Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft
Berlin-Dahlem

Data requirements and criteria for decision-making in the European Union and the Federal Republic of Germany for the authorization procedure of plant protection products

compiled by

the Department for Plant Protection Products and Application Techniques
(Abteilung für Pflanzenschutzmittel und Anwendungstechnik)

Federal Biological Research Centre
for Agriculture and Forestry
Braunschweig

Heft 358

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Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA)

Präsident: Professor Dr. Fred Klingauf, Messeweg 11/12, D-38104 Braunschweig

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President: Professor Dr. Fred Klingauf, Messeweg 11/12, D-38104 Braunschweig

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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,
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FOREWORD

In the Member States of the European Union (EU), plant protection products require authorization. Uniform requirements for documents and criteria for decision-making for the various areas of testing are governed by the "Council Directive of 5 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)".

In the Federal Republic of Germany, the Plant Protection Act of 15 September 1986*, in the version of 27 June 1994, is in the process of being amended to enable the implementation of Directive 91/414/EEC into national law. This forthcoming implementation will involve in particular the introduction of a fundamentally new procedure by stages. The first stage involves the testing of an active substance on EU level. A positive assessment of the active substance results in inclusion of the active substance in Annex I of the Directive. The second stage then incorporates the results of this testing in the decision by the Member States of the EU, upon application, as to whether the plant protection products should be authorized.

The Federal Biological Research Centre for Agriculture and Forestry (BBA) is the authority in Germany responsible for the authorization of plant protection products. The Federal Institute for Health Protection of Consumer and Veterinary Medicine (BgVV) regarding effects on human and animal health, and the Federal Environmental Protection Agency (UBA) concerning prevention of damage through contamination of water and air, as well as waste from plant protection products, are also involved in the comprehensive evaluation procedure. Their right of participation regarding consent for authorization is established by law. Through the intended amendment of the Plant Protection Act, the previous regulation regarding this consent for authorization will be extended to include the area of soil for the BgVV and the complete area of the natural balance (environment) for the UBA.

The tables compiled here enable direct comparison between data requirements and criteria for decision-making for all areas of testing relevant to the authorization procedure for plant protection products under Directive 91/414/EEC and the regulations issued by the EU and the present procedure in Germany in this respect. The participating authorities in the consent for authorization mentioned above were involved in this compilation.

* The amended Plant Protection Act of 14 May 1998 will come into force on 1 July 1998.

The tables for the area of toxicology were compiled in intensive co-operation with the BgVV.

An essential aim of the tables is the condensed tabular presentation of this comparison for the following areas of testing:

- Efficacy and phytotoxicity
- Identity
- Physico-chemical and technical data
- Analytical methods (formulation and residue analysis)
- Fate and behaviour in soil, water and air
- Effects on non-target organisms
- Residue behaviour
- Toxicology.

Furthermore, the tables aim to show the necessary action to be taken regarding further harmonization of data requirements and criteria for decision-making. This translated version of the BBA-Heft 354 (1998) contains some supplements in a few chapters.

"Efficacy and phytotoxicity" is the oldest area of testing and also the starting point for the testing procedure in Germany. The principles for this official testing, which at the time was optional, were determined as early as 1919/20. This area of testing has been extended in the course of time. The applicant must state the application modalities for each field of use of a plant protection product (amount of product and water used, timing and application technique, maximum number of applications) and provide proof of sufficient efficacy. This is a prerequisite for the evaluation of documents in the areas of "Fate and behaviour in soil, water and air", "Effects on non-target organisms", "Residue behaviour" and "Toxicology". Studies of the latter areas serve to point out and prevent possible dangers to human and animal health and the natural balance due to the use of plant protection products. The principle of prevention is restricted however, in the field of natural balance, because the effects on the natural balance have to be tolerable in the light of current scientific knowledge.

Some table headings are as to data requirements for the individual areas of testing are explained as follows:

Data Requirements
Assignment

The figures concerned employed by the EU originate from Directive 91/414/EEC; numbers under Annex II concern information on active substances and under Annex III on the preparation (plant protection product). Corresponding national data refer to the BBA Directive I, 1-2 (1990) or the current application form for authorization of a plant protection product (BBA AP-01-05).

Reasons/Conditions

"Obligatory" is stated as a reason if the tests concerned are demanded by either the EU or Germany. As a rule, application and exposition outdoors are prerequisites for this.

Number of trials (Directive)

Statements as to the number of trials necessary are based on international guidelines , whose application the EU provides for in its documents, and on BBA guidelines. However, for the areas of "Efficacy and phytotoxicity" and "Effects on non-target organisms", individual statements are not made in the guidelines. Statements as to the number of trials in the appropriate columns of the tables therefore reflect the present situation.

Most of the study methods (guidelines) of the EU mentioned here portray the incorporation of methods (guidelines) which were developed by international organizations (e.g. OECD).
After the comparative list of data requirements, the criteria for decision-making for the individual areas of testing are presented. In this respect, the following explanatory notes have been made:

Criteria for decision-making

EU criteria for decision-making

The criteria relevant to the decision for authorization of plant protection products according to Annex VI, part C of Directive 91/414/EEC are shown in the tables.

BBA principles of evaluation

The principles of evaluation for the BBA in deciding on the authorization of plant protection products are shown in the tables. The basis is mainly formed by the principles of evaluation as published in Reports from the BBA in 1993 in the English version of issue No. 285. In the area of "Effects on aquatic organisms" the principles of evaluation are already in accordance with Annex VI of Directive 91/414/EEC, on the grounds of international usage. In respect to this area the contents of the tables are largely identical.

The conclusions on authorization resulting from EU criteria for decision-making according to Annex VI of Directive 91/414/EEC and the BBA principles of evaluation are listed in the tables. They include a thorough risk assessment which is made for the purpose of authorization on the grounds of the so-called "Unless..." clauses under Annex VI. These clauses however have to be defined. In some areas of testing - as already in the current national procedure - decisions on authorization can still be made dependent on a risk/benefit analysis. This possibility has not been provided for in the area of the environmental under the criteria in Annex VI.

According to article 20 of the Plant Protection Act, the label contains above all safety phrases and warnings as well as information required or deemed applicable by the BBA regarding instructions for use (Article 15, Paragraph 3 of the Plant Protection Act). They have not been listed in this compilation, because the harmonization concerning labelling of plant protection products on EU level has not been completed yet.

Necessary action and/or research

The respective columns of the tables mainly state the action to be taken with respect to deficiencies, further developments and revisions for a functionally, increasingly harmonised authorization procedure within the Member States of the EU.

As the comparative presentation of the requirements regarding documents and criteria for decision-making shows, the EU procedure and the German authorization procedure have much in common. Deviations are there, where a clearer definition of the data requirements and criteria for decision-making is required, e.g. in the area of "Fate in air".

Braunschweig, March 1998

Professor Dr. Fred Klingauf
President of the Federal Biological Research Centre for Agriculture and Forestry (BBA)

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The German version of this publication the BBA-Heft 354 (1998): "Datenanforderungen und Entscheidungskriterien der Europäischen Union und der Bundesrepublik Deutschland im Zulassungsverfahren für Pflanzenschutzmittel" was translated into English by ZENECA Agro. I would like to express my particular thanks to this company for the thorough translation.

Data Requirements:

Efficacy and Phytotoxicity

Data requirements: Efficacy and phytotoxicity

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Efficacy - Preliminary trials For determining the biological activity and the necessary product dose rate	Preparation III 6.1	Upon request screening trials to determine the effective dose rate	No information	C/2 No. 9	Obligatory, examination of the dose rate applied for	At least **3** (see literature: BBA, Teil I, Nr. 1 - 2)
- Efficacy trials[1] For controlling harmful organisms or achieving other intended purposes	Preparation III 6.2	Obligatory	Sufficient number (EPPO guidelines or upon request according to guidelines which at least satisfy the requirements of the EPPO guidelines)	C/2 No. 7	Obligatory	**3 - 15** Per field of use (BBA, Teil II, 1; Reihe 3 - 22)

[1] Testing the efficacy of additives is not provided for by the European Union, but it is obligatory in Germany in the context of the current national authorization procedure (Plant Protection Act Article 2 Para. 1 No. 9 f in connection with Article 15 Para. 1 No. 1 and 3).

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
- Actual or possible development of resistance	Preparation III 6.3	Obligatory	No information	——	Not requested in the context of the authorization; however, must be notified by the holder of authorization in case of subsequent occurrence	No information

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Effects on the quantity and/or quality of the yield of treated plants or plant products	Preparation III 6.4					
- Effects on the quality of plants or plant products	Preparation III 6.4.1	Trials with double the normal dose rate	Sufficient number	C/2 No. 4	Trials with the maximum dose rate applied for	
Evaluation of possible effects on colour, odour or other quality characteristics of plants or plant products		Presentation partly obligatory, otherwise in case of justified assumption			Presentation partly obligatory, otherwise in case of justified assumption Example wines: evaluation of possible effects on fermentation, odour and taste	**6 - 12** White and red wine varieties (BBA, Teil II, Reihe 22 - 9)

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
- Impact on processing Evaluation of possible detrimental effects on processing and the quality of processed products	Preparation III 6.4.2	Obligatory if the treated plants or plant products are to be processed, if considerable residues are present at the time of harvest, or if there is another justified assumption	Sufficient number	C/2 No. 4	Presentation for wines obligatory, otherwise in case of justified assumption	No information
- Impact on the yield of treated plants or plant products Evaluation of a possible decrease of yield or storage loss of treated plants or plant products	Preparation III 6.4.3	Testing in the context of efficacy trials Obligatory, as far as relevant	Sufficient number	C/2 No. 7	Testing in the context of efficacy trials Obligatory, as far as relevant	See efficacy trials

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Phytotoxicity to crops (including varieties) or crop products Evaluation of possible effects on emergence, growth and development and other damage to plants	Preparation III 6.5	Obligatory in the context of efficacy trials (for herbicides with double the normal dose rate)	Sufficient number (EPPO guidelines, especially No. 135 or upon request according to guidelines which at least satisfy the requirements of the EPPO guidelines)	C/2 No. 7	Obligatory in the context of efficacy trials	See efficacy trials
Observation of undesirable or unintentional side-effects	Preparation III 6.6					
- Effects on succeeding crops Field trials with common succeeding crops to evaluate possible harmful effects on such crops	Preparation III 6.6.1	Obligatory in case of justified assumption	No information (EPPO draft guideline: effects on succeeding crops)	C/2 No. 7 No. 9	Obligatory in case of justified assumption	At least **3** from two vegetation periods (BBA, Teil VI, 13-1; preliminary guideline)

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
- Effects on other plants, including adjacent crops Observation in the context of efficacy trials to evaluate possible harmful effects on other plants, including adjacent crops	Preparation III 6.6.2	Obligatory in case of justified assumption	See efficacy trials	C/2 No. 7 No. 9	Obligatory in case of justified assumption	See efficacy trials

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
- Effects on treated plants or plant products used for multiplication Trials for evaluating possible harmful effects on plants used for multiplication	Preparation III 6.6.3	Obligatory	Sufficient number (in case of seeds, according to ISTA methods)	C/2 No. 9	Obligatory: In case of treated seed for vigour in cereals except for maize and in case of growth regulators for acceleration of ripening in oil seeds and large-grain leguminosae	At least **3** (BBA, Teil II, 4-1.1.2) (BBA, Teil II, 15-1.1.6.1)

Data requirements: Efficacy and phytotoxicity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
- Effects on beneficials and other organisms except for target organisms Observation in the context of efficacy trials to identify positive and negative effects on other harmful organisms, beneficial organisms and the remaining flora and fauna	Preparation III 6.6.4	Obligatory (special studies in relation to the effects on non-target organisms)	See efficacy trials	C/2 No. 7	Information on peculiarities (special studies in relation to the effects on non-target organisms)	See efficacy trials

Criteria for Decision-Making:

Efficacy and Phytotoxicity

Criteria for decision-making: Efficacy and phytotoxicity

Study	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Efficacy - Preliminary trials - Efficacy trials (including, yield assessments, if appropriate) - Development of resistance	Intensity, uniformity and long-term effect of control, protection or other intended effects must - be comparable with a suitable reference product - show a clear benefit ⇒ **Positive evaluation***	Sufficient efficacy according to the state of scientific knowledge and the state of the art ⇒ **Positive evaluation***	No difference	Preparation of guidelines for trials to determine the lowest dose rate and the development of resistance ⇒ **EPPO** Preparation and revision of efficacy guidelines ⇒ **EPPO / BBA**

* Authorization with the corresponding field of use, if necessary with requirements. The efficacy and phytotoxicity are evaluated for each field of use in consideration of the necessary studies mentioned above and, if necessary, after a risk/ benefit assessment.

