Zbornik predavanj in referatov s 3. Slovenskega posvetovanja o varstvu rastlin, Portorož, 4. - 5. marec 1997 str. 9-31

AUTHORIZATION OF PLANT PROTECTION PRODUCTS IN GERMANY AND THE EU

Fred Klingauf[1]

The Federal Biological Research Centre for Agriculture and Forestry (BBA), which originates from the Biological Division at the Imperial Health Office, founded in Berlin in 1898, is a federal authority in its own right and federal research centre in the jurisdiction of the Federal Ministry of Food, Agriculture and Forestry (BML). Its tasks are mainly defined by the Plant Protection Act as well as the Gene Technology Act and include among others:

- research in the whole field of plant protection and stored products protection,
- examination and authorization of plant protection products,
- registration and examination of plant protection equipment,
- participation in authorizing genetically modified organisms deliberately released and issued, including investigations on biosafety,
- cooperation in assessing chemicals of environmental relevance according to the Chemical Act.

The research work of the BBA provides decisional foundations not only in the political field of food, agriculture and forestry, but also for consumer policy. There are more than 900 employees, including 300 scientists, who work at the BBA (internet: www.bba.de).

Initial plant protection regulations were laid down in Germany at the beginning of this century, establishing the first basic rules in 1937. Whereas the early regulations dealt merely with control actions against pests, the major part of the 1968 Act provided for placing products on the market for the first time, and also particularly for authorizations of plant protection products. Since the late 1970's, the renewal of plant protection regulations, and here specifically those pertaining to the improvement of protection for the various ecosystem components (soil, water, air, species), has been discussed at length. Discussions ceased temporarily, however, with the passage of the new Plant Protection Act in 1986. This Act, which at the moment is still in force, provides comprehensively for the protection of natural resources. § 6 emphasizes that good agricultural practice has to take into consideration the principles of integrated pest management. Integrated pest management is defined as a combination of methods in which particular attention is paid to biological, biotechnical, plant breeding and cultivation related measures, whereby the use of chemical plant protection products is limited to the essential minimum.

The purpose of the Plant Protection Act is

1. the protection of plants, particularly crop plants, against harmful organisms and against non-parasitic impairments;
2. the protection of plant products against harmful organisms;
3. the aversion of dangers which may result from the use of plant protection products or other plant protection measures, in particular where the health of man and animals and the natural balance are concerned.

---

[1] Federal Biological Research Centre for Agriculture and Forestry, Berlin and Braunschweig

The balance of nature consists of the components soil, water, air, wild species of fauna and flora, as well as any interaction between them.

According to Article 15 of the Plant Protection Act, the Federal Biological Research Centre shall grant the applicant authorization if the application fulfils the requirements of §12, and an examination of the plant protection product shows that

1. the plant protection product is sufficiently effective in the light of scientific knowledge and technique;
2. no objections exist as far as the precautions necessary for the protection of human and animal health in dealings with dangerous materials are concerned, and
3. the plant protection product, when used for its intended purpose and in the correct manner, or as a result of such use,
   a) does not have any harmful effects on human and animal health or on groundwater and
   b) does not have any other effects, particularly with regard to the natural balance, which are not justifiable in the light of the present state of scientific knowledge.

What are „other effects"? The interpretation of this concept has been defined by a sentence from the senate of the Federal Administrative Court of November 10th, 1988: „Other effects", according to Article 15 (1), point 3b of the Plant Protection Act, are all those effects which cannot be excluded with a probability next to security. For a decision on whether the effects of a plant protection product are „not justifiable" in the light of scientific knowledge,

- the likelihood of the occurrence of the effects,
- the significance of the disadvantage of the effects,
- the chance of finding replacements for the products, and
- the disadvantage of not using the product

are to be balanced against one another. When deciding on „not justifiable" concerning these other effects, the authority has no scope when making an assessment. Thus, an authorization can only be granted if other effects, especially those affecting the balance of nature, can almost certainly be ruled out.

According to Article 15, the Federal Biological Research Centre for Agriculture and Forestry decides on the compliance of the requirement to health, in consent with the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV), and to the avoidance of harm through the contamination of water and air, as well as waste from plant protection products, in consent with the Federal Environmental Office (UBA). The consent of both federal offices guarantees a thorough examination of the effects of plant protection products.

The authorization of plant protection products has been tightened dramatically by this new legislation. Whilst efficacy, residues in food stuffs, toxicology in human beings and analytics had been given chief attention until the Plant Protection Act came into force, aspects of the balance of nature are now of equal significance. Not only the probable contamination of ground and surface water, but also the effects of plant protection products on the aquatic biocoenosis, on beneficial arthropods and its fate in the air, amongst many other problems, are of eminent importance (Table 1).

An applicant who seeks for authorization of products has first of all to submit a prescribed application form with the required data. The applicant is obliged to present all available data including negative results. Many standard guidelines and leaflets exist on how to conduct the different trials. Many guidelines have been harmonized throughout the members of the European Plant Protection Organization (EPPO) or the Organization of Economic Coopera tion and Development (OECD). Thus the trials are to be carried out in a uniform way, and comparable results can be obtained.

PLANT PROTECTION ACT
Germany 1986

SCOPE OF TESTING IN THE COURSE OF AUTHORIZATION PROCEDURE

- physical and chemical properties including analytical methods and waste disposal
- efficacy and phytotoxicity
- residue behaviour and fate in/on plants, plant products and products of animal origin
- toxicology for man and animal
- fate and behaviour in soil, water and air
- effects on the natural balance
  - ⇨ activity of soil microflora
  - ⇨ soil fauna
  - ⇨ aquatic biocoenosis
  - ⇨ free-living mammals
  - ⇨ birds
  - ⇨ honey bees
  - ⇨ other beneficial organisms

Table 1

If the submitted data and documents are sufficient, and the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) and the Federal Environmental Office (UBA) have given their consents for clearance, the application is presented to an Expert Advisory Committee. This committee has 25 members who are appointed by the Federal Ministry of Food, Agriculture and Forestry. It consists of competent experts from the Plant Protection Services of the Federal States (Länder), universities and other research institutes. The Expert Committee acts as an independent consultant, and the Federal Biological Research Centre for Agriculture and Forestry decides on the authorization of a plant protection product after it has consulted this committee.

When authorization is granted (by certificate), the Federal Biological Research Centre may, as far as it is necessary, stipulate directions for application, which have to be shown on the label of the product, and which contain a warning that any violation of these will lead to punishment by fine. Such a direction will be stipulated, for example, when plant protection products are authorized with active substances which have a

tendency to leach, if there is a danger that the product or its metabolites may contaminate groundwater to an extent of more than 0.1 µg/l.

What are the consequences of a more rigid clearance procedure?

As a result of tightened requirements for authorization, the number of plant protection products and the active substances they contained declined by half, and a third respectively, after the German Plant Protection Act was passed in 1986 (Fig. 1). Seen from the viewpoint of environmental protection, this aspect, which at first perhaps seems to be a positive one, has however serious negative consequences. The reasons for this decline were not only tighter requirements on a product, but also the severely increasing costs for its authorization. As a result, the manufacturer emphasized his efforts on the authorization of plant protection products which had a broader effect, and were used for more important cultures, and which promised a higher turnover than specifically effective products, which can naturally only conquer a smaller share of the market. The variety of products decreased in particular for cultures which were economically less important. For certain problem areas, there are no products available. As long as these gaps cannot be closed, there is a danger of the culture concerned no longer being grown. Possible consequences are reduced flexibility as far as the farmer is concerned, a reduced cropping spectrum and restricted crop rotation; all aspects which are also unwelcome from an ecological point of view. The authorization of plant protection products for minor uses therefore poses a serious problem at present.

An analysis on the state of authorizations for plant protection products carried out by PALLUTT identified 900 uses that are not specified as fields of use in pesticide authorization. 380 of these gaps must be closed as a top priority, otherwise the production of these crops will be jeopardized, resulting in a severe distortion of competition. Vegetables and medicinal and aromatic plants representing 50 % of theses gaps are especially hard hit. Particularly challenged are fruits, especially berries, special crops, and increasingly also crops with rapidly expanding growing areas like, for example, sunflowers and flax. Minor uses are fields of application (uses) on a small scale or of minor economic significance, for which there is no existing plant protection measure, or for which the authorized plant protection products do not or insufficiently guarantee a solution to the problem, namely with a view to ensuring integrated pest management. Resistance problems normally require that several products with different modes of action are available for a given use (Pallutt and Schmidt 1996)*.

