

The revision of Directive 91/414/EEC – facing new challenges, chances and limits





Introduction of the BVL

Federal Office of Consumer Protection and Food Safety, Germany



Berlin



Braunschweig



www.bvl.bund.de



Federal Office of Consumer Protection and Food Safety

- established 1st. November 2002
- under the jurisdiction of the Federal Ministry of Food, Agriculture and Consumer Protection
- located in Braunschweig and Berlin
- about 475 employees
(about 120 employees within Unit 2 – plant protection products)

- Contact point for the Food and Veterinary Office (FVO)
- Authorisation of
 - Plant protection products
 - Veterinary drugs
 - Feed additives
 - Genetically modified organisms





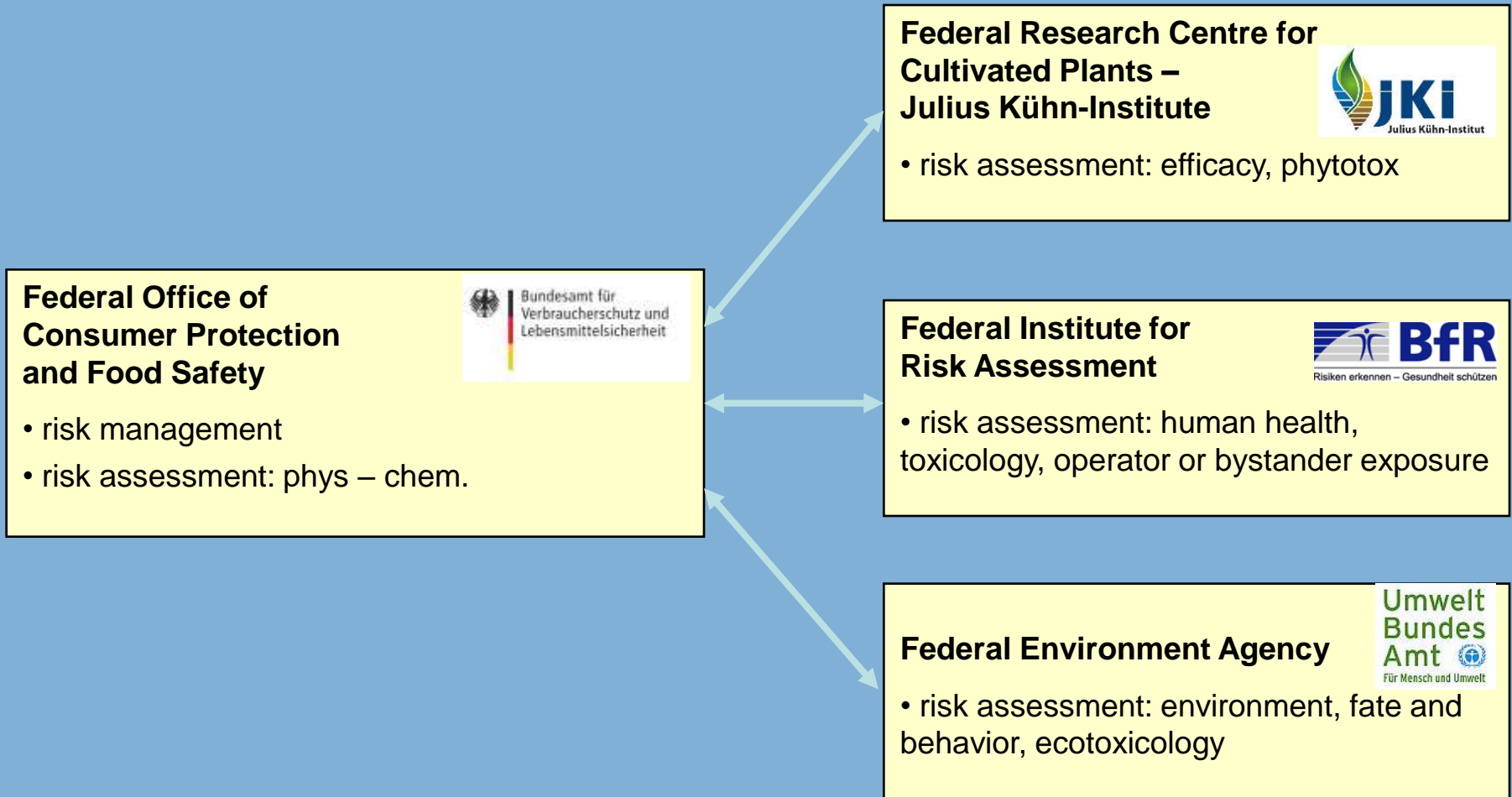
- Co-ordination of food and feed surveillance on the federal level

