



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Electronic submission of applications and the electronic workflow of evaluation for authorisations of plant protection products in the BVL

Overview

- **Electronic submission of applications**
- **Electronic workflow of the evaluation and decision**


Application for authorisation yesterday ...



... and today

Electronic Application for Plant Protection Products - eAntrag (PSM)



 Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Dienststelle Braunschweig
Abteilung 2 - Pflanzenschutzmittel -
Messeweg 11-12
D-38104 Braunschweig

eAntrag (PSM) | Antrag auf Zulassung eines Pflanzenschutzmittels

ABSCHNITT I ADMINISTRATIVE ANGABEN

1. Angaben zum Mittel

Handelsbezeichnung des Pflanzenschutzmittels

Versuchsbezeichnung

1 2 3 4 5

1 | Firmencode
2 | Zahlencode
3 | Wirkungsbereich (max. fünf Eingaben möglich)
4 | Nummer der Formulierung
5 | Art der Formulierung

Electronic submission of applications

- **Voluntary electronic applications for authorisations via a portal possible since 2007**
- **Since February 2014 obligatory for all applications for**
 - authorisation of plant protection products
 - extensions of use (incl. minor uses)
 - MRL setting
- **The portal provides a secured internet connection between the applicant and the BVL**

Electronic submission of applications

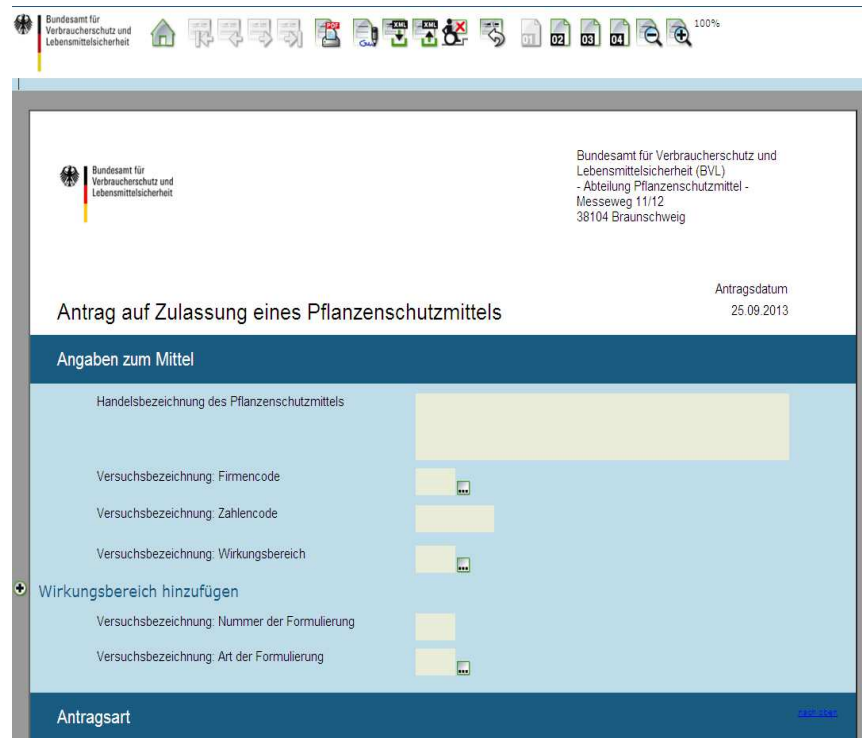
- **Each applying company needs a personalized registration for the portal**
- **Applicants submit a completed application form via the portal**
- **Application forms available in German and English**

Electronic submission of applications

- Dossiers to be submitted either via portal (few number of documents) or in CADDY-xml format (www.caddy.ecpa.com)
- CADDY is an purpose-built electronic format for the exchange and archiving of complex dossiers, developed jointly by industry and regulatory authorities
- CADDY will be superseded in the near future by the OECD Global Harmonized Transport System (GHSTS)

Electronic submission of applications

- **Application form includes**
 - administrative data,
 - data on active substance(s),
 - data on the formulation,
 - data on each use
- **Data from the application form are imported in an BVL database**



The screenshot shows a web-based application form for the submission of plant protection products. The header includes the logo of the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) and the text "Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) - Abteilung Pflanzenschutzmittel - Messeweg 11/12 38104 Braunschweig". The form title is "Antrag auf Zulassung eines Pflanzenschutzmittels" with the submission date "Antragsdatum 25.09.2013". The main section is titled "Angaben zum Mittel" and contains several input fields for product details: "Handelsbezeichnung des Pflanzenschutzmittels", "Versuchsbezeichnung: Firmencode", "Versuchsbezeichnung: Zahlencode", "Versuchsbezeichnung: Wirkungsbereich", "Versuchsbezeichnung: Nummer der Formulierung", and "Versuchsbezeichnung: Art der Formulierung". A button labeled "Wirkungsbereich hinzufügen" is also visible. The bottom of the form has a section for "Antragsart" and a "Drucken" button.