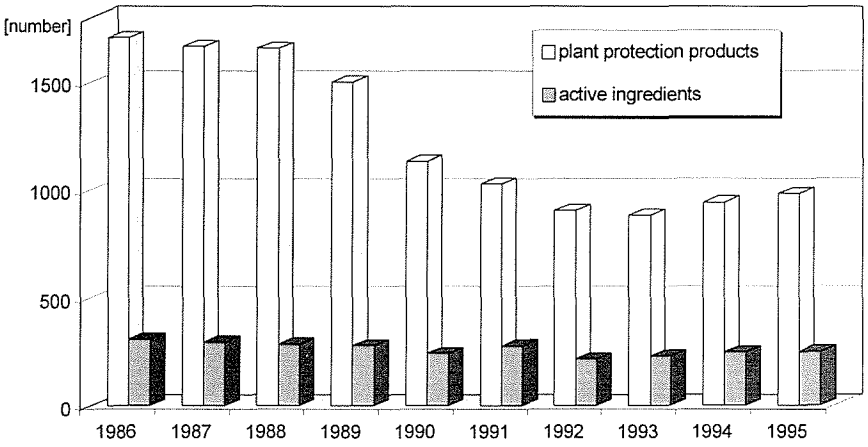
The authorization of plant protection products should also be viewed in connection with the Drinking Water Ordinance of May 22nd 1986, through which the EC Directive concerning the quality of water was transferred to national law. The Ordinance fixes the maximum residue level for active substances of plant protection products at 0.1 µg single substance per litre drinking water or 0.5 µg in total. In my opinion, it is important to emphasize that it is not a question here of substantiated toxicological values indicating potential dangers, but rather of a political stipulation

* W. Pallutt and Schmidt, H. H., Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft Berlin-Dahlem, Vol. 324, 1996

which takes into account the desire for drinking water which contains no residues from plant protection products.

All this leads to the fact that the era of cheap plant protection products is over; tightened requirements concerning environmental protection have lead to an increase in developing costs, which unavoidably affect product prices. The research and developing costs for a new active substance for a plant protection product amount to around 250 million German marks today.

Development of the number of authorized plant protection products and their active ingredients by years



1706	1664	1656	1501	1131	1025	905	882	942	981
308	295	286	280	243	277	217	229	248	249

Figure 1

It is hard to say if biological plant protection products, having a highly selective effect and an accordingly smaller market, have less chance of being developed by industry. In fact, the number of biological agents did not expand considerably after a hopeful stage of development approximately ten years ago. Nor did natural substances, as for example neem extracts, really succeed in breaking through onto the European market, despite the multiple efforts of scientific investigations. At present, only three biological preparations on the basis of micro-organisms (including viruses) are authorized in Germany: pathotypes of Bacillus thuringiensis, Metarhizium anisopliae (against soil born pests) and the codling moth granulosis virus. The OECD has established a task force to deal with test methods for biological plant protection products. Minimum requirements in the test areas of ecotoxicology include, according to the present state of discussion:

- free-living mammals: data available from the area of human toxicology is used,
- birds: when used outdoors, tests for toxicity / pathogenicity on at least one species of bird,

- soil microflora: as a rule no tests necessary,
- earth worms: tests necessary if the product can enter into soil,
- bees: tests for infectiousness / pathogenicity on bees and brood or scientific evidence of the specificity / selectivity of the product,
- beneficial arthropods: tests for infectiousness / pathogenicity on sensitive development stages of arthropods from four ecological groups (according to the SETAC Guidance Document) or scientific evidence of the specificity / selectivity of the product,
- aquatic organisms: algae test according to OECD Directive, a chironomid test according to BBA Directive and a static test with rainbow trout according to OECD Directive.

Directive 91/414/EEC, which regulates the authorization, distribution and use of plant protection products within the European Union, was adopted on July 15th 1991 after many years of discussion and negotiations (Table 2). The high standard of the authorization of plant protection products in Germany remains to a large extent untouched by this. An amendment of the Plant Protection Act is underway at the moment to convert the Directive into German law.

The Council Directive 91/414/EEC of July 15, 1991 concerning the placing of plant protection products on the market, is structured as follows:

1. Scope, definitions, general provisions (Articles 1 to 3)
2. Granting, review and withdrawal of authorizations of plant protection products; information on potentially harmful effects (Articles 4 and 7)
3. Inclusion of active substances in Annex I (Art. 5 and 6)
4. Transitional measures and derogations (Article 8)
5. Application for authorization (Article 9)
6. Mutual recognition of authorizations (Articles 10 and 11)
7. Exchange of informations (Article 12)
8. Data requirements, data protection and confidentiality (Articles 13 and 14)
9. Packaging and labelling of plant protection products (Articles 15 and 16)
10. Control measures (Article 17)
11. Administrative provisions (Articles 18 to 21)
12. Research and development (Article 22)
13. Implementation of the Directive (Articles 23 and 24)
14. Annexes I to VI

Table 2

The Directive stipulates that the authorization of plant protection products remains the responsibility of the Member States. Different environmental conditions in the individual nations was a major reason for not founding a central EU authorizing body. The Directive contains six annexes which regulate important modalities of authorizations, and contain important information.

The following points characterize the future EU authorization procedure:

- Plant protection products and active substances will be assessed and evaluated separately. Active substances will be examined on community level and– providing a positive vote is reached by the Standing Committee for Plant Health– accepted for inclusion in Annex I of the Directive by the European Commission for a maximum of 10 years. After this a renewal of listing is possible. This Annex represents, as a so called "positive list", a catalogue of active substances which are fundamentally suitable. Not until the active substance has been included in this list is the authorizaton of a respective plant protection product possible by a Member State.
- When examining a plant protection product to decide if it fulfils the requirements for authorization, the same uniform principles should be used by all Member States' authorities as laid down in Annex VI.
- There are harmonized data requirements for active substances (Annex II) and plant protection products (Annex III).
- After the product has been authorized, the other Member States must on request authorize its fundamental distribution and use in their own country (Article 10). However, for authorization in another country, the applicant must show that the relevant conditions of use for the plant protection product are similar (environment, agriculture, plant protection).
- Plant protection products are authorized for a maximum of 10 years. After this, a renewal of authorization is possible. In supported cases, the authorization may be subject at any time to checks.
- Plant protection products are authorized for distribution and specific uses („Indikationszulassung"). This means that the preparations may generally only be used on the cultures, or against the respective harmful organisms, on the basis of which an authorization was given. I have already mentioned the problem of minor uses associated with this.
- Plant protection products have to be used in accordance with good professional practice, i.e. among other things, principles of integrated plant protection. Persons using plant protection products in agriculture, horticulture etc. or surveying apprentices in this use, must dispose of adequate professional knowledge and skill to prevent avoidable damage to man, animal and nature. Competent authorities can prohibit these activities when these conditions are not met. Adequate knowledge and experience must be demonstrated to competent authorities on request. Requirements are: certificate of qualification as a farmer, horticulturist, wine grower, forester, agricultural laboratory or technical assistant or graduate in agriculture, horticulture or forestry of a college of advanced education. Another possibility is to have passed a test on theoretical and practical knowledge of plant protection. This test covers in its theoretical part: integrated pest control, causes of plant damage, indirect and direct pest control measures, properties of plant protection products, application of plant protection products and handling of plant protection machinery, health protection, especially the use of protective clothing and protection against inhalation, first aid, prevention of damage to man, animal and environment, storage of plant protection products, adequate disposal of remnants of plant protection products and containers and legal rules in relevant areas; in its practical part: professional handling of plant protection products and application equipment.

The authorization procedure for plant protection products containing a new active substance is shown in Figure 2. Until the new methods of authorization come into force, it is possible to carry out authorizations on a national basis according to old law; these authorizations are however only applicable in the authorizing country itself.