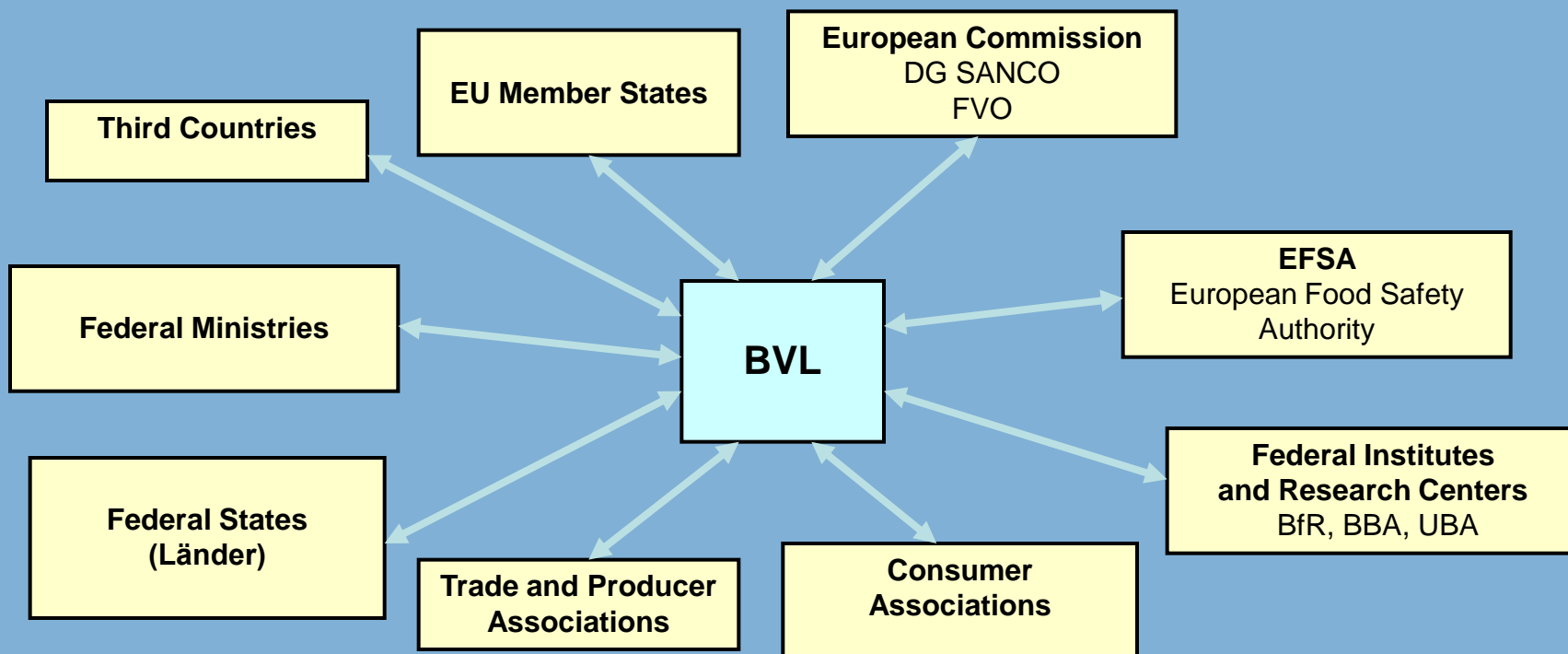
- Reference laboratory and other services for surveillance

- National contact point for the European Rapid Alert System for Food and Feed (RASFF)



Authorisation of plant protection products – associated authorities





efficacy studies in Germany



The **German Plant Protection Act**

in connection with

the **Plant Protection Ordinance** states:

- appropriate guidelines of the European and Mediterranean Plant Protection Organisation (EPPO) must be used as a base for the testing of efficacy of plant protection products within the framework of the authorisation procedure.

For some EPPO guidelines **German versions** were drawn up by various working groups consisting of representatives of the official plant protection services, the industrial association (Industrieverband Agrar, IVA) and the Julius Kühn Institute (JKI).

The explanations are recommendatory for the testing of efficacy of plant protection products in Germany.

The **English original** text of the EPPO guidelines **is legally binding**.

Efficacy studies which are generated for applications for authorisation can only be accepted if they have been conducted according to the principles of **good experimental practice** by **official or officially recognized testing facilities**.

- The legal basis: Directive 93/71/EEC amending Council Directive 91/414/EEC referring to the **EPPO Standard PP 1/181 (3) „Conduct and reporting of efficacy evaluation trials, including good experimental practice“** requiring GEP standard for efficacy trials in the authorisation procedure

Compliance with GEP is **obligatory** for studies which have been started **after 1 July 1999** (ensuring EC harmonized approach and high quality).

The GEP-recognition of **testing facilities** in Germany is in the responsibility of the **Länder** (*federal states*).

The requirements for GEP facilities conducting efficacy trials with plant protection products and the procedure of recognition are described in a „Guidance Document on GEP“ (only in German).

efficacy studies under mutual recognition:

compliance with GEP is **obligatory** for efficacy studies which have been started **after 1 July 1999**

by **official** or **officially recognized testing facilities**

declaration of comparability by applicant

- climate conditions
- occurrence of pest organisms
- soil conditions
- cultivation techniques (e.g. sowing date, crop rotation)

authorisations

7 products



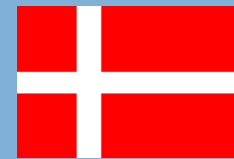
1



2



2



1



1

main examination

27 applications



1



18



4



1



3

preliminary examination (compliance check) 19 applications



1



11



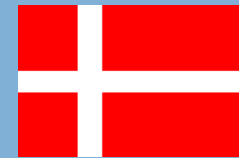
1



2



2




1



1

Replacing Directive 91/414/EEC



- 24th. September 2009 – Council adopted the new Regulation replacing Directive 91/414/EEC
- coming into force April/May 2011 
- discussions on implementation of the new Regulation started in Germany during summer 2009

challenges

- tied time frame of 120 days for takeover of zonal authorisations or for mutual recognition
- efficacy as criteria for the assessment of active substances
- necessity of detailed assessment and registration reports
- implementation of new procedures (comparative assessment)
- integration of specific national rules (e.g. German Bee Protection Ordinance)
- EU or zonal guidance on comparability? (according to EPPO PP1/241 (1) „comparable climates“)
 - climate, edaphic conditions, cultivation techniques, regional plant sorts, pest organisms (resistance)

chances

- strong necessity for harmonisation of the application description
 - e.g. codes for pest organisms or cultivated plants, dose rates, area of application, growth stages
- availability of plant protection products for farmers
- new format for registration report
- trust building between national authorities by work-sharing especially within the zone
- avoiding double work for authorities and industry

limits

- some doubts about comparability of the climatical or agricultural conditions within the central zone (e.g. Ireland, Hungary, Romania)
- up to now: lack of harmonisation (e. g. in the national risk assessment)

**Thank you very much
for your attention**

Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit (BVL)
Braunschweig / Germany