is over. For administrative reasons, a second stop of the clock is not possible, even if the 6-month period has not been used up for the first post-submission.</p> <p>During the dRR commenting period, the applicant should also address which information he sees unfit for publication, as there will be no possibility for sanitization prior to publication later. The notifier will not have a possibility to address the comments of the other MS, but all comments will be made available to all participants together with an evaluation by Germany at the end of the evaluation process.</p> <p>In this second interim report, stop of the clock issues can be addressed arising from either core dossier or national German issues. The difference will be indicated clearly. If not, the BVL should be contacted.</p>
Post submission reception and distribution to UBA, BfR and JKI	1 week	-
Evaluation by UBA, BfR and JKI	6 weeks	-
Management / organization of dRR by BVL	2 weeks	-
Commenting of dRR by applicant / cMS	6 weeks	-
Depending on comments: re-evaluation by UBA, BfR and JKI; amendment / finalization of RR	10 weeks	At this stage, all comments of the cMS and applicant will be collected in one table.
Issuance of registration certificate	2 weeks	In case an application is rejected, the notifier will be given a commenting period prior to taking effect. This possibility exists in all different application scenarios described here.

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Table for detailed description ZV3 (Germany as cMS)

Action	Time frame	Comment
Pre-meeting	6 months prior to submission of dossier	Strongly recommended, but voluntary.
Application reception by BVL	Start	Being cMS, Germany will accept a certain delay in submission of the application documents, but this should be discussed in advance with the BVL. In case of timing problems, Germany would prefer a MR application.
Initial completeness check; confirmation of reception to applicant and pre-evaluation by BVL	10 weeks	No first interim report is issued and sent to applicant
Reception of dRR from zRMS by BVL	Start	-
Pre-evaluation by BVL	1 week	
Commenting by UBA, BfR and JKI	4 weeks	-
Management / organization of commenting table by BVL	1 week	After commenting of the dRR, Germany will issue an interim report (= second interim report in other evaluation processes) to the applicant including a GAP as it will be evaluated in Germany: The applicant should check this carefully.
Reception of RR and registration certificate from zRMS by BVL	Start	-
Adjustment of applications and distribution to UBA, BfR and JKI	20 days	
Evaluation by UBA, BfR and JKI	60 days	
Risk management adjustment by BVL	30 days	
Issuance of registration certificate	10 days	In case an application is rejected, the notifier will be given a commenting option before taking effect. This possibility exists in all different application scenarios described here.

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Revision of the format for the draft Registration Reports (dRR)

Dr. Birgit Schreiber, BVL

Currently valid is SANCO/6895/2009 rev 1 from 15 July 2011, which applies to submissions made after 1 June 2012. Compared to the previous version, the GAP table was amended and Section 8 (toxicological relevance of ground water metabolites) was newly created.

On 20 - 21 February 2012, a coordinating meeting was held in Braunschweig to amend the dRR. Participants were BASF, Bayer, DuPont, Syngenta, and officials from DE, FR, LV, NL, AT, PL, SE, CZ, HU and UK. The minutes should be available from ECPA. BVL will also check whether it is possible to put the minutes on their homepage. Comments also of industry are welcome.

The following points were agreed upon or referred to sub-committees for further processing:

- The Registration Report (RR) should be a stand alone document. No summary references should be made to other RRs.
- A new part B Section 0 should contain general information, e.g. all approvals already available, EU a.s. data, GAP-table with all uses, new a.s. data.
- Within one zone, national addenda should no longer be issued. All information should be presented in the core dossier as all data should be assessed by the zRMS. It is extra work for the zRMS to integrate addenda information into the core assessment.
- Information should be presented only once. The existing parts should be cleansed; e.g., Section 1 contains toxicological information, which should no longer appear here.
- For clarity, tables should be used instead of text wherever possible.
- Each Section should contain at the beginning an abstract of the section, secondly the risk assessments and, in an appendix, the study descriptions. At the beginning of the study description, a commenting box should be placed. This box is only to be filled in by the MS, not the applicant. Furthermore, the relevant application areas should be stated at the beginning of the section.
- National GAPs should only be presented in Part A.
- Data protection claims should be addressed in a reference list in Part A; they are national issues.
- In the sectional reference lists (Part B), the MSs should state whether a study was necessary for the evaluation.

- The dRR is to be numbered consecutively, with the OECD point following the headline (same as DAR).
- Open point: Where should new Annex II data be located: in the dRR or into a separate document?

Further ongoing activities which are to be synchronized with the dRR revision are a dRR on minor uses, dRR for microorganisms (draft from BE) and guidance on checklists to be submitted in addition to dRRs.

The work is planned to be presented to the standing committee in fall 2012. New rules will become applicable in fall 2013 at the earliest.

Applications in the electronic format to BVL

Dr. Henning Bruno, BVL

Currently 30% of all applications are electronic applications. The application forms available are still the old versions and in German language only (except AP-01-07 for paper based applications), due to delays in programming (IT could only start after German PPP law was renewed). It is intended that all application forms be updated and available in German and English in September 2012. Electronic and paper application forms will then be congruent. It is planned to have a specific applicants meeting on electronic applications at that time. By then, it is planned to be able to accept all different applications as electronic applications, including electronic MRL applications.

Documents to be presented:

For applications according to Art 29 / 15c

- Application form part A
- Application form part B for each individual application area
- Lists of completeness according to Article 29
 - o a.s. data (also for safeness and synergists)
 - o phys.-chem. documents (new documents)
 - o LoA (original, signed document)
 - o Reference to documents submitted
 - o Reference to documents referred to but not submitted (from previous applicant)

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- A complete reference list for a complete dossier for each a.s. (safener and synergist), as published in the Bundesanzeiger January 2012. The list can be obtained from the BVL. Not submitting the lists will be a reason for blockage / stop of the clock. No evaluation will start without these lists!
- Complete product dossier including reference lists.
- Data protection claim lists (can be included in reference lists above).
- German GAP
- Draft of German instructions for use
- List of documents submitted.
- Copies of registration certificates by other MS.
- Results of a.s. equivalence check if done by other MS (ref. to CIRCA sufficient, no data to be submitted.)

If Germany is zRMS, dRR Part A, B and C of all sections and the German national addendum as well as all other national addenda of the zone should be submitted as pdf and WORD files.

If Germany is cMS, dRR Part A, B and C of all sections and the German national addendum to be submitted as a pdf file. In addition, the German national addendum should be submitted as a WORD file.

It is intended in the central zone to eliminate all national addenda by including all risk assessments into the core dossier, as has already been done by the Northern zone.

For applications according to Art 40 (mutual recognition):

- Application forms as above
- Check list according to Art 40
- Translation of the reference MSs registration certificate (for the original a reference to the RR is sufficient)
- Declaration on identity of the product
- Copy of the original and German translation of the instructions for use

It is intended to update the CADDY to accommodate the new dRR structure as presented above. Intended timeframe would be similar to dRR update.

Data protection and data sharing

Mr. Joachim Kunze, BVL

Data protection and data sharing are stipulated in Chapter V, Articles 59 to 62 of Regulation 1107/2009. The utilization of existing vertebrate data by authorities for second applicants has been simplified. The provisions of Article 62 (sharing of tests and studies involving vertebrate animals) apply as of 14 June 2011 (applicability of Regulation 1107/2009).

For data protection, the measures of Article 80 (2) govern the transitional period, thus the data protection provisions of Article 13 of Directive 91/414 remain applicable for certain cases. Data protection is awarded for 5 years to the respective studies submitted for existing active substances and for 10 years for new active substances, as of the date of Annex I inclusion. Thus, respective data for the EAS Dazomet, included into Annex I on 1 June 2011, will be protected until 31 May 2016 and for the NAS Profoxydim, included into Annex I on 1 August 2011, will be protected until 31 July 2021 (examples as given by lecturer).

Also for the renewal of the inclusion or renewal of the approval for active substances whose inclusion in Annex I to Directive 91/414/EEC expired by 24 November 2011, the data protection provisions of Article 13 of Directive 91/414 remain applicable, i.e. 5 years of data protection are awarded to the respective studies.

Directive 91/414/EEC shall continue to apply with respect to the procedure and the conditions for approval in the following cases:

- (a) to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011;
- (b) to active substances listed in Annex I to Regulation (EC) No 737/2007;
- (c) to active substances for which completeness has been established in accordance with Article 16 of Regulation (EC) No 33/2008;
- (d) to active substances for which completeness has been established in accordance with Article 6 of Regulation (EC) No 33/2008 before 14 June 2011.

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Extension of authorizations for minor uses (Article 51 of Regulation 1107/2009)

Dr Rainer Savinsky, BVL

Current situation: 66 applications are under evaluation, nine registration certificates have been issued.

In addition, registrations for minor uses are applied for and evaluated under the zonal approach. Germany will only evaluate those parts of the respective minor use dossier that deviate from the dossier of the underlying basic registration. Moreover, it is intended to keep the evaluation time well below the prescribed time of one year for regular applications. The authorities will even write the dRR format, should this be needed. Currently, the BVL is preparing the electronic format application (see presentation Dr Bruno above) for minor uses. Once this application format is implemented, presumably fall of 2012, there will no longer be the possibility for paper format application. To facilitate the application, data will be accepted in other electronic formats than the normally required CADDY format. Currently the existing G18 paper format application remains valid.

For minor use applications where Germany is the zRMS and it is a first application for Germany, a first interim report will be sent to the applicant at the end of the pre-evaluation, including the assessment by the JKI on whether the application is in the public interest as well as the exact GAP that is to be evaluated.

Reduction / exemption from fees

Dr. Henning Bruno, BVL

Currently three different pieces of legislation govern the levying of fees in Germany. Applicability depends on the time the application was submitted. According to a court decision on animal veterinary drugs, a formal delay of an evaluation begins 4 years after the submission of an application. For this reason, BVL will issue a second invoice for advance fees after 4 years.

Reduction / exemption from fees is regulated in paragraph 5 (1 and 2) of the German Pflanzenschutzmittel-Kosten Verordnung (PfSchuMKostV; Plant protection product cost act). Reduction / exemption from fees is possible:

- Only upon an application by the applicant
- If it is in the public interest (to cover gaps in the protective portfolio of PPPs, are of interest for biological farming, contain basic substances)

- The commercial benefit is not expected to be significant (up to a 75% reduction) or if profits are expected to be negligible (up to 100% reduction) for the applicant.

Calculations of profitability are made by JKI. Minor use applications made by official services are always being evaluated without fees.

The relation of Regulation 1107/2009 and 396/2005 with respect to the evaluation of new active substances – when to submit an MRL application

Dr. Romy Heintze, BVL

An authorization for a PPP use cannot be issued unless a valid MRL is in place for this use.

The best solution is the synchronization of the three independent evaluation processes involved (timeframes based on BVL experience):

1. approval of the active substance (timeframe: 25 to 37 months)
2. implementation of an MRL (timeframe: 17 to 20 months)
3. authorization of the plant protection product (12 months)

If processes 1 and 2 are submitted simultaneously, it is possible for the DAR (from 1) to also contain an MRL proposal. It is recommended that the MRL dossier should cover all intended uses, not only the representative uses of the active substance approval application. Of course, all MRL relevant studies (incl. metabolism, feeding, storage stability) must also be available.

With this synchronized process, the work load can be reduced and it can be ensured that all necessary MRLs are in place when the PPP is up for authorization.

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Trial permits in Germany

Dr. Daniela Felsmann, BVL

According to paragraph 20 (1) of the new German plant protection law, trial permits have to be applied for if PPPs are to be used outdoors and are not yet approved, or if they are to be applied to uses that are not approved. This requirement is based on the Article 54 of Regulation 1107/2009. Respective application forms are available on the BVL homepage:

(http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/03_Antragsteller/05_Genehmigungsverfahren/01_Versuche/psm_Versuche_node.html).

The BVL will evaluate the application and issue the permit to the applicant as well as inform the responsible federal state authority of the permit. The evaluation takes approximately 5 to 6 weeks.

If the producer of the PPP or a trial station on his behalf conducts trials with a PPP as described above, only a notification to the BVL is necessary. This notification must be made at least one month prior to starting the trial. BVL will only revert, if the notification is to be rejected or if further clarification is needed.

In both cases, the trial must also be notified to the federal state authority where the trial is to be conducted.

BVL has worked on 1600 applications and notifications for trial permits in 2012.

Article 12 Pesticide use or risks in specific areas

Dr Martina Erdman-Vourliotis, BVL

With paragraph 17 of the new German plant protection act (Anwendung von Pflanzenschutzmitteln auf Flächen, die für die Allgemeinheit bestimmt sind), Article 12 (Reduction of pesticide use or risks in specific areas) of "Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides" is implemented in German legislation. In these specific areas, the use of conventional plant protection products is to be minimized or prohibited. They are to be replaced where possible by low risk plant protection products (no registered products available yet) or biological products.

The areas which are to be classified as specific areas as stipulated in the above Directive was lively discussed during the question and answer session.

Applications for these uses in specific areas can be made during the zonal procedure supplemental to the normal application.

Alternatively, they can be applied for after the zonal application is completed. Then a national German procedure applies. The national application form can be found on the BVL homepage: (http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/03_Antragsteller/05_Genehmigungsverfahren/03_FlaechenAllgemeinheit/psm_FlaechenAllgemeinheit_node.html).

To be eligible for uses in specific areas, a respective use must be included or have already been approved during the zonal evaluation, i.e. lawn use included / approved and then extended to a special area involving lawns (for example golf courses, although it was heavily disputed that golf courses should fall under these special areas at all). For the application in specific areas, the respective use must be put more precisely, i.e. further specification of application equipment.

In the national German procedure the application must contain, apart from the detailed description of the use, a justification, why granting the use should be in the public interest. The application can be filed also by third parties without the consent of the owner of the registration. The applicant receives a confirmation of reception. The owner of the registration is informed that an application was received. At the same time, the documents are submitted to the evaluating authorities. Finally, a registration certificate is issued and the use included on the BVL homepage:

http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/01_OnlineDatenbank/psm_onlineDB_node.html.

Further information

A presentation was planned regarding the application of PPPs in home and garden uses, but could not be given due to the necessity of further clarification with the ministry. It is intended to finalize the open issue before the summer break.

A few additional important points covered during the meeting include:

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1. When Germany is zRMS, Germany wants to receive all national addenda. Germany proposes to include all risk assessment into the core dossier instead of writing national addenda. This proposal is not harmonized in the central zone (Dr. Axel Wilkening, BVL).
2. According to Dr. Roland Solecki (BfR), the current German and UK OPEX models are being harmonized. No details were given.
3. In Germany, it will not be possible to extend the authorization period of a PPP to harmonize the evaluation with the evaluation of the respective active substance. An extension of an existing PPP authorization is only possible if a complete new application is available at the BVL. The BVL indicated addressing this issue in a written statement (Mr. Joachim Kunze, BVL)
4. According to paragraph 28 (4) of the German plant protection act, expired products can only be distributed when they are already in free trade. As Article 46 of Regulation 1107/2009 is a discretionary provision, it can be interpreted in the national law (Mr. Joachim Kunze, BVL).
5. Areal application in viticulture should be applied for via the zonal procedure. Legal clarification on this issue is expected this fall (Dr Hans-Gerd Nolting, BVL).
6. Industry (Dr. Braunwarth, Spiess-Urania) proposed providing an offline version of the e-application sheet.
7. The BVL (confirmation by Dr. Hähnel) informed that no original data are required concerning active substance specification if an equivalence report by RMS is available on CIRCA.

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