

Newsletter

Volume 13, No. 1M, October 2013



MEETING REPORT

BVL-Meeting / Mandatory electronic Application starts in 2014

Dear subscribers,

on 25.09.2013 the German Federal Office of Consumer Protection and Food Safety (BVL) gave a special information meeting on the use of the new electronic application which is mandatory as of 01.02.2014.

Paragraphs 1 and 3 of the German Plant Protection Products Regulation (PflSchMV) stipulate that, as of 01.02.2014, applications for registration of Plant Protection Products must be provided in electronic format. In particular, applications according to article 29 (standard applications), article 40 (mutual recognition), article 43 (renewal of registration authorisation) and article 45 (modification of application areas) of Regulation 1107/2009 must adhere to this format.

Please find enclosed relevant information on the announced application procedure of the German authority (BVL) for plant protection products (PPP).

For more information, please do not hesitate to contact Dr. Bernd Brielbeck (bernd.brielbeck@scc-gmbh.de).

BVL Portal and virtual mail server

Central to these new electronic applications is the BVL portal through which all communication is executed. Since August 2013 a new version of this portal is available. To use the portal an application (in writing to the BVL) is necessary.

The respective form sheet is provided on the BVL homepage (www.bvl.bund.de/epsm). The registration is linked to the individual person applying for the registration. The user will be given a username, a password, and a certificate. By mail a PIN will also be provided to authorise the certificate. It is most important to note that the BVL portal currently can only be used under the JAVA Runtime Environment JAVA 1.5 (which is an outdated (!) version of the JAVA script). The portal has been tested by BVL under the Microsoft internet explorer as well as the Firefox browser. Upon first use of the portal the user must have administrative rights on his computer to adjust the computer to the needed of the contact with the portal.

The portal is now, to a very large extent, available in English language as well as the original German. So are the form sheets that are to be used for the applications. If one clicks on the button "Submit new application" a catalogue of form

sheets is opened and one can select the appropriate sheet. The form sheet server is currently working under LIP 3.2 (by LUCOM). The form sheets which can be opened from this part of the portal can be filled in, downloaded and saved on the local environment of the user. At a later time the partially filled in form sheets can be uploaded again to the portal and work can continue.

A second button on the portal is entitled "Process on submitted applications". This allows access to application related data of previously submitted applications. The applications are protected and the applicant, it's leading registrant or his representative, will be provided with a synonym number, which is particular to each single application and only the application related to this number, can be viewed by the user. In this part of the portal all, the documents exchanged between the applicant and the authorities or vice versa are listed and can be viewed and requested for download. The request will be executed with a short delay in time, because the server only checks requests every ten minutes.

This part of the portal also contains all the dates at which certain steps of the evaluation procedure has to be fulfilled, as well as the dates when they actually have been completed.

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Also a post-submission form sheet is available here and a limited number of documents can be submitted via this portal using this form sheet.

The number of documents submitted in this way is not necessarily limited, but a limit is placed upon the speed and feasibility by the size of the documents to be uploaded through the portal. In the post-submission form sheet information can be detailed in a comment field. Important information, such as applications or any significant details of the submission should rather be provided as an attachment to the form sheet and not in this comment field. In any case, if documents are submitted, a reference list is to be provided as an attachment to the form sheet.

If the number and size of documents to be post-submitted is significantly larger than what is feasible via the portal, a submission must be made as for a normal application, i.e. submission of the post-submission form sheet via the portal and providing the documents by CADDY format on a separate CD which is mailed to the BVL.

Having completed the filling in of the form sheets, these documents are then provided to the BVL through the virtual mail server (VPS).

Lead registrant and representative

The difference between the leading registrant notified in the application and his representative is based on the fact that the leading registrant is informed by email, if any new documents have been generated. His representative must actively access the portal with his password and user name and then finds the same documents, as described above.

The leading registrant and his representative can belong to different companies, but both must previously have applied for use of the portal, as described above.

If a change of the leading registrant or representative is notified to the BVL, the synonym number of the application remains the same, but as the user name is directly associated with this number, the old lead registrant or representative is

no longer able to view the documents related to this application after the change.

CADDY

Documents associated with an application are to be submitted in CADDY format by mail to the BVL. The CADDY has to be generated with the latest version of XML CADDY. If a submission by CADDY is not possible for an applicant, the applicant can apply in writing to the BVL to be allowed a paper submission of the documents. This exemption must be well justified and might be refused by the BVL, if the reasons are not sufficient. Attached to the electronic application should be a cover letter, a table of content, a reference list (as always requested by BVL), a letter of authorisation, a letter of access and a completeness check document. These documents can be sent via the portal described above. But signed letters of access and letters of authorisation must be submitted in original writing by mail to the BVL.

Application forms

The application form on the authorisation of a Plant Protection Product now consists of four pages. Page one contains administrative information, page two information on the Plant Protection Product, page three information on the active substances contained in the Plant Protection Product and page four the application areas. On all pages there are code lists in drop down menus which simplify the filling out of the form sheets. The mandatory fields are gray, while the other fields are clear white.

As a special service by BVL the applicants can submit their page four (application areas) before the dossier is submitted for advanced checking and clarification. To indicate that this is not an official submission it is suggested that on page one under trade name of the product the trade name should be amended by the expression "pre-application request for checking the application areas".

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Currently, there is planning to improve the application forms, because, as of now, if 15 to 20 uses are included into the form sheet, the response becomes very slow.

In this case the additional application areas can be filled into part B of the current paper application version and should be attached to the application in pdf-format.

All other applications, for which no electronic application is available yet, can be submitted through the BVL portal by using the post-submission form sheet.

In addition to the application forms describe above, MRL applications, modifications of applications areas and applications for minor uses can be submitted electronically. Unlike for all other applications, the minor use application can still be submitted in paper without prior justification of the Authorities. Nevertheless, BVL strongly requests applicants to make use of the new time saving possibilities now provided to the applicant.

Miscellaneous issues

In the future, registration certificates will only be provided in electronic format. If a stamped and signed paper copy is required a specific application is necessary to the BVL.

Questions should always be sent to the official help line UHD-e-psm@bvl.bund.de.

The speaker asks to also submit screen shots of the problems observed, to make it easier to follow the problems in the environment where they occurred.

The application form sheets and all the exchange of documents will remain on the BVL homepage, the portal after the application has been completed, and the registration certificate has been sent. They can still be accessed for review and checking of possible future applications.

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