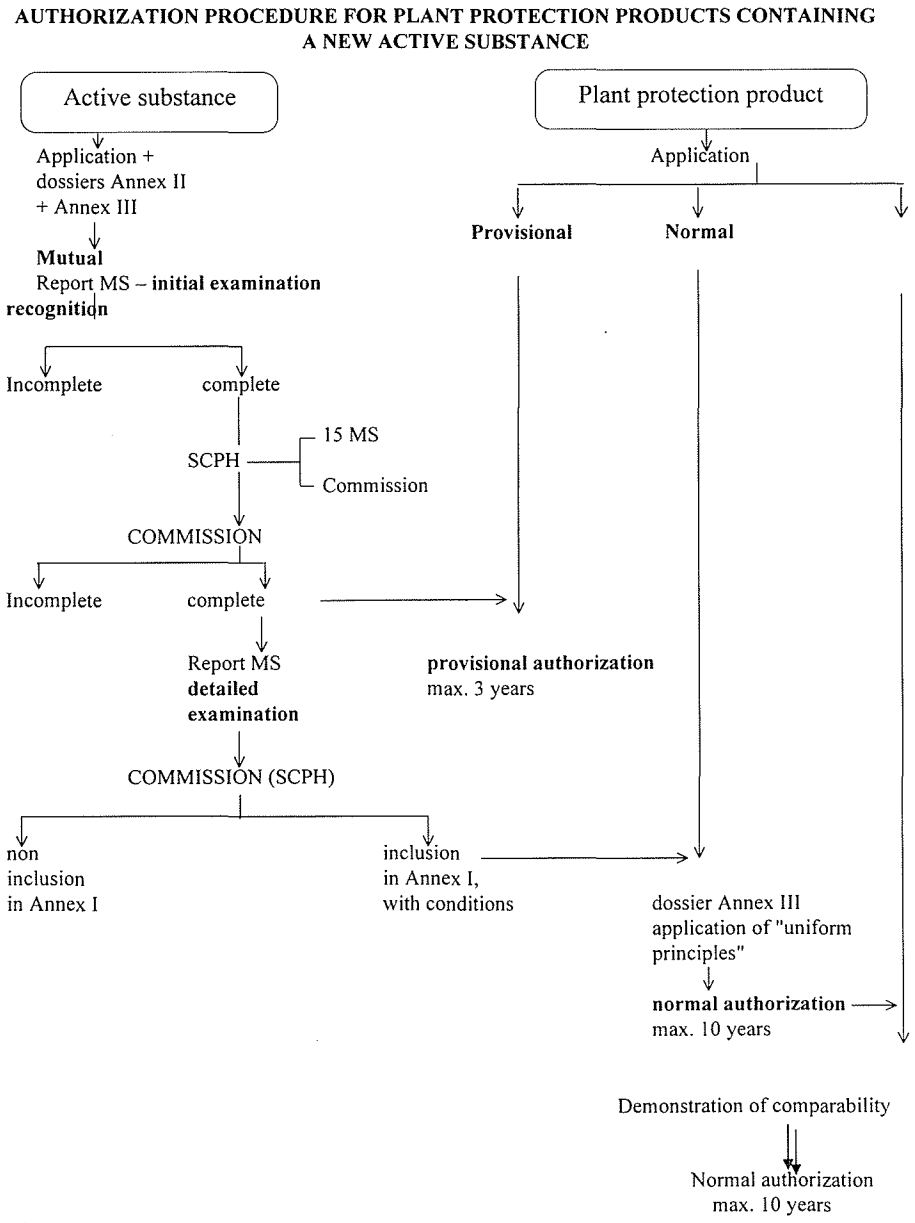


Figure 2

They must concern plant protection products containing "existing" active substances, that means active substances which had already been brought out onto the market before July 25th 1993. Plant protection products containing "new" active substances which are not listed in Annex I can however be authorized provisionally nationally– although only for a maximum of 3 years. However a provisional authorization can only be granted if all 15 Member States and the European Commission are of the opinion that the dossier submitted is complete (vote by the Standing Committee on Plant Health - SCPH).

On the basis of Article 8 paragraph 2 of Directive 91/414/EEC, in Regulation (EEC) no. 3600/92 of the Commission of December 11th 1992, more detailed implementation regulations are set down concerning the first stage of the working programme for 90 of 800 "existing" active substances (Fig. 3). Fundamentally, all Member States are involved; for reasons of practicality however, the main workload is divided amongst the individual nations. In the first round, Germany is responsible for 11 „existing" active substances. The regulation allows the notifiers[2)] one year to submit information concerning the active substance (so called dossiers) and the Member States one year also for examining the submitted information and draft a possible decision (monograph). The information required for the active substance is listed in Annex II of Directive 91/414/EEC.

Examination of the extensive information is divided into several stages:

1. Examination by the rapporteur Member State

– Initial Examination
  After the applicants have submitted their dossiers, the Member State checks them first of all for completeness, according to Article 6 paragraph 2 and 3 of Regulation (EEC) no. 3600/92.

  If the submitted information clearly does not meet the requirements of paragraphs 2 and 3, the rapporteur Member State informs the European Commission, stating the reasons for justification given to him by the applicants.

  On the basis of the report submitted by the rapporteur Member State, the European Commission presents the Standing Committee on Plant Health (SCPH) with a draft decision (withdrawal or prohibition).

– Detailed Examination
  If the rapporteur Member State is of the opinion that at least one of the submitted dossiers on the active substance is complete, he begins with the detailed examination. For the detailed examination, all the information received by him is put together, examined and assessed. Within one year as from commencement of the examination, the rapporteur Member State produces a report, including a proposed decision, (monograph) and hands this over to the Commission.

[2] Manufacturer or his representative of the respective active substances

2. Examination on Community Level

Peer Review
After receiving the monograph, the European Commission charges the European Commission Co-ordination (ECCO) Team with the organisation of expert meetings in order to examine the monograph, attended by all Member States (Peer Review), and to draft a proposed decision.

REGULATION (EEC) N° 3600/92 - REEVALUATION PROGRAMME

This commission regulation covers the reevaluation procedure for a first group of 90 existing substances. The regime is based on shared responsibilty between:

Industry: Delivery of data according to the data requirements in Directive 91/414/EEC (dossier)

↓

Rapporteur Member States: evaluation, assessment and drafting recommendations for decision making (monograph)

↓

Commission: coordination and, with the assistance of the Standing Committee on Plant Health, decision making on inclusion of active substances in the positive list.

↓

Possible decisions

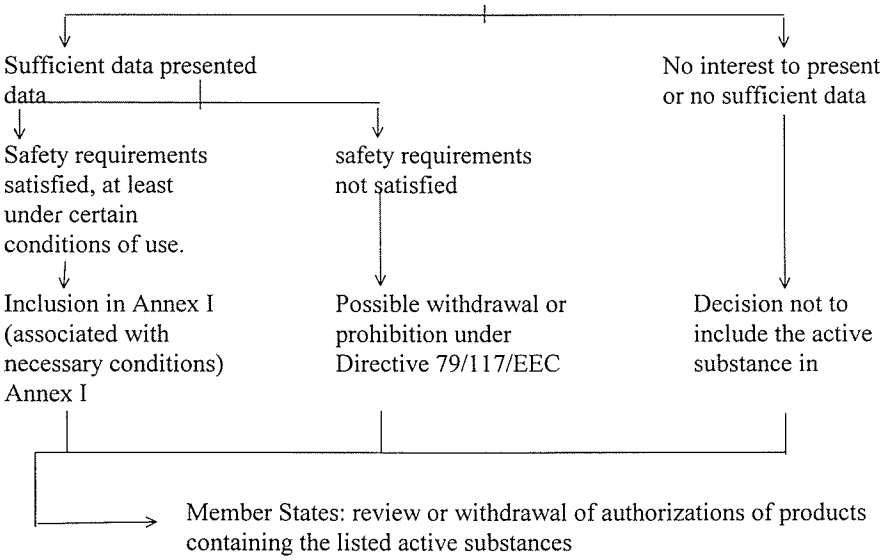


Figure 3

- Examination and Decision by the Standing Committee on Plant Health (SCPH) The Standing Committee on Plant Health, in which the Federal Government is represented by the Federal Ministry of Food, Agriculture and Forestry, decides with qualified majority on the inclusion of the active substance in Annex I of Directive 91/414/EEC, and on any conditions and restrictions in association with this.

The decision of the Standing Committee on Plant Health is prepared by the working group „Plant Protection Products" (evaluation), of which representatives of the European Commission and all 15 Member States are members.

For the re-evaluation of all „existing" active substances, a period of at least twelve years has been planned. The costs per active substance have been estimated at approximately 2 mill. German marks.