Criteria for decision-making: Efficacy and phytotoxicity (continued)

Study	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Effects on the quantity and/or quality of the yield of treated plants or plant products				
- Impact on the yield of treated plants or plant products	Yield not less than without treatment, unless the plant protection product has other benefits (e.g. enhanced quality) ⇒ **Positive evaluation***	Yield not less than without application, unless the plant protection product has other benefits (e.g. enhanced quality) ⇒ **Positive evaluation***	No difference	No need
Phytotoxicity to crops (including varieties) or crop products	No phytotoxic effects, unless the plant protection product has other benefits ⇒ **Positive evaluation***	No phytotoxic effects, unless the plant protection product has other benefits ⇒ **Positive evaluation***	No difference	See efficacy trials

* Authorization with the corresponding field of use, if necessary with requirements. The efficacy and phytotoxicity are evaluated for each field of use in consideration of the necessary studies mentioned above and, if necessary, after a risk/benefit assessment.

Criteria for decision-making: Efficacy and phytotoxicity (continued)

Study	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Observation of undesirable or unintentional side-effects				
- Effects on succeeding crops	No unacceptable detrimental effects on succeeding crops, unless endangered crops are excluded ⇒ **Positive evaluation***	No unacceptable detrimental effects on succeeding main crops ⇒ **Positive evaluation***	In the EU procedure, crops, including main crops, can be excluded as succeeding crops	Preparation of a guideline ⇒ **EPPO** Development of suitable simulation models for assessing the risk to succeeding crops ⇒ **BBA**
- Effects on other plants, including adjacent crops	No unacceptable detrimental effects on adjacent crops ⇒ **Positive evaluation***	No unacceptable detrimental effects on adjacent crops ⇒ **Positive evaluation***	No difference	No need

* Authorization with the corresponding field of use, if necessary with requirements. The efficacy and phytotoxicity are evaluated for each field of use in consideration of the necessary studies mentioned above and, if necessary, after a risk/benefit assessment.

Criteria for decision-making: Efficacy and phytotoxicity (continued)

Study	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Effects on treated plants or plant products used for multiplication	No unacceptable detrimental effects on plants or plant products ⇒ **Positive evaluation***	No unacceptable detrimental effects on plants or plant products ⇒ **Positive evaluation***	No difference	No need
Risk minimisation by:	Conditions at the Member States' discretion	Conditions	——	Revision of conditions ⇒ **BBA**

* Authorization with the corresponding field of use, if necessary with requirements. The efficacy and phytotoxicity are evaluated for each field of use in consideration of the necessary studies mentioned above and, if necessary, after a risk/benefit assessment.

Data requirements:

Identity / further information

Data requirements: Identity

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Active substance						
Applicant	II 1.1	Obligatory	—	A/1 No. 4	Obligatory	—
Manufacturer	II 1.2	Obligatory	—	B/5 No. 2	Obligatory	—
Common name and synonyms	II 1.3	Obligatory	(ISO 1750)	B/1 No. 1	Obligatory	(ISO 1750)
Chemical name	II 1.4	Obligatory	(67/548/EEC Annex I)	B/6 No. 3	Obligatory	—
Manufacturer's code number(s)	II 1.5	Obligatory	—	—	—	—
CAS, EEC and CIPAC numbers	II 1.6	Obligatory	—	B/6 No. 4/5	Obligatory	—
Molecular and structural formulas	II 1.7	Obligatory	—	B/6 No. 6/7	Obligatory	—
Method of manufacture	II 1.8	Obligatory	—	B/5 No. 3	Obligatory	—
Minimum content	II 1.9	Obligatory	—	B/5 No. 1	Obligatory	—

Data requirements: Identity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Identity of isomers, impurities and additives	II 1.10	Obligatory	—	B/5 No. 9	Obligatory	—
Analytical profile of batches	II 1.11	Obligatory	5	—	—	—
Preparation						
Applicant	III 1.1	Obligatory	—	A/1 No. 4	Obligatory	—
Manufacturer of the preparation and the active substances	III 1.2	Obligatory	—	B/5 No. 2	Obligatory	—
Trade name	III 1.3	Obligatory	—	A/1 No. 1	Obligatory	—
Composition of the preparation	III 1.4					
- Content of both technical and pure active substance	III 1.4.1	Obligatory	(Art. 6 Para. 2 78/631/EEC)	B/1 No. 1	Obligatory	—
- Content of formulants	III 1.4.1	Obligatory	(Art. 6 Para. 2 78/631/EEC)	B/1 No. 2	Obligatory	—

Data requirements: Identity (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Active substance: - ISO common names, CIPAC number, EEC, EINECS, ELINCