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**Examination and Approval
of Plant Protection Products in the Federal
Republic of Germany and their legal Basis**

by

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Already during the first twenty years after the second world war, in many countries the production of plant protection products raised enormously. This also was the case in the Federal Republic of Germany. So, it is easy to understand that during that time the examination of these products did increase in a corresponding size and significance. The official examination of plant protection products did take an analogous development. In Germany this examination already was practised since the year of 1919, where it was realized by the former "Biologische Reichsanstalt", that means the Biological Research Centre of the Reich. This institution, which in the meantime got the name "Biologische Zentralanstalt für das Nordwestdeutsche Gebiet", that means Biological Central Institute for the Northwest German Territory, did reorganize this task since 1947. On the 1 st September 1948 the first post-war edition of the official list of plant protection products has been published. Meanwhile this list has been enlarged so far that since several years it must be re-edited annually in seven separated parts by the Federal Biological Research Centre in Braunschweig. It contains all declarations for a correct application of the products including the necessary prescriptions. For each commercial product all details have been taken into consideration, which are important for the user.

The examination of plant protection products has been voluntary till 1968. Up to that time it did mainly include the efficacy of the products against the pests to be controled, the phytotoxicity, the influence on harvested crops, the chemical composition and the chemical and physical properties. Already to that time the judgement relating to health did take place in coordination with the future Federal Health Office in Berlin on the basis of the declarations of the firms concerning the toxicological properties of the active ingredients. If necessary, the Federal Health Office layed down tolerable values, which were transformed in waiting periods by the future Federal Biological Research Centre.

If the complete examination was concluded with a positive result, the Federal Biological Research Centre did grant the so-called "acknowledgement" of the product to the applicant, who was then authorized to mark the plant protection product as "officially examined and acknowledged" (that means licensed) and to use a special "mark of acknowledgement".

The legal basis for the examination of plant protection products by the former Biological Central Institute and future Federal Biological Research Centre is the "Gesetz zum Schutze der landwirtschaftlichen Kulturpflanzen", that means the Law for the Protection of Agricultural Cultivated Plants of 5 th March 1937, which has been amended by the "Gesetz zum Schutze der Kulturpflanzen", that means the Law for the Protection of Cultivated Plants of 26 th August 1949. This law did serve the protection of plants and stored food with priority; but it did already comprise the possibility, to issue regulations concerning the protection and use of animals and microorganisms, which are useful for plant protection. This was the basis for the "Verordnung über bienenschädliche Pflanzenschutzmittel", that means the Ordinance on Plant Protection Products harmful to Honeybees of 25 th May 1950, by which has been demanded to mark all last-mentioned plant protection products, beginning from the 1 st January 1951. Since this time already, the Federal Biological Research Centre carries out regularly an examination of plant protection products on honeybees. This examination has been an important step to the consideration of environmental aspects in the official examination of plant protection products in the Federal Republik of Germany.

A further contribution to environment protection - here especially to the protection of human health - was created by the "Verordnung über Pflanzenschutz-, Schädlingsbekämpfungs- und Vorratsschutzmittel in oder auf Lebensmitteln pflanzlicher Herkunft", that means the Ordinance on Maximum Quantities in Phytogetic Foodstuffs of 30 th November 1966. On the basis of this ordinance, which did originally result from the "Lebens-

mittelgesetz", that means Food Law, and later on from the amended version of this law from 15 th August 1974, there were layed down by law for the first time tolerable maximum quantities for numerous active ingredients of plant protection compounds and their degradation products in or on foodstuffs. By this ordinance the determination of waiting periods did get a legal character. In the official list of plant protection products waiting periods are named since 1964. In the leaflets and instruction sheets of the Federal Biological Research Centre these data have been published since 1953, and from 1960 to 1963 they were given in the "Nachrichtenblatt des Deutschen Pflanzenschutzdienstes", that is the Bulletin of the West-German Plant Protection Service.

In the Federal Republic of Germany a new period in the history of plant protection and especially in the examination of plant protection products has been founded by the "Pflanzenschutzgesetz", that is the Plant Protection Law of 10 th May 1968, which came into force with a part of its regulations on 16 th May 1968; the other part came into force not before 15 th May 1970, in order to allow the necessary interim regulations. The Plant Protection Law in connection with the "Verordnung über die Prüfung und Zulassung von Pflanzenschutzmitteln", that is the Approval Ordinance of 4 th March 1969, and the "Pflanzenschutz-Kostengesetz", that is the Plant Protection Cost Law of 26 th August 1969, did give the basis for the first approval procedure for plant protection products, which did replace the voluntary examination. This did lead to an obligatory examination and approval of all plant protection products. Not included by the Plant Protection Law are other pesticides, such as preparations against hygienic pests (so-called desinfestation products and household sprays), furthermore wood protectants, preparations against destructive insects on wool and fur, and other pests on material as well. For these preparations do exist special testing regulations, and except for wool and fur protectants, other testing institutes are competent.

The above-mentioned Approval Ordinance contains detailed regulations concerning the realization of examination of plant protection products, whereas the Cost Law regulates all costs which are joined to the examination of these products; it includes a detailed tariff for the individual examination objects. This law has been replaced by the "Verordnung über Kosten der Biologischen Bundesanstalt für Land- und Forstwirtschaft", that is a special Cost Ordinance for the Federal Biological Research Centre, which was announced officially on 1 st September 1981, by which among other things the tariffs are adapted to the higher cost level of the last years.