Electronic submission of applications

Through the portal the applicant can directly

- **send** any communication to the BVL
- **access**
 - communications of the BVL addressed to applicant,
 - communications of third parties, e.g. German competent authorities,
 - a schedule of evaluation milestones (planned and realized dates)

Electronic workflow

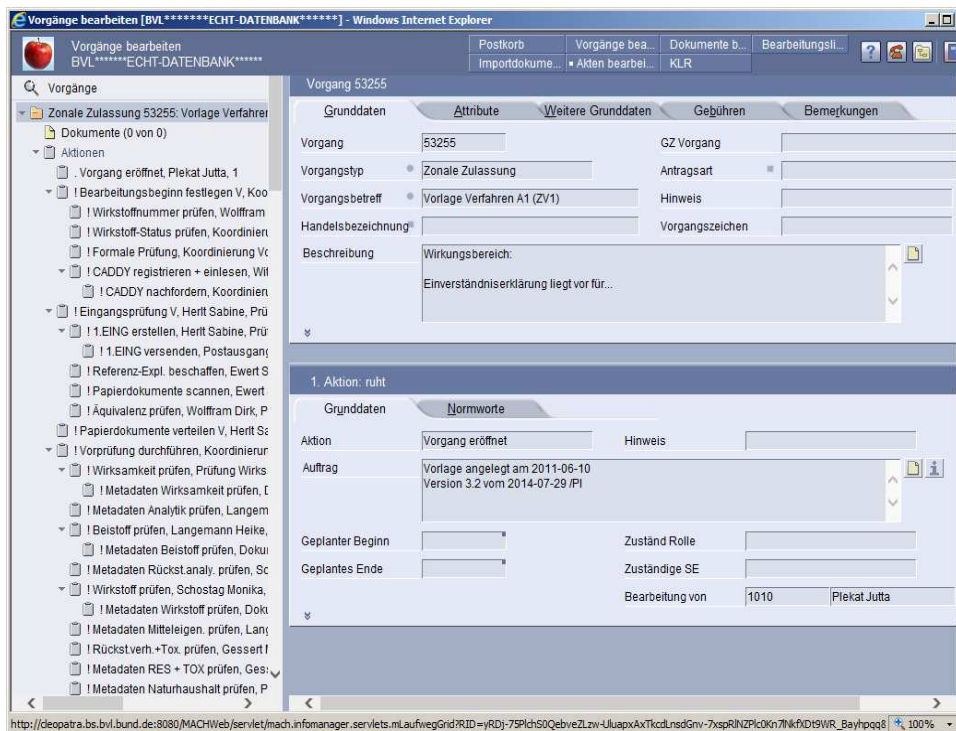
- **When receiving an application the electronic workflow for the evaluation and management procedure within the BVL is started**
- **The CADDY-xml dossier is imported into the workflow database**
- **The competent authorities receive an export of the imported application documents (e.g. application form, draft registration report, studies)**
- **Exchange of documentation between BVL and the competent authorities via portal or data export on DVD**

Electronic workflow

The electronic workflow contains the **complete sequence of all steps** and detailed **description of the required action** of each step

- for the regular procedure with DE being zRMS

currently 139 single actions



Vorgänge bearbeiten [BVL*****ECHT-DATENBANK*****] - Windows Internet Explorer

Vorgänge bearbeiten
BVL*****ECHT-DATENBANK*****

Vorgang 53255

Grunddaten Attribute Weitere Grunddaten Gebühren Bemerkungen

Vorgang 53255

Vorgangstyp Zonale Zulassung

Vorgangsbetreff Vorlage Verfahren A1 (ZV1)

Handelsbezeichnung

Beschreibung Wirkungsbereich:
Einverständniserklärung liegt vor für...

1. Aktion: ruht

Grunddaten Normworte

Aktion Vorgang eröffnet Hinweis

Auftrag Vorlage angelegt am 2011-06-10
Version 3.2 vom 2014-07-29 /PI

Geplanter Beginn

Geplantes Ende

Zustand Rolle

Zuständige SE

Bearbeitung von 1010 Plekat Jutta

Electronic workflow

The electronic workflow in the BVL allows for

- easy and fast access to all relevant documents,
- structured and transparent organisation of all steps in the evaluation and decision making process,
- time control and planning,
- flexibility to adapt to required changes in the workflow,
- scanning and integration of all incoming mail and emails,
- quick approval of draft letters by hierarchy,
- a reduced paper archive

Thank you for your attention