- A complete dossier comprises 5 - 15 m files (30 000 - 100 000 pages) and 300 - 1 000 different reports. At present, the possibility of submitting information on CD-ROM is being investigated.

- The estimated work load needed for a rapporteur Member State to produce a monograph is about 1.5 man years. A monograph consists of 300 - 1 000 pages.

To help compile, submit and examine the information, the European Commission together with the Member States has set down procedures and examination processes in so called Guidance Documents.

For this reason, the first joint meeting of the competent and designated authorities of all 15 Member States took place in June 1994 (1st Joint Meeting of the Competent and Designated Authorities - 1st JMCDA) at the Federal Biological Research Centre for Agriculture and Forestry (BBA) in Braunschweig with the financial support of the European Commission. During this meeting, Guidance Documents concerning
- the production of active substance dossiers by the applicants and
- the production of assessment monographs by the rapporteur Member States
were discussed and adopted. Based on the results and recommendations of this meeting, the Federal Biological Research Centre and the authorizing body in the United Kingdom (Pesticides Safety Directorate = PSD) organized a pilot project in 1995. In a series of 13 expert meetings (European Community Pilot Project Meeting = ECPPM) in which all Member States and representatives of the European Commission were present, the form and content of three example monographs produced by the BBA and PSD for the examination and assessment of active substances were discussed and developed further.

In the meantime, 90 „existing" active substances (i. e. active substances which were already on the market on July 25th 1993), and about 30 new active substances are currently in the various stages of examination in the respective designated rapporteur Member States, and on Community level. This examination and assessment results in a decision by the Standing Committee on Plant Health at the European Commission regarding the inclusion of the active substances in Annex I of Directive 91/414/EEC.

In August 1996, the BBA signed in addition a contract with the European Commission in the form of a research project, to coordinate the peer review (ECCO project; ECCO = European Commission Co ordination). Based on previous positive joint experience, the BBA has decided to share this difficult and extensive project with the Pesticides Safety Directorate / UK. ECCO-teams were founded in both authorities consisting of 4-5 employees each, who work together closely to organize 40 expert meetings (ECCO meetings) in the first year, in which decisions for 25 active substances are prepared. The meetings take place alternatively in the BBA in Braunschweig and the PSD in York/United Kingdom attended by the Member States and the European Commission.

Only after an active substance has been included in Annex I of Directive 91/414/EEC full national authorization, based on the Directive, and mutual recognition of authorizations for plant protection products containing this active substance can be granted by the Member States.

In order to arrive at the end at a world-wide division of work concerning the re-evaluation of „existing" active substances, discussions on OECD-level on the world-wide harmonization of the examination of active substances have been taking place for some time. The preliminary work done by the European Community is viewed by many OECD Member States as an excellent foundation. The aim is , after a series of expert discussions in 1997 financed by the European Commission, to decide on harmonized directives at a joint conference of OECD Member States in September 1997. This would result in the adaptation of a harmonized approach in re-evaluation of active substances world-wide, and also in a considerable contribution to cuts in processing information for the examination of plant protection products. I would like to hope that Slovenia will participate with us as a future member of the European Union.

REGISTRACIJA FITOFARMACEVTSKIH SREDSTEV V ZR NEMČIJI IN V EVROPSKI SKUPNOSTI

Fred Klingauf[1]

Zvezna biološka ustanova za kmetijstvo in gozdarstvo (izvirno ime Biologische Bundesanstalt für Land- und Forstwirtschaft, kratica BBA) izhaja iz Biološkega oddelka Cesarskega zdravstvenega urada, ki je bil ustanovljen v Berlinu l. 1898 in je zvezni oblastni organ s svojimi pristojnostmi in zvezna raziskovalna ustanova v pristojnosti Zveznega ministrstva za kmetijstvo, gozdarstvo in prehrano (izvirno ime Bundesministrium für Ernährung, Landwirtschaft und Forsten, kratica BML). Njene naloge in pristojnosti so v glavnem določene z Zakonom o zdravstvenem varstvu rastlin kot tudi z Zakonom o genski tehnologiji in vključujejo med drugim:

- raziskave na vsem področju varstva rastlin in varstva vskladiščenih pridelkov,
- preiskave in registracijo fitofarmacevtskih sredstev,
- preiskave in registracijo tehničnih naprav za varstvo rastlin,
- sodelovanje pri registraciji genetsko spremenjenih organizmov, ki se uporabljajo in preudarno spuščajo v okolje, vključno z raziskavami biovarnosti,
- sodelovanje pri oceni kemičnih snovi glede na njihov pomen v okolju v skladu z Zakonom o kemičnih snoveh.

Raziskovalno delo BBA omogoča temeljne odločitve ne le na političnem področju prehrane, kmetijstva in gozdarstva, temveč tudi na področju potrošniške politike. Pri BBA je zaposlenih več kot 900 ljudi, med njimi 300 znanstvenikov (internet: www.bba.de).

Začetne uredbe o varstvu rastlin so v Nemčiji sprejeli že v začetku tega stoletja, prva temeljna pravila pa so izdali l. 1937. Medtem ko so se prve uredbe ukvarjale v glavnem z zatiranjem bolezni in škodljivcev, je večji del Zakona o zdravstvenem varstvu rastlin iz l. 1968 zajemal prvo spravljanje fitofarmacevtskih pripravkov na trg in posebej še njihovo registracijo. Od poznih sedemdesetih let so na dolgo in široko razpravljali o posodabljanju uredb o varstvu rastlin in tu zlasti tistih, ki naj bi zagotovile boljše varstvo različnih sestavin ekosistemov (tla, voda, zrak, vrstna sestava rastlin in živali). Te razprave so se začasno nehale z novim Zakonom o zdravstvenem varstvu rastlin iz l. 1986. Ta zakon, ki še zdaj velja, predpisuje obsežno varstvo naravnih virov. Šesti člen poudarja, da mora dobra kmetijska praksa upoštevati načela integriranega uravnavanja populacij bolezni in škodljivcev (integriranega varstva rastlin). Integrirano varstvo rastlin pa je opredeljeno kot kombinacija metod, kjer je posebna pozornost namenjena biotičnim biotehniškim metodam, žlahtnjenju rastlin, gojitvenim in podobnim načinom, kjer je uporaba fitofarmacevtskih sredstev omejena na neobhodni minimum.

Namen Zakona o zdravstvenem varstvu rastlin je

1. varstvo rastlin, predvsem gojenih pred škodljivimi organizmi in proti neparazitskim poškodbam (motnjam);
2. varstvo rastlinskih pridelkov pred škodljivimi organizmi;

---

[1] Zvezna biološka postaja za kmetijstvo in gozdarstvo Berlin in Braunschweig

3. odpor do nevarnosti, ki lahko nastanejo pri uporabi fitofarmacevtskih sredstev ali drugih varstvenih ukrepov, zlasti kolikor se nanašajo na zdravje ljudi in živali ter naravno ravnovesje.

Naravno ravnovesje sestavljajo komponente tla, voda, zrak, samonikle živalske in rastlinske vrste kot tudi razmerja med njimi.

Po členu 15 Zakona o zdravstvenem varstvu rastlin je Zvezna biološka ustanova za kmetijstvo in gozdarstvo dolžna predlagatelju dati registracijo, če prijava izpolnjuje zahteve iz člena 12 in je preiskava fitofarmacevtskega sredstva potrdila, da

1. je to sredstvo zadosti učinkovito v luči znanstvenih spoznanj in tehnike;
2. da ni ugovorov, razen nujnih ukrepov za zaščito zdravja ljudi in živali, kolikor se nanašajo na nevarne snovi, in
3. da fitofarmacevtsko sredstvo, če se uporablja za ustrezen namen na pravilen način, ali kot rezultat te uporabe
   a) nima nikakršnih škodljivih učinkov na zdravje ljudi in živali ali na podtalnico, in
   b) da nima nikakršnih drugih učinkov, zlasti glede naravnega ravnovesja, ki ne bi bili upravičljivi v luči sedanjega stanja znanstvenih spoznanj.

Kaj so "drugi učinki"? Razlago tega koncepta je dal senat Zveznega upravnega sodišča dne 10. novembra 1988 s stavkom: "Drugi učinki", so v skladu s členom 15(1), točka 3b Zakona o zdravstvenem varstvu rastlin, vsi tisti učinki, ki jih ni mogoče izključiti z verjetnostjo. ki se bliža gotovosti. Za odločitev ali niso učinki kakega fitofarmacevtskega sredstva "opravičljivi" v luči znanstvenih spoznanj, je treba naslednje postavke izbalansirati med seboj in sicer:

- verjetnost pojava učinkov,
- pomen slabih strani učinkov,
- možnosti, da se najdejo nadomestila za sredstvo, in
- slabe strani, če se pripravek ne bi uporabljal

če se oblast odloči, da ti drugi učinki niso upravičljivi.

Zato se lahko registracija izda le, če se drugi učinki, zlasti tisti, ki vplivajo na ravnovesje v naravi skoraj zanesljivo izključijo.

Glede na člen 15 odloča Zvezna biološka ustanova za kmetijstvo in gozdarstvo o skladnosti zahtev za zdravje v soglasju z Zveznim inštitutom za varstvo potrošnikov in veterinarsko medicino (BgVV) in da bi se preprečile nevarnosti kontaminacije vode in zraka v soglasju z Zveznim uradom za varstvo okolja (UBA). Soglasje obeh zveznih organov zagotavlja temeljito preiskavo učinkov fitofarmacevtskih sredstev.

Registracija fitofarmacevtskih sredstev se je s to novo zakonodajo dramatično zaostrila. Medtem ko je po starem zakonu bil glavni poudarek dan učinkovitosti, ostankom fitofarmacevtskih sredstev, toksikologiji pri ljudeh in analitiki, so z novim Zakonom o zdravstvenem varstvu rastlin dobili aspekti naravnega ravnovesja enak pomen. Velik pomen so pridobili ne le verjetno onesnaženje podtalnice in površinskih voda temveč tudi učinki fitofarmacevtskih sredstev na akvatične življenjske združbe,

na koristne členonožce in na obnašanje v zraku, seveda med številnimi drugimi ptoblemi (preglednica 1).

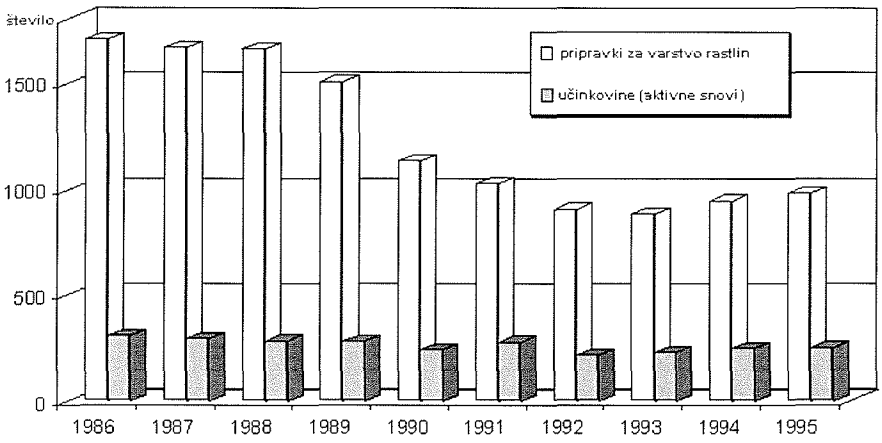
Preglednica 1: Nemški zakon o zdravstvenem varstvu rastlin iz l. 1986

Obseg testiranja za postopek registracije

- fizikalne in kemične lastnosti vključno z analitskimi metodami in odstranjevanjem odpadkov
- učinkovitost in fitotoksičnost
- obnašanje in usoda ostankov na/v rastlinah, rastlinskih pridelkih in živalskih proizvodih
- toksikologija za ljudi in živali
- obnašanje in usoda v tleh, vodi in zraku
- učinki na naravno ravnovesje
  - ↦ aktivnost talne mikroflore
  - ↦ talna favna
  - ↦ vodna življenjska združba
  - ↦ prosto živeči sesalci
  - ↦ ptice
  - ↦ čebele
  - ↦ drugi koristni organizmi

Predlagatelj, ki si prizadeva za registracijo fitofarmacevtskega sredstva mora predvsem predložiti predpisano vlogo z zahtevanimi podatki. Predlagatelj je dolžan predložiti vse razpoložljive podatke, vključno s tistimi z negativnimi rezultati. Obstajajo številne standardne smernice in letaki o tem, kako je treba izvajati različne poskuse. Številne smernice so uskladili med člani Evropske organizacije za varstvo rastlin (EPPO) in Organizacijo za gospodarsko sodelovanje in razvoj (OECD). Tako se poskusi lahko opravljajo na enoten način in je mogoče dobiti primerljive rezultate.

Če predloženi podatki in dokumenti zadovoljujejo zahteve in sta inštitut za varstvo potrošnikov in veterinarsko medicino (BgVV) in Zvezni urad za varstvo okolja (UBA) dala svoje soglasje se vloga predloži Svetovalnemu odboru strokovnjakov. Ta odbor ima 25 članov, ki jih imenuje Zvezno ministrstvo za prehrano, kmetijstvo in gozdarstvo. Sestavljajo ga priznani strokovnjaki Službe za varstvo rastlin zveznih dežel (Länder), univerz in drugih raziskovalnih inštitutov. Odbor strokovnjakov deluje kot neodvisno svetovalno telo. Zvezna biološka ustanova za kmetijstvo in gozdarstvo odloča o registraciji fitofarmacevtskega sredstva, ko je pridobila mnenje tega odbora. Ko je registracija odobrena (z odločbo), lahko Zvezna biološka ustanova, če je potrebno, zahteva (predpiše) navodilo za uporabo, ki mora biti natisnjeno na etiketi pripravka in ki vsebuje opozorilo, da se vsaka kršitev kaznuje z globo. Takšno navodilo se npr. zahteva, če je registrirano fitofarmacevtsko sredstvo z aktivno učinkovino, ki se izpira in če je nevarnost, da bodo pripravek ali njegovi metaboliti kontaminirali podtalnico, v obsegu večjem kot 0,1 µg/l.



1706	1664	1656	1501	1131	1025	905	882	942	981
308	295	286	280	243	277	217	229	248	249

Slika 1: Nihanje števila registriranih fitofarmacevtskih pripravkov in njihovih učinkovin (aktivnih snovi) po letih

Kakšne so posledice bolj strogega registracijskega postopka?

Kot posledica zaostrenih zahtev pri registraciji pripravkov za varstvo rastlin in učinkovin (aktivnih snovi), ki jih ti vsebujejo se je po sprejemu nemškega Zakona o zdravstvenem varstvu rastlin v l. 1986 to število zmanjšalo za polovico oz. za tretjino (slika 1). S stališča varstva okolja pa ima ta vidik, čeprav se na prvi pogled zdi pozitiven vendarle resne negativne posledice. Razlogi za to zmanjšanje niso le zaostrene zahteve glede lastnosti pripravkov, temveč tudi pomembno povečanje stroškov z njihovo registracijo. Kot rezultat tega si proizvajalci pripravkov prizadevajo za registracijo takih, ki imajo širši spekter učinkovanja in se uporabljajo pri pomembnih posevkih in nasadih in ki obetajo večjo prodajo, kakor specifično učinkujoči pripravki, ki seveda lahko zavzamejo le manjši delež na trgu. Izbira pripravkov se zmanjšuje zlasti pri gojenih rastlinah, ki so gospodarsko manj pomembne. Za varstvo nekaterih rastlin zdaj ni na voljo nikakršnih fitofarmacevtskih sredstev. Dokler te vrzeli ne bodo zapolnjene, obstaja nevarnost, da pridelovalci takih rastlin ne bodo več gojili. Možne posledice so zmanjšana prilagodljivost pridelovalcev, zmanjšano število posevkov, omejen kolobar, kar so vse aspekti, ki so nezaželeni tudi s stališča ohranjanja okolja. Registracija fitofarmacevtskih sredstev za tako imenovano majhno uporabo (minor uses, Lückenindikation) je zato prav zdaj resna težava.

Pri analizi stanja registracije fitofarmacevtskih sredstev, ki sta jo opravila Pallutt in Schmidt (1996) sta našla 900 vrst uporab, ki niso zajete v registracijski odločbi. 380 teh vrzeli je treba zapolniti z vrhunsko prioriteto, sicer bo gojitev teh posevkov in nasadov v nevarnosti, kar bo povzročilo resne motnje v konkurenčnosti. 50 odstotkov teh vrzeli je pri vrtninah, zdravilnih zeliščih in dišavnicah, kar je posebno hud udarec. Poseben izziv je sadno drevje, zlasti jagodičevje, posebni posevki in čedalje bolj tudi posevki, ki se v zadnjem času širijo na vse večje zemljiške komplekse, kot so npr.

sončnice in lan. Manjše uporabe so področja aplikacije (uporabe) na manjših zemljiščih ali pri rastlinah z manjšim gospodarskim pomenom, za katera ne obstajajo ustrezni varstveni ukrepi ali za katera registrirana fitofarmacevtska sredstva sploh ne zagotavljajo ali zagotavljajo v premajhnem obsegu rešitev varstvenega problema, še zlasti ne po načelih integriranega varstva rastlin. Težave z rezistenco pri povzročiteljih bolezni in škodljivcih proti fitofarmacevtskim sredstvom nalagajo, da morajo biti na voljo za določeno indikacijo pripravki z različnimi mehanizmi učinkovanja.

Registracijo fitofarmacevtskih sredstev moramo gledati tudi s stališča Uredbe o pitni vodi z dne 22. maja 1986, s katero je bila smernica Evropske komisije prenesena v nemško državno pravo. Ta uredba opredeljuje najvišjo raven za aktivne snovi fitofarmacevtskih sredstev z 0,1 µg posamezne snovi na liter pitne vode ali 0,5µg vseh snovi skupaj na liter. Po mojem mnenju je potrebno poudariti, da tu ne gre za vprašanje utemeljene toksikološke vrednosti, ki nakazuje potencialno nevarnost, temveč bolj za politično zahtevo, ki upošteva željo prebivalcev po pitni vodi, ki ne vsebuje nobenih ostankov fitofarmacevtskih sredstev.

Vse to vodi do dejstva, da je era poceni fitofarmacevtskih sredstev minila; zaostrene zahteve glede varstva okolja so povzročile povečanje razvojnih stroškov, ki neizbežno vplivajo na cene pripravkov. Stroški z raziskavami in razvojem za eno samo novo aktivno snov znašajo v Nemčiji zdaj 250 milijonov DEM.

Težko je reči ali imajo biotična fitofarmacevtska sredstva z močno specifičnim učinkom in ustrezno manjšim trgom manj možnosti, da bi jih razvijala industrija. Dejstvo je, da se število biotičnih agensov ni znatno povečalo po obetajočem začetnem razvoju pred približno desetimi leti. Niti naravne snovi, kot npr. izvlečki drevesa neem se niso uspele prebiti na evropski trg, kljub izdatnim naporom pri znanstvenih raziskavah. Za zdaj so le trije biotični pripravki na podlagi mikroorganizmov (z virusi vred) registrirani v Nemčiji: patotipi *Bacillus thuringiensis*, *Metarhizium anisopliae* (proti talnim škodljivcem) in granulozni virus jabolčnega zavijača. OECD (Evropska organizacija za gospodarsko sodelovanje in razvoj) je postavila posebno delovno skupino, ki se ukvarja s preučevanjem testnih metod za biotična fitofarmacevtska sredstva. Minimalne zahteve na področju ekotoksioloških testov so, v skladu s sedanjim stanjem diskusij:

- prosto živeči sesalci: uporabljajo se podatki iz območja toksikologije človeka,
- ptice: če se naj sredstvo uporablja na prostem testi za patogenost/strupenost na najmanj eni vrsti ptic,
- talna mikroflora: kot pravilo velja, da testi niso potrebni,
- deževniki: testi so potrebni, če pripravek lahko dospe v tla,
- čebele: testi za nalezljivost/patogenost na čebelah in zalegi ali znanstveni dokaz za specifičnost/selektivnost pripravka,
- koristni členonožci: test za nalezljivost/patogenost pri občutljivih stadijih členonožcev iz štirih ekoloških skupin (v skladu s smernico SETAC) ali znanstveni dokaz za specifičnost/selektivnost pripravka,
- vodni organizmi: test z algami v skladu s smernico OECD, hironomidni test po smernici BBA in statični test s postrvjo po smernici OECD.

Smernica 91/414/EEC, ki obravnava registracijo, diskusijo in uporabo fitofarmacevtskih sredstev znotraj Evropske skupnosti, so sprejeli 15. julija 1991 po dolgih letih razprav in pogajanj (preglednica 2). Visok standard registracije fitofarmacevtskih sredstev v Nemčiji ostaja kljub temu v glavnem nespremenjen.

Preglednica 2: Smernica Evropskega sveta 91/414/EEC z dne 15. julija 1991, ki se nanaša na spravljanje fitofarmacevtskih pridelkov na trg je strukturirana takole:

1. Področje, definicije, splošni ukrepi (členi 1 do 3)
2. Podelitev, pregled in preklic registracije fitofarmacevtskih sredstev, informacija o možnih škodljivh vplivih (člena 4 in 7)
3. Vključitev aktivnih snovi v Aneks I (člena 5 in 6)
4. Prehodni ukrepi in kršitve (člen 8)
5. Vloga za registracijo (člen 9)
6. Medsebojno priznavanje registracij (člena 10 in 11)
7. Izmenjava informacij (člen 12)
8. Zahteve po podatkih, varstvo podatkov in zaupnost (člena 13 in 14)
9. Pakiranje in označevanje fitofarmacevtskih sredstev (člena 15 in 16)
10. Zatiralni ukrepi (člen 17)
11. Administrativni ukrepi (členi 18 do 21)
12. Raziskave in razvoj (člen 22)
13. Vgraditev (vključitev) smernice (člena 23 in 24)
14. Aneksi I. do VI.

Trenutno je v postopku amandma, s katerim bi v nemški Zakon o zdravstvenem varstvu rastlin prenesli to smernico v nemško pravo.

Smernica določa, da registracija fitofarmacevtskih sredstev ostaja v pristojnosti držav članic Evropske skupnosti. Različne okoljske razmere v posameznih državah so bile razlog, da se ni ustanovil osrednji organ Evropske skupnosti za registracijo. Smernici je dodanih šest aneksov, ki uravnavajo pomembne načine registracije in vsebujejo pomembne informacije.

Naslednje točke označujejo prihodnjo registracijo v Evropski skupnosti:

- Fitofarmacevtski pripravki in aktivne snovi se bodo ocenjevale in vrednotile ločeno. Aktivne snovi bodo preiskovali na ravni Skupnosti in če bo dal soglasje stalni odbor za rastlinsko zdravje jih bodo vključili v Aneks I smernice Evropske komisije za najdlje 10 let. Po preteku teh let je možno podaljšanje vpisa. Ti Aneksi predstavljajo kot tako imenovani pozitivni seznami pregled aktivnih snovi, ki v temelju ustrezajo. Dokler kaka aktivna snov ni vključena v ta seznam lahko registracijo ustreznega fitofarmacevtskega pripravka opravi država članica.
- Pri preverjanju ali kako fitofarmacevtsko sredstvo izpolnjuje zahteve za registracijo, se morajo oblastni organi držav članic ravnati po enotnih načelih, zapisanih v Aneksu VI.
- Obstajajo usklajene zahteve po podatkih o aktivnih snoveh (Aneks II) in fitofarmacevtskih pripravkih (Aneks III).
- Ko se fitofarmacevtski pripravek registrira, morajo države članice na zahtevo registrirati osnovno razpečavanje in uporabo v lastni državi (člen 10). Za registracijo v drugi državi pa mora predlagatelj dokazati, da so pomembne razmere

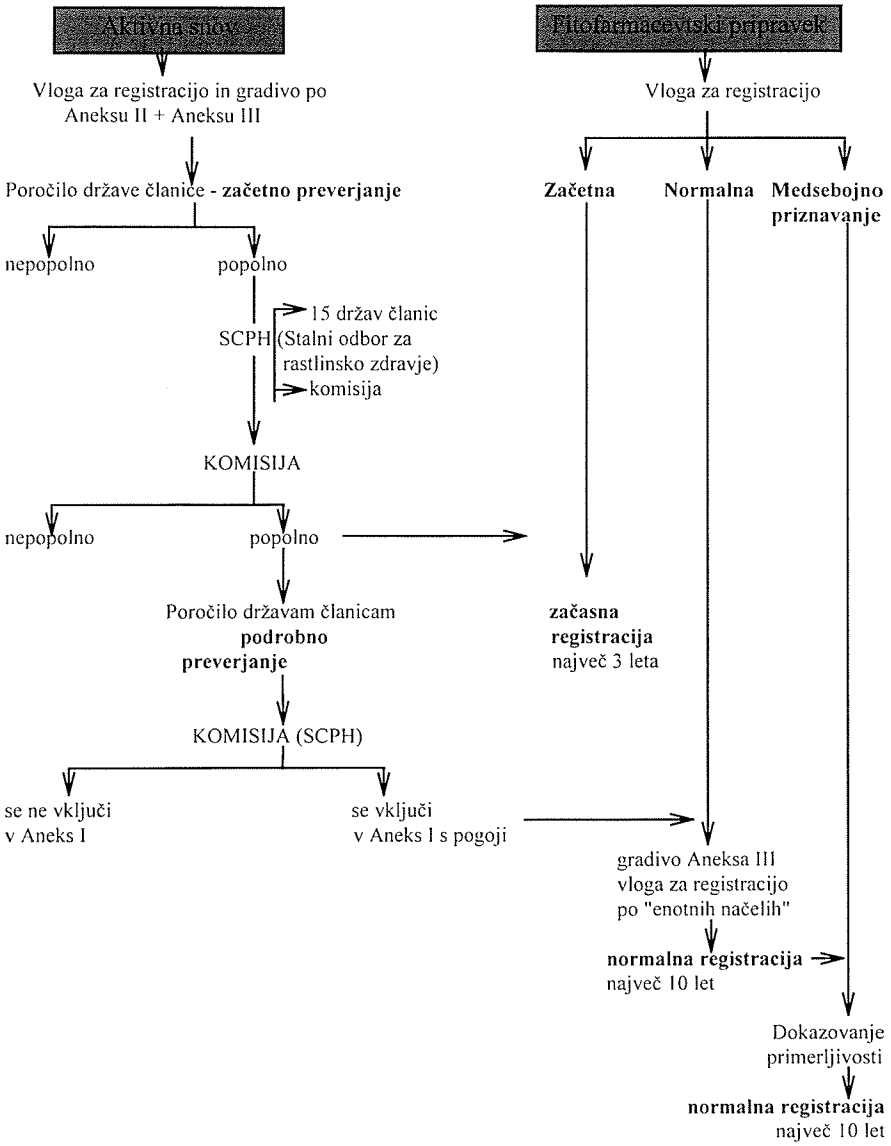
za uporabo fitofarmacevtskega pripravka podobne (okolje, kmetijstvo, varstvo rastlin).

- Fitofarmacevtski pripravki se registrirajo za najdlje 10 let. Po tem je mogoča obnovitev registracije. V utemeljenih primerih se registracija lahko prekliče v vsakem času.
- Fitofarmacevtski pripravki so registrirani za razpečavanje in specifične uporabe ("Indikationszulassung"). To pomeni, da se sme pripravek na splošno uporabljati le pri določenih rastlinah ali proti ustreznim škodljivim organizmom, za katere je bila dana registracija. Omenil pa sem že težave z majhno uporabo (minor uses), ki je povezana s tem.
- Fitofarmacevtski pripravki se morajo uporabljati v skladu z dobro strokovno prakso, t. j. med drugimi stvarmi, tudi po načelih integriranega varstva rastlin. Osebe, ki uporabljajo fitofarmacevtska sredstva v kmetijstvu, hortikulturi itn. ali izobražujejo vajence na tem področju, morajo imeti ustrezno strokovno znanje in izkušnje, da se preprečijo škode pri ljudeh, živalih in naravi. Pristojni oblastni organi lahko prepovedo te dejavnosti, če gornji pogoji niso izpolnjeni. Na zahtevo oblastnih organov je treba ustrezno znanje in izkušnje demonstrirati. Zahteve so: potrdilo o kvalifikaciji kot kmet, vrtnar, vinogradnik, sadjar, gozdar, kmetijski laborant ali tehnični asistent ali diploma visoke strokovne šole ali fakultete za kmetijstvo-rastlinska smer-, hortikulturo ali gozdarstvo. Druga možnost je, da se opravi test o teoretičnem in praktičnem znanju iz varstva rastlin. Ta test zajema v teoretičnem delu: integrirano varstvo rastlin, povzročitelje poškodb na rastlinah, posredne in neposredne zatiralne ukrepe, lastnosti fitofarmacevtskih sredstev, uporabo fitofarmacevtskih sredstev in uporabo strojev za varstvo rastlin, varstvo pri delu (varstvo zdravja), zlasti nošenje zaščitne obleke in zaščito pred vdihavanjem strupenih snovi, prvo pomoč, preprečevanje zastrupitev pri ljudeh, živalih in motenj v naravi, shranjevanje fitofarmacevtskih sredstev, ustrezno odstranjevanje ostankov fitofarmacevtskih sredstev (pripravkov v izvirni embalaži, škropilne brozge) in embalaže ter pomembne pravne predpise s področja varstva rastlin. V praktičnem delu testa je zajeto strokovno ravnanje s fitofarmacevtskimi pripravki in stroji za varstvo rastlin.

Registracijski postopek za fitofarmacevtske pripravke, ki vsebujejo novo aktivno snov je prikazan na sliki 2.

Dokler novi načini registracije še ne veljajo, je možno izvesti registracijo po starih predpisih posameznih držav. Te registracije pa veljajo le v državi, ki je registracijo izvedla. Te se morajo nanašati na fitofarmacevtske pripravke "obstoječih" aktivnih snovi, t. j. tistih, ki so bile dane na trg pred 25. julijem 1993. Fitofarmacevtski pripravki, ki vsebujejo "nove" aktivne snovi, ki jih ne vsebuje Aneks I, se lahko registrirajo na državni ravni - vendar le začasno, za največ 3 leta. Toda začasna registracija se odobri le, če vseh 15 držav članic in Evropska komisija soglašajo, da je predložena dokumentacija popolna (odobritev Stalnega odbora za rastlinsko zdravje - Standing Committee of Plant Health - SCPH).

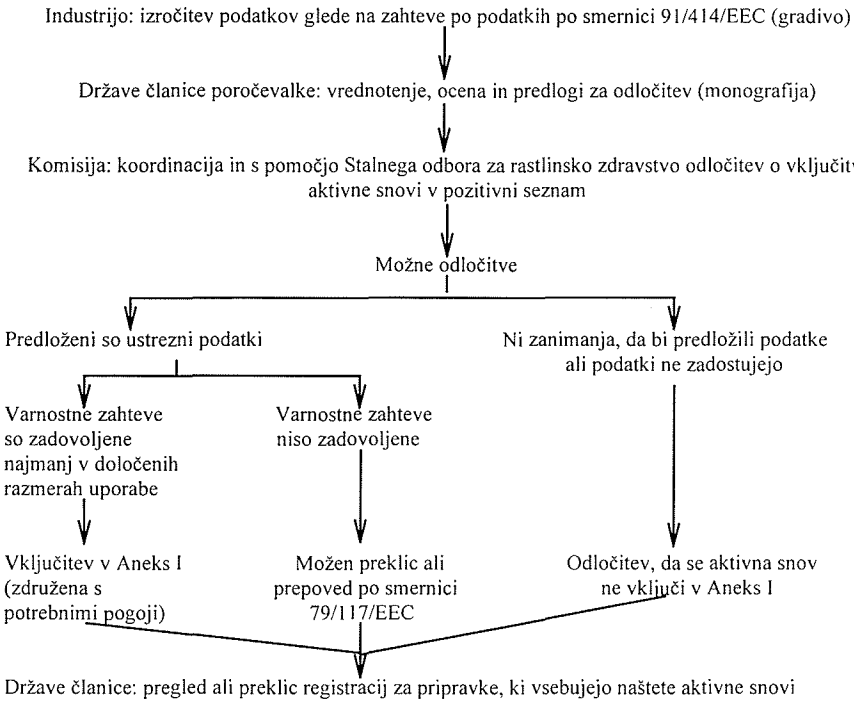
Na podlagi 8. člena, 2. odstavka 2 Smernice 91/414/EEC v Uredbi Evropske gospodarske komisije (EEC) št. 3600/92 z dne 11. decembra 1992 so postavljena bolj podrobna določila o vključitvi odredb, ki se nanašajo na prvo stopnjo delovnega programa za 90 od 800 "obstoječih" aktivnih snovi (slika 3).



Slika 2: Registracijski postopek za fitofarmacevtske pripravke, ki vsebujejo novo aktivno snov

UREDBA (EEC) št. 3600/92-PROGRAM REEVALUACIJE

Ta uredba komisije ureja postopek reevaluacije za prvo skupino 90 obstoječih snovi. Ureditev temelji na deljeni odgovornosti med:



Slika 3

V osnovi so vključene vse države članice, zaradi praktičnih razlogov pa je breme dela razdeljeno med posamezne države. V prvem krogu je ZR Nemčija zadolžena za 11 "obstoječih" aktivnih snovi. Uredba dovoljuje notifikatorjem[2], da v enem letu predložijo informacije (dokumentacijo), ki se nanašajo na aktivno snov (tako imenovani dosje, v tem referatu prevedeno kot gradivo) in predlog morebitne odločitve (monografijo). Informacije, ki se zahtevajo za aktivne snovi so naštete v Aneksu II Smernice 91/414/EEC.

Preverjanje obsežne informacije je razdeljeno v več stopenj:

1. Preverjanje pri državi članici poročevalki

- začetno preverjanje

Ko je predlagatelj izročil svoje gradivo (dosje), ga država članica najprej pregleda predvsem ali je popolno, po členu 6, odstavku 2 in 3 Uredbe (EEC) št. 3600/92.

---

[2] proizvajalcem ali njihovim zastopnikom ustrezne aktivne snovi

Če predložena informacija jasno ne ustreza zahtevam člena 2 in 3, država članica poročevalka obvesti Evropsko komisijo in navede razloge za opravičilo, ki ji jih je dal predlagatelj.

Na podlagi poročila, ki ga je dala država članica poročevalka Evropska komisija izroči Stalnemu odboru za rastlinsko zdravje (SCPH) predlog odločitve (preklic ali prepoved).

- Podrobno preverjanje
Če je država članica poročevalka mnenja, da je vsaj eno od predloženih gradiv (dosje) o aktivni snovi popolno, začne s podrobnim preverjanjem. Za to podrobno preverjanje se vse informacije, ki jih je prejela, združijo, preverijo in ocenijo. V enem letu od začetka preverjanja mora država poročevalka izdelati poročilo, ki vključuje predlog odločitve (monografijo) in preda to komisiji.

2. Preverjanje na ravni Skupnosti

- strokovna recenzija (peer review)
Ko Evropska komisija dobi monografijo naloži ekipi Evropske komisije za koordinacijo (ECCO), da začne organizirati srečanje strokovnjakov (ekspertov) z udeležbo vseh držav članic, z namenim, da bi preverili monografijo in da bi dali osnutek predlagane odločitve.
- Preverjanje in odločitev pri Stalnem odboru za rastlinsko zdravstvo (SCPH)

Stalni odbor za rastlinsko zdravstvo, v kateri nemško zvezno vlado zastopa Zvezno ministrstvo za prehrano, kmetijstvo in gozdarstvo, odloča s kvalificirano večino o vključitvi aktivne snovi v Aneks I Smernice 91/414/EEC in o pogojih in omejitvah povezanih s tem.

Odločitev Stalnega odbora za rastlinsko zdravstvo pripravlja delovna skupina "Fitofarmacevtska sredstva" (evaluacija), v kateri so člani zastopniki Evropske komisije in vseh 15 držav članic.

Za reevaluacijo vseh "obstoječih" aktivnih snovi so predvideli dobo najmanj 12 let. Stroški za eno aktivno snov znašajo približno 2 milijona DEM.

- Popolno gradivo (dosje) obsega 5-15 m fasciklov (30.000-100.000 strani) in 300-1.000 različnih poročil. Zdaj preučujejo možnost, da bi interesenti predlagali dokumentacijo na CD-ROMu.

- Ocenjeno delovno obremenitev za državo članico poročevalko, ki pripravlja monografijo bo predvidoma zmogel poldrugi strokovnjak v enem letu. Monografija obsega 300-1.000 strani.

Da bi pomagala pri zbiranju, predlaganju in preverjanju informacij, je Evropska komisija skupaj z državami članicami v tako imenovani Smernici za dokumente določila procedure in procese preverjanja.

Za ta namen se je junija 1994 s finančno podporo Evropske komisije sestala mešana konferenca pristojnih in imenovanih oblastnih organov vseh 15 članic (1st Joint Meeting of the Competent and Designated Authorities - 1st JMCDA) na Zvezni biološki ustanovi za kmetijstvo in gozdarstvo (BBA) v Braunschweigu. Na tem srečanju so obravnavali in sprejeli Smernico za dokumente, ki predpisuje
- kako morajo proizvajalci aktivnih snovi pripraviti (izdelati) gradivo (dosjeje),
- kako morajo države članice poročevalke pripraviti monografijo za ocenitev.

Na podlagi rezulatov in priporočil tega srečanja sta Zvezna biološka ustanova (BBA) in registracijska oblast v Združenem kraljestvu (Direktorat za varnost fitofarmacevtskih sredstev - Pesticide Safety Directorat = PSD) organizirali l. 1995 pilotni projekt. Na 13 sestankih strokovnjakov Srečanja pilotnega projekta Evropske skupnosti (European Community Pilot Project Meeting = ECPPM), ki so se ga udeležile vse države članice in predstavniki Evropske komisije, so obravnavali in naprej razvili obliko in vsebino treh vzorčnih monografij, ki sta jih izdelali BBA in PSD.

V vmesnem času je za preverjanje in oceno aktivnih substanc v različnih stopnjah preverjanja 90 "obstoječih" aktivnih snovi (t. j. takih, ki so že bile na trgu 25. julija 1993) in približno 30 novih aktivnih snovi. To preverjanje in ocenjevanje se bo odrazilo v odločitvi Stalnega odbora za rastlinsko zdravstvo pri Evropski komisiji glede vključitve aktivne snovi v Aneks I Smernice 91/414/EEC.

V avgustu 1996 je Zvezna biološka ustanova dodatno podpisala pogodbo z Evropsko komisijo v obliki raziskovalnega projekta za koordiniranje strokovnih recenzij (peer review) - Projekt Evropske komisije za koordinacijo (ECCO project; ECCO = European Commission Co Ordination). Na podlagi prejšnjih pozitivnih izkušenj pri skupnem sodelovanju se je BBA odločila, da bo delila ta težaven in obsežen project z angleškim direktoratom za varnost fitofarmacevtskih sredstev (PSD-UK). Ekipe ECCO so oblikovali v obeh oblastnih organih in jih v vsakem sestavlja 4-5 zaposlenih, ki tesno sodelujejo, da bi organizirali 40 srečanj strokovnjakov (srečanj ECCO) v prvem letu, za katero se pripravlja odločitev za 25 aktivnih substanc. Srečanja potekajo menjaje se pri BBA v Braunschweigu in pri PSD v Yorku v Angliji in se jih udeležujejo zastopniki držav članic in Evropske komisije.

Šele potem, ko je aktivna snov bila vključena v Aneks I Smernice 91/414/EEC smejo države članice na podlagi te Smernice in po medsebojnem priznanju registracije fitofarmacevtskih pripravkov, ki vsebujejo to aktivno snov, izdati registracijsko odločbo.

Z namenom, da bi naposled dosegli svetovno delitev dela pri reevaluaciji "obstoječih" aktivnih snovi, potekajo v zadnjem času na ravni Evropske organizacije za gospodarstvo in razvoj (OECD) razprave o svetovni harmonizaciji pri preverjanju teh aktivnih snovi. Preliminarno delo, ki ga je opravila Evropska skupnost, štejejo številne članice OECD kot odlično izhodišče. Po vrsti razprav v l. 1997 v okviru strokovnjakov, ki jih financira Evropska skupnost, je cilj doseči harmonizacijo smernic na skupni konferenci držav članic OECD septembra 1997. To naj bi se izražalo v harmoniziranem pristopu k reevaluaciji aktivnih snovi v svetovnem merilu in tudi k precejšnjemu prispevku k preprečevanju oviranja informacij glede preverjanja fitofarmacevtskih pripravkov. Želel bi upati, da bo tudi Slovenija sodelovala z nami kot prihodnja članica Evropske skupnosti.

Prevedel Jože Maček