By the "Gesetz zur Änderung des Pflanzenschutzgesetzes", that means the Law for the Amendment of the Plant Protection Law of 27 th July 1971 also the additives have been included in the approval procedure. By additives are understood substances and preparations of substances, which are destined to be added to plant protection products - and later on also to growth-regulators - with the intention, to change their properties or their mode of action.

The "Zweites Gesetz zur Änderung des Pflanzenschutzgesetzes", that is the Second Law for the Amendment of the Plant Protection Law of 15 th August 1975 brings the inclusion of the growth-regulators into the approval procedure. The growth-regulators are substances, which are destined to influence the life processes of plants, without serving to phytotrophy. Moreover, in this law the expression "plant treatment chemicals" is used for the first time; under this term plant protection products and growth-regulators including the additives are subsumed.

The Plant Protection Law was amended for the last time by the "Drittes Gesetz zur Änderung des Pflanzenschutzgesetzes", that ist the Third Law for the Amendment of the Plant Protec-

tion Law of 16 th June 1978. The purpose of this law *) is,

1. to protect plants against pests and diseases, that means plant protection,
2. to protect plant products against pests, that means protection of stored food,
3. to influence life processes of plants by substances serving not to phytotrophy and
4. to prevent any harmful effects that may result from the use of plant treatment chemicals or other measures of protection of plants or stored food, in particular on the health of human beings and animals.

Herewith the law intends a stronger protection of the user of the preparations and of the consumer of the treated agricultural products as well as of the whole animated environment against unwanted side-effects of plant treatment chemicals. During the last years this special purpose of the law became more and more important.

The protection of plants and stored food also includes

1. the use and protection of animals, plants and microorganisms by which pests or diseases can be controled, and
2. the control of the muskrat (*Ondatra zibethicus* L.).

The control also includes the prevention of the incidence or spread of pests or diseases.

*) I would like to express my thanks to Dr. D.G. Ashby from the FBC Limited, Chesterford Park Research Station, Saffron Walden, Great Britain, for sending me an English translation of the German Plant Protection Law, from which I did take over some parts.

According to the Plant Protection Law plant treatment chemicals may only be imported or distributed professionally if they have been approved by the Federal Biological Research Centre for Agriculture and Forestry. This shall not apply to plant treatment chemicals intended for export as well as to growth-regulators intended for application on cut ornamental plants except material for cultivation.

Applications for approval of a plant treatment chemical can be made by the manufacturer or the distributor or the importer of the product. For this purpose the applicant must present to the Federal Biological Research Centre a completely filled in application for approval including all documents, which are required for the judgement of the product. For this, a special questionnaire is prescribed, which contains in the version of January 1981 more than 150 questions to be answered according to precisely defined instructions. The application is classified in four sections:

The first section contains the trade name of the product, instructions on dangers and safety measures, data concerning the packaging as well as names and addresses of the applicant, the manufacturer and the distributive enterprises.

The second section contains data for the preparation, on the analysis of the chemical, on the technical and pure active ingredients, on the behaviour of residues of the chemical in the plant, in foodstuffs and feeds of phytogetic origin as well as in foodstuffs of animal origin and in shaped and processed phytogetic products. Moreover, in this section a proposal for tolerance is required as well as data on the behaviour of the chemical in the soil and in waters. For water-herbicides also data on residues in fishes have to be considered.

The third section deals with data on the application of the product. To this belong the directions for use and the required test reports on the efficacy of the preparation in the indications applied for. In addition, also applications licensed

abroad and test reports from foreign countries can be considered. Moreover, data on the effect of the product on the honey-bee are required. If it is intended to give evidence on the side-effects of the chemical on beneficial arthropods, it is necessary to present test reports in this matter. The information on a possible phytotoxicity of the product comes from the test reports, in which data on this subject are always required. Furthermore, detailed data on the application of the plant-treatment chemical are needed; they concern the noxious organisms to be controlled respectively the appropriation of the product, its quantity per hectare, the quantities of active ingredients and of water per hectare, the time and number of applications, the method of application and the cultivated plants to be treated. Also waiting periods must be given or proposed.

The fourth section contains the data on toxicology. These data are examined and judged by the Federal Health Office in Berlin. In the main this concerns the acute toxicity of the technical active ingredient (or ingredients) on rats and on an other species of animals, and on fishes, on *Daphnia* (that is a water flea), on Algae, and on two species of birds. Also data concerning the effect on human beings are expected as far as such data are known, as well as data on the cumulative-toxic effect of the technical active ingredient, 90-day-feeding-studies with technical active ingredient on rats and dogs or on an other non-rodent, and studies on agricultural domestic animals. Furthermore, long term feeding tests on rats (appropriate two years) and on an other species of animals have to be done. Metabolic tests and data on the effects on fishes are required too. In addition, there are to present special investigations for the assessment of the cancerogenic, teratogenic and mutagenic risk. Within the required data on the acute toxicity of the commercial preparation there are to present certain investigations on bird toxicity for all bait preparations destined for outdoor application as well as for special granulated materials and for seed-dressings. To the documents

which are to submit by the applicant also belong a bibliography of publications dealing with the toxicology of the active ingredient, a recapitulating toxicological assessment of the preparation and a proposal for tolerance. Finally, in this section data are wanted on the classification of the product into a poison class as well as warning hints and precautionary measures. - The whole questionnaire has been adapted meanwhile to the electronic data processing, because the approval procedure will be converted to this system in a short time.

In order to make it possible for the applicants to fill in regularly the application for approval, and to make sure that the test reports and all investigations are made out in an uniform way, the Federal Biological Research Centre has edited - partly in collaboration with the Federal Health Office - a lot of leaflets and guidelines, which contain precise details on the required investigations. Only by this way it is possible for the approval authorities to deal with the large quantities of documents within a routine procedure. Therefore a fundamental leaflet exists concerning the "Procedure of Examination and Approval of Plant Treatment Chemicals", in which are named besides the course of the approval procedure all data, which have to be presented together with the application for approval; furthermore, it contains a list of all ranges of application and of all official testing stations as well as a compilation of all formulars, leaflets and guidelines which are needed for the examination of the products. Also there exist special leaflets each for the completion of the application for approval, for the data on toxicology, for the residue investigations, for the elaboration of data on the behaviour of plant treatment chemicals in the soil, and for testing the leachability of the product. In addition to this, there are more than 120 single guidelines for testing the products concerning their efficacy and phytotoxicity; these guidelines are partially designated for testing the products against single pests or diseases, and in some cases

against larger groups of noxious organisms. There are also guidelines for testing the effects of the products on the honeybee and on other beneficial arthropods. All guidelines, leaflets and formulars, which are needed for the official examination of plant treatment chemicals, are commercially available by the ACO Druck GmbH in Braunschweig.

Some remarks have to be mentioned first, before the new approval procedure will be described: After the previous procedure according to the Plant Protection Law was practised from 1969 to 1980, and in that period was permanently adapted on the new legal regulations, since January 1981 a completely new organized approval procedure has been introduced, which should make possible a greater flexibility, a shorter working time and a better clearness. In the years of 1981 and 1982 the previous and the new procedure will be practised side by side, in order to make possible a transitional period without interruption as well for the firms as for the approval authorities. For reasons of clearness here will be considered only the new procedure, especially, since it is authoritative for the future regulations (Fig. 1).

So, the applicant has to present the completely filled in application for approval together with all necessary documents in three copies to the Federal Biological Research Centre. Only the applicant is responsible for these documents and that they are suitable for the assessment of the product. Therefore he is obliged to make out before all required testing results and data. He can elaborate these investigations by himself - like it is done by many big firms - or he can give instructions to official testing stations or institutes as well as to private institutions to do this work. Just for testing on efficacy and phytotoxicity fixed minimum numbers of official test reports are prescribed. The purpose of this regulation is, that these tests are carried out under the different climatic conditions and soil conditions in the Federal Republic of Germany, especially, since the testing stations of the German Plant Protection Service are situated in

The Course of the Approval Procedure
for Plant Protection Products
in the Federal Republic of Germany

BBA = Federal Biological Research Centre, Braunschweig
BGA = Federal Health Office, Berlin

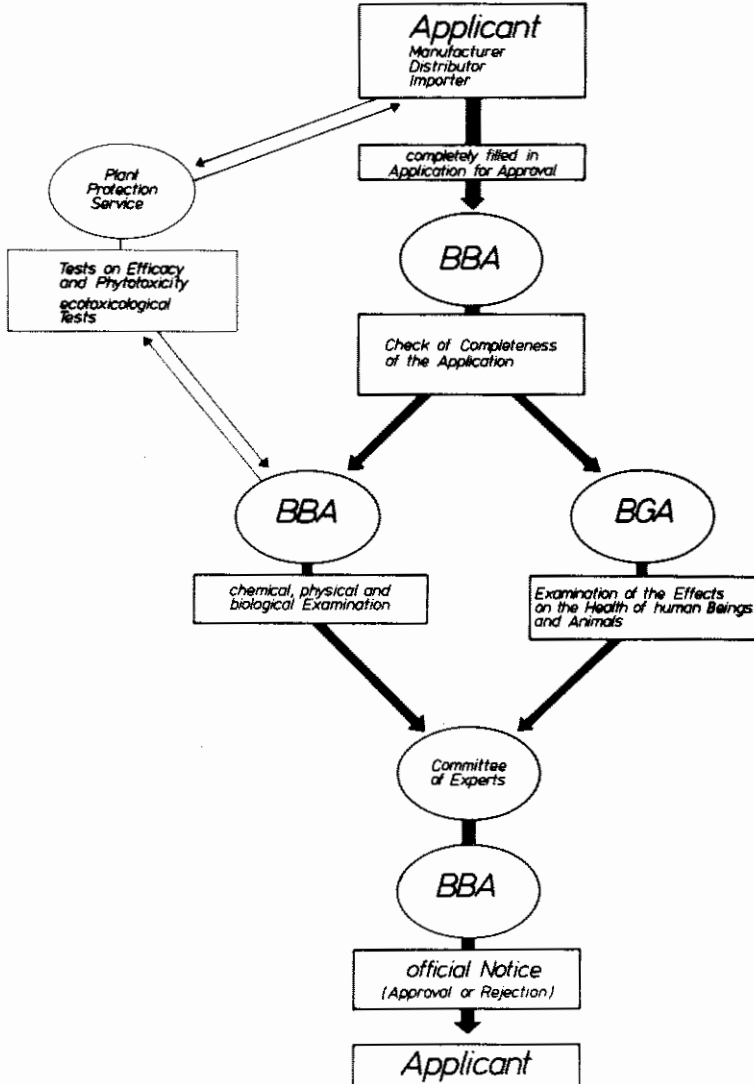


Fig. 1. The course of the approval procedure for plant protection products in the Federal Republic of Germany.
BBA = Federal Biological Research Centre for
Agriculture and Forestry, Braunschweig
BGA = Federal Health Office, West-Berlin

the different Federal Länder and West Berlin. A similar regulation is in force for the testing of bee toxicity, because the genetically different bee material and the varying physiological state of the bees should be considered within the tests.

From the three copies of the application for approval two copies remain in the Federal Biological Research Centre, whereas one copy including the documents belonging to it, is passed on to the Federal Health Office. By this way a simultaneous adaptation in both authorities is possible. As for the rest, an application for approval can be made at the Federal Biological Research Centre at any time; the filing of an application is no more bound on determined time limits.

Usually the Federal Biological Research Centre and the Federal Health Office have about 5 1/2 months at their disposal to examine the documents presented with the application for approval. During this time the Federal Biological Research Centre examines the chemical, physical and biological data, whereas the Federal Health Office examines the toxicological data. If data or documents are incomplete or unclear, they can be demanded subsequently from the applicant within this period, whilst the authorities fix the time limit. In the case that the applicant does not observe this time limit, which usually should not exceed six weeks, or if the applicant needs more time to present these documents, the treatment of the application for approval will be interrupted until those documents have been presented. That means, the application is suspended as long as it is completed by the required new documents. Only thereafter the working time begins anew, so that the applicant must accept a considerable loss of time for the treatment of his application. Independent of these supplementary demands to the applicant, the Federal Biological Research Centre as well as the Federal Health Office are able to elaborate by themselves additional findings by own experimental research work concerning certain facts; they also can let elaborate such data by other authorities or private institutions. So, the Federal Biological Research Centre carries out regularly a chemical and physical examination and

often also residue investigations of the product and arranges in many cases for additional residue investigations and tests on efficacy by official testing stations, whereas the Federal Health Office does make own toxicological investigations on the products in several cases.

As soon as the documents are conform with the official requirements and make possible a judgement in this way, the Federal Biological Research Centre presents the result of examination to the "Sachverständigenausschuß für die Zulassung von Pflanzenbehandlungsmitteln", that is a special "Committee of Experts for the Approval of Plant Treatment Chemicals". This committee has 30 members, which are appointed by the Federal Minister of Food, Agriculture and Forestry. To this committee belong the competent experts from the Federal Biological Research Centre, from the Federal Health Office and from the Plant Protection Service of the Federal Länder. Also representatives from universities and from research institutes as well as from other professional institutions of the Federal Government and of the Länder can be appointed. Furthermore, the Federal Biological Research Centre consults special experts from governmental institutions for discussion of single problems if necessary. The Committee of Experts does advise the Federal Biological Research Centre before its decision on approval of plant treatment chemicals. At the sessions of this committee it is discussed on all problems, which have to do with the application and the side-effects of the single products or product groups; an increasing importance is attributed to the aspects of environment protection.

If the application is ready for decision after hearing the Expert Committee, the Federal Biological Research Centre gives the official notice of approval or rejection of the application to the applicant; if possible, this notice is given within 8 months after the presentation of the complete application. In case that all documents are satisfactory, the approval - that means the licence - can be given. Normal-

ly, the approval is connected with certain conditions, which can have a different character; in parts they concern the marking of the containers and of the ready-to-sell packings. These conditions have to be reproduced partly in contents and partly word-for-word. Other conditions have to be observed by the manufacturer of the product. In each case certain informations have to be given on the containers and on the ready-to-sell packings. Among other things belong to them the name of the product, the approval number (licence number), the name or firm of the manufacturer, importer or distributive enterprise domiciled in a member state of the European Communities, nature and quantity of the active ingredients, in the case of plant treatment chemicals of limited durability the data by which they must be used, the directions for use, and the reference that these and the other prescribed informations correspond to the conditions of the Federal Biological Research Centre. - As soon as the approval has been given, the product can be marked with the "approval mark" (Fig. 2).



Fig. 2. Approval mark for plant protection products.

According to the Plant Protection Law the approval shall be given after examination of the plant treatment chemical, if

1. the plant treatment chemical is sufficiently effective in the light of present scientific knowledge and technique,
2. the requirements of protection of the health of human beings and animals in case of trade with dangerous substances do not preclude it, and
3. the plant treatment chemical, when applied properly and as intended, has no harmful effects on the health of human beings or animals and no other harmful effects that are unjustifiable in the light of present scientific knowledge.

The Federal Biological Research Centre decides in agreement with the Federal Health Office upon the prerequisite health conditions. The approval shall expire at the latest 10 years after the end of the year in which it was given; it is renewable. In particular cases a shorter period of approval can be fixed too. This happens for instance, if further documents are still required to confirm unclear data, or if additional knowledge on the product is desired. In the last-mentioned cases the essential facts are settled however, so that an approval with a time limit of a few years is justifiable. The approval shall be withdrawn, if one of the conditions was absent when it was given. The approval shall be cancelled, if one of the conditions has subsequently been dropped. It can be cancelled too, if the holder of the approval fails to comply with a condition given, or if the applicant requests the cancellation. - If there is a well-founded suspicion on harmful effects on the health or on other unwanted effects, after a plant treatment chemical has been examined, or in the case that the product is not sufficiently effective, the application is rejected. It is possible to require additional investigations. After the conclusion of these new investigations the application for approval can be made anew for this product.

The official examination of plant treatment chemicals has to be payed by the applicant. The charges are fixed by the above-mentioned Cost Ordinance of 1981.

In consideration of the increasing importance of environmental viewpoints also for testing of plant protection products, ecotoxicological investigations are becoming obligatory more and more. This concerns partly tests in a narrower sense, partly the presentation of data and documents, which allow to judge the respective criteria. In the particular case it depends on the type and field of application of the product, which of these tests and documents are necessary. As far as these demands come into consideration in the single case, they are obligatory with exception of the tests on beneficial arthropods. In this field a voluntary examination is possible - except on bees - on six species of beneficial arthropods in the laboratory as well as on two species in so-called "semi-field tests" and an examination on beneficial arthropods in fruit trees in the field. Further testing objects will follow.

In the near future an examination of plant treatment chemicals will be intended on earthworms and on soil microorganisms. Finally, in case of need, data on other unwanted effects of the products are requested, as for instance concerning the post-cultivation effects on cultivated plants, impairment of rigidity of cultivated plants, diminution of germination capacity of seeds of cultivated plants, impairments of taste and fermentation behaviour in wine.

In the following further legal regulations are discussed in chronological order each, which have or will have an influence upon the examination and approval of plant treatment chemicals in the Federal Republic of Germany:

The already mentioned Ordinance on Maximum Quantities for Phytogetic Foodstuffs of 1966 has been continuously adapted to the meanwhile gained level of knowledge; amended versions of this ordinance have been effected on 14 th December 1972,

on 5 th June 1973, on 4 th February 1976 and on 13 th June 1978. Furthermore, there exists the "Verordnung über Höchstmengen an DDT und anderen Pestiziden in oder auf Lebensmitteln tierischer Herkunft", that is the Ordinance on Maximum Quantities for Foodstuffs of Animal Origin of 15 th November 1973, in the amended version of 29 th August 1978.

Both aforementioned ordinances were prolonged by a common ordinance ("Verordnung zur Änderung der Höchstmengenverordnung, tierische Lebensmittel und der Höchstmengenverordnung Pflanzenbehandlungsmittel") of 22 nd December 1981, which results in the "Verordnung über Höchstmengen an Pflanzenschutz- und sonstigen Mitteln sowie anderen Schädlingsbekämpfungsmitteln in oder auf Lebensmitteln und Tabakerzeugnissen", that is an Ordinance on Maximum Quantities for Foodstuffs of Animal and Phytogetic Origin including Tobacco Products. This new ordinance was announced officially on 24 th June 1982. It contains maximum permissible quantities for all substances and isomers, which can be found in foodstuffs. The list of considered substances includes not only the plant protection products but also other pesticides, and exceeds the substances approved in the Federal Republic of Germany by far.

Also an amended ordinance in the version of 19 th April 1974, basing on the "Futtermittelgesetz", that means the Feed Law of 22 nd December 1926 has an importance for the approval of plant treatment chemicals. This ordinance contains prescriptions for the content of several substances in individual feeds. An additional ordinance regulates the maximum permissible quantities for a number of harmful substances in mixed feeds. These regulations are reflected in the approval of those plant treatment chemicals coming into consideration in the relevant sense; they can get corresponding conditions and restrictions.

Consequently the residue situation in foodstuffs of phytogetic and animal origin as well as of feeds is included precisely within the approval procedure.

An immediate importance for examination and approval of plant treatment chemicals has the "Verordnung über Anwendungsverbote und -beschränkungen für Pflanzenschutzmittel", that means the Ordinance governing Bans and Limitations on Use of Plant Protection Products of 23 rd July 1971 and its amended versions of 31 st May 1974, of 7 th April 1977, of 19 th December 1980 and of 2 nd August 1982. Whereas the Plant Protection Law regulates fundamentally the distribution and the import of the products, this ordinance regulates the application of many products, subsumed under groups of active ingredients; the ordinance also lays down that some uses are only allowed with consent of the competent authority. In the versions which are in force now, the named ordinance includes complete bans on use for 25 active ingredients respectively their compounds, which are contained in plant treatment chemicals; furthermore, this ordinance does fix limitations on use for 11 other substances, and regulates bans on use in certain cases for 31 additional substances. The ordinance takes in account the contamination of soil and waters by residues and products of decomposition of plant treatment chemicals and does prevent an accumulation of these substances in the food chain. The approvals of plant treatment chemicals affected by the aforementioned Application Ordinance are restricted, or connected with the required conditions. In each case the approvals are synchronized with this ordinance.

The "Gesetz über die Beseitigung von Abfällen", that means the Law on Removal of Waste of 7 th June 1972 has an indirect impact on the approval of plant treatment chemicals in so far as it is necessary to make declarations within the application for approval of a plant treatment chemical concerning the removal of remainders of the product; in addition it is possible that the approval authorities give corresponding marking conditions for the product.

There is also a connection between the "Tierschutzgesetz", that is the Animal Protection Law of 24 th July 1972 and the

approval procedure, for it has to be considered that plant protection products and products to protect stored food, which are intended to kill vertebrates, as rats and mice, do not cause more pain than unavoidable. That means that no product is taken into examination or even would be approved, which later on in the practical use will cause an avoidable cruelty to animals. As an example can be quoted the use of glue to catch mice. Altogether, viewpoints of animal protection will have an increasing influence, especially on the biological and toxicological experimental work.

The "Gesetz über den Verkehr mit DDT", that means the Law on Trade with DDT of 7 th August 1972, which prohibits among other things manufacturing, trade and application of DDT and DDT-preparations, does not have additional effects on the approval procedure of plant treatment chemicals, because it was adapted to the Application Ordinance in this matter.

In contrast to this the "Gesetz zur Ordnung des Wasserhaushalts", that means the Law for the Order of the Household of Water of 27 th July 1957 in the amended version of 16 th October 1976 has an immediate impact on the approval of plant treatment chemicals. This law serves also for the prevention of noxious effects on waters, which can lead to a change of the physical, chemical or biological quality of the water. Furthermore it makes possible the determination of water protection areas, in which among other things certain acts are prohibited or only limitedly admissible. In these water protection areas the application of plant treatment chemicals is regulated by so-called "conditions for water protection areas", which are given with the approval of the products. Moreover, there exist further marking conditions for water protection, which are connected with the approval.

The "Verordnung zum Schutz der Bienen vor Gefahren durch Pflanzenschutzmittel", that means the Ordinance on Bee Protection of 19 th December 1972, which came out of the Ordinance on Plant Protection Products harmful to Honeybees of

the year 1950, did lead to an obligatory testing of all plant treatment chemicals concerning their effects on the honeybee. All products which can be harmful to bees on account of their mode of application, get a marking condition within the approval, corresponding to the test result.

The "Verordnung über besonders geschützte Arten wildlebender Tiere und wildwachsender Pflanzen", that is the Federal Ordinance on Protection of wild living Species of 25 th August 1980, which is based on the Federal Nature Protection Law, has consequences for the approval of plant treatment chemicals as well.

Animal species which are named in this ordinance, have to be removed from the list of pests to be controled, or they can only be controled in case of a regional gradation. If plant protection products are approved including these animals - as for instance hamster and mole - it is given the condition, that the application only is permitted in case of serious damages. In a similar way it has been proceeded with a product against the hedge butterfly (*Aporia crateagi* L.), which is allowed to be used only in years of gradation of this insect.

Apart from the discussed laws and ordinances of the Federal Government numerous ordinances of the Federal Länder have a direct influence upon the official examination of plant treatment chemicals, about which it is not possible to refer in detail now. Above all the Giftverordnungen der Länder, that are the Poison Ordinances of the Länder, are important because they have taken over the regulations on classification, packaging and marking according to corresponding guidelines of the European Communities. Accordingly the following markings have been prescribed for toxic substances and preparations:

1. Danger symbols and description of dangers (Fig. 3).
2. Hints on special dangers (so-called R-sentences); that are hints on certain risks as for example: toxic when

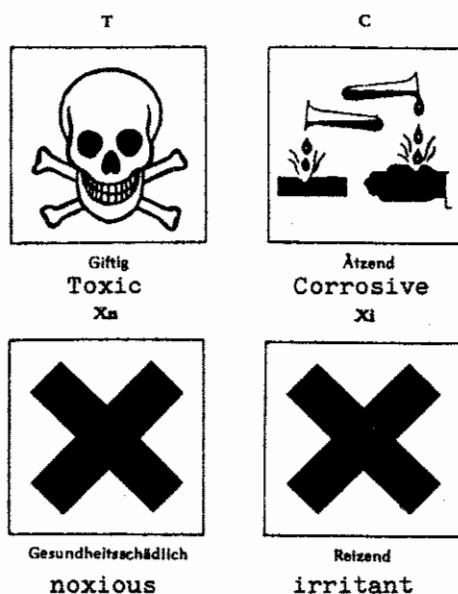


Fig. 3. The new danger symbols for marking of toxic (T), corrosive (C), noxious (Xn) and irritant (Xi) substances resp. their preparations.

inhaling, does cause erodes, irritates the eyes.

3. Safety advices (so-called S-sentences); that are advices for a safe handling of chemicals as for example: Keep cool, no smoking at work, do wear safety goggles.

For toxic plant protection products these marking prescriptions came into force on 1 st yanuary 1981.

With the aid of legislation the prospective further development of the examination and approval of plant treatment chemicals in the Federal Republic of Germany is discussed in the last part of these comments:

The high political rank of environment protection finds expression in the legislation of the Federal Republic more and

more and leads to consequences for the approval procedure in many cases. So, in some legal regulations of the last years the protection of the so-called "household of nature" has been specially demanded. This is the case for instance in the "Gesetz zur Erhaltung des Waldes und zur Förderung der Forstwirtschaft", that means the Federal Forest Law of 2nd May 1975, in the "Gesetz über Naturschutz und Landschaftspflege", that means the Federal Nature Protection Law of 20 th December 1976, in the "Düngemittelgesetz", that means the Fertilizer Law of 15 th November 1977 and in the "Gesetz zum Schutz vor gefährlichen Stoffen", that means the Chemicals Law (corresponding to the American Toxic Substances Control Act) of 16 th September 1980.

Also in the present draft of a new Plant Protection Law of August 1982 the protection of the "household of nature" has been specially pointed out. In the argumentation of this draft is understood by the term "household of nature" the system of activities of soil, waters and air as well as of plants and animals of all species. Of course, the noxious organisms, against which the plant protection measures are directed, will be excepted as up to now. The incorporation of this demand into the law probably will present the introduction of further ecological tests in a wide scale. Moreover this bill provides a regulation of application of plant protection products in many respects. These regulations can bring with them conditions and restrictions in case of approving certain plant protection products. An essential reform in this bill is finally an extensive supervision of plant protection equipment. This regulation shall help to diminish or to avoid unwanted side-effects of the use of plant protection products, as there are harmful effects on cultivated plants, drift, drip losses, and impermissible residues in harvested crops. - Moreover, in the new Plant Protection Law the term "Pflanzenbehandlungsmittel", that means plant treatment chemical is no more provided, because this term did not find acceptance in the linguistic usage; therefore the old term

"Pflanzenschutzmittel", that means plant protection product will be introduced again.

At the moment, further detailed considerations deal with the intention to introduce an obligatory testing on beneficial arthropods; this will concern all plant treatment chemicals, which can be harmful to these species. Since many years a working group of the "International Organization for Biological Control of Noxious Animals and Plants (West Palaearctic Regional Section)" has been elaborating special test methods for this purpose. According to the time-table fixed by this working group the essential testing guidelines should be finished till 1984, so that from the technical point of view it would be possible to enter into a broad testing programme with numerous species of beneficial arthropods, beginning 1985. However it is not yet certain, when and in what dimension these tests will become obligatory, because also economic viewpoints have to be considered. These criteria can only be clarified slowly, for they are different for each species of beneficial arthropods.

It also is intended to elaborate simplified examination requirements for the so-called biological plant-protective agents, as for instance *Bacillus thuringiensis* preparations, preparations on the basis of insect-pathogenic fungi and viruses as well as pheromone preparations. This measure shall help to give these preparations a better chance on the market and to support their further development. A working group of the European Communities did already elaborate the fundamentals of this project. At the moment, these suggestions are **being** considered in the light of the approval procedure in the Federal Republic of Germany.

Many of the above-mentioned suggestions and projects have been named also in the "Umweltgutachten 1978", that is the Environment Report 1978, which is published by the "Rat von Sachverständigen für Umweltfragen", that is the Council of Experts for Environmental Questions in February 1978 in the

Federal Republic of Germany. This report did give reason for extensive discussions on environment protection. In 1982 the named Council did contact the Federal Biological Research Centre because of questions concerning the examination and approval of plant protection products; this will lead to a close cooperation. In this direction all demands of environment protection, which are scientifically well-founded and realizable in practice, will be considered also in the approval procedure for plant protection products in the Federal Republic of Germany.

Abstract

The development of the official examination of plant protection products in the Federal Republic of Germany after the second world war is described shortly. This examination has been voluntary till 1968. A new period in the history of plant protection and especially in the examination of plant protection products has been founded by the Plant Protection Law of 10 th May 1968. This law and some ordinances depending on it did lead to an obligatory examination of all plant treatment chemicals including additives and growth-regulators. Not included by the Plant Protection Law are other pesticides, such as preparations against hygienic pests, wood protectants, preparations against destructive insects on wool and fur, and other pests on materials as well.

The purpose of the Plant Protection Law is described exactly. On the basis of this law and of some special ordinances the examination of plant treatment chemicals and the approval procedure are explained in detail. Applications for approval can be made by the manufacturer or the distributor or the importer

of the product. For this purpose the applicant must present to the Federal Biological Research Centre in Braunschweig a completely filled in application for approval including all documents, which are required for the judgement of the product. For this, a special questionnaire with more than 150 questions is prescribed. The evaluation of the questionnaire and of the documents is made by the Federal Biological Research Centre and the Federal Health Office in West Berlin. Both authorities also carry out special investigations concerning the plant treatment chemicals, if they need further data or informations. Regularly the tests on efficacy and phytotoxicity are made by the Plant Protection Stations of the Federal Länder or by the applicants (firms) themselves. The results of the whole examination are discussed in a special Committee of Experts, which does advise the Federal Biological Research Centre before its decision on approval of the plant treatment chemicals. There are special legal regulations, in which cases a product will be approved. The approval (licence) is given for at most 10 years and connected with several conditions.

The obligatory approval procedure concerns only the distribution and the import of plant treatment chemicals in the Federal Republic of Germany. Products intended for export do not fall under these regulations. Also the application of the products is not generally regulated by the Plant Protection Law. For this purpose a special ordinance does exist, which contains bans and limitations on use for certain plant treatment chemicals, whose application can cause environmental hazards in some cases. Environment protection has a high rank within the examination and approval of plant treatment chemicals. The approval procedure does realize these criteria in a wide scale by many special tests and investigations, which are named and explained in detail.

Numerous laws and ordinances contain regulations, which are important for the approval procedure. They always are brought on the level of present scientific knowledge and technique by

amendments. These laws and ordinances are described concerning their effects on the examination and approval of plant treatment chemicals.

Finally, the prospective further development concerning the examination and approval of plant treatment chemicals in the Federal Republic of Germany is discussed with the aid of legislation. In this connection the protection of the so-called "household of nature" is of an increasing importance including the protection of wild living animals and plants. The protection of honeybees and other beneficial arthropods belongs to this scope of duties.

Altogether, the examination and approval of plant treatment chemicals is an important step to a better protection of the user of the preparations and of the consumer of the treated agricultural products as well as of the whole animated environment against unwanted side-effects of plant protection measures.

Prüfung und Zulassung von Pflanzenbehandlungsmitteln
und ihre gesetzlichen Grundlagen

Zusammenfassung

Die Entwicklung der amtlichen Pflanzenschutzmittelprüfung in der Bundesrepublik Deutschland nach dem Zweiten Weltkrieg wird kurz beschrieben. Diese Prüfung war bis 1968 freiwillig. Ein neuer Abschnitt in der Geschichte des Pflanzenschutzes und insbesondere in der Prüfung der Pflanzenschutzmittel wurde durch das Pflanzenschutzgesetz vom 10. Mai 1968 begründet. Dieses Gesetz und einige darauf beruhende Verordnungen führten zu einer obligatorischen Prüfung aller Pflanzenbehand-

lungsmittel einschließlich von Zusatzstoffen und Wachstumsreglern. Nicht vom Pflanzenschutzgesetz erfaßt sind andere Schädlingsbekämpfungsmittel wie Mittel gegen Hygieneschädlinge, Holzschutzmittel, Mittel gegen Woll- und Pelzschädlinge sowie gegen andere Materialschädlinge.

Der Zweck des Pflanzenschutzgesetzes wird genau dargelegt. Auf der Grundlage dieses Gesetzes und einiger spezieller Verordnungen werden die Prüfung der Pflanzenbehandlungsmittel und das Zulassungsverfahren genau erläutert. Zulassungsanträge können vom Hersteller des Mittels, vom Vertreiber oder vom Einführer gestellt werden. Zu diesem Zweck muß der Antragsteller der Biologischen Bundesanstalt in Braunschweig einen vollständig ausgefüllten Zulassungsantrag vorlegen, einschließlich aller Unterlagen, die für die Beurteilung des Mittels erforderlich sind. Hierzu ist ein spezieller Fragebogen mit über 150 Fragen vorgeschrieben. Die Auswertung des Fragebogens und der Unterlagen erfolgt durch die Biologische Bundesanstalt und das Bundesgesundheitsamt in West-Berlin. Beide Behörden führen auch selbst spezielle Untersuchungen über die Pflanzenbehandlungsmittel durch, wenn sie weitere Angaben oder Informationen benötigen. In der Regel werden die Versuche zur Wirksamkeit und zur Pflanzenverträglichkeit von den Pflanzenschutzdienststellen der Bundesländer oder von den Antragstellern (Firmen) selbst erstellt. Die Ergebnisse der genannten Prüfung werden in einem speziellen Sachverständigenausschuß diskutiert, der die Biologische Bundesanstalt vor ihrer Entscheidung über die Zulassung der Pflanzenbehandlungsmittel berät. Es gibt besondere gesetzliche Regelungen, in welchen Fällen ein Mittel zugelassen wird. Die Zulassung wird für höchstens 10 Jahre erteilt und mit verschiedenen Auflagen verbunden.

Das obligatorische Zulassungsverfahren betrifft nur den Vertrieb und die Einfuhr von Pflanzenbehandlungsmitteln in der Bundesrepublik Deutschland. Für den Export vorgesehene Mittel fallen nicht unter diese Bestimmungen. Auch die Anwendung der Mittel wird durch das Pflanzenschutzgesetz nicht allgemein ge-

regelt. Für diesen Zweck besteht eine besondere Verordnung, die Anwendungsverbote und -beschränkungen für bestimmte Pflanzenbehandlungsmittel beinhaltet, deren Anwendung in gewissen Fällen Umweltschäden verursachen kann. Der Umweltschutz hat im Rahmen der Prüfung und Zulassung von Pflanzenbehandlungsmitteln einen hohen Stellenwert. Das Zulassungsverfahren verwirklicht diese Kriterien in weitem Umfang durch spezielle Prüfungen und Untersuchungen, welche genannt und im einzelnen erläutert werden.

Zahlreiche Gesetze und Verordnungen enthalten Bestimmungen, die für das Zulassungsverfahren von Bedeutung sind. Sie werden durch Änderungen stets auf den neuesten Stand der wissenschaftlichen Erkenntnisse und der Technik gebracht. Diese Gesetze und Verordnungen werden hinsichtlich ihrer Auswirkungen auf die Prüfung und Zulassung der Pflanzenbehandlungsmittel beschrieben.

Schließlich wird die voraussichtliche weitere Entwicklung der Prüfung und Zulassung von Pflanzenbehandlungsmitteln in der Bundesrepublik Deutschland anhand der Gesetzgebung erörtert. In diesem Zusammenhang ist der Schutz des sogenannten "Naturhaushalts" unter Einbeziehung des Schutzes wildlebender Tiere und Pflanzen von zunehmender Bedeutung. Der Schutz der Honigbiene und anderer Nutzarthropoden gehört zu diesem Aufgabengebiet.

Insgesamt ist die Prüfung und Zulassung der Pflanzenbehandlungsmittel ein wesentlicher Schritt zu einem besseren Schutz der Anwender der Mittel und der Verbraucher der behandelten Erntegüter sowie der gesamten belebten Umwelt gegen unerwünschte Nebenwirkungen von Pflanzenschutzmaßnahmen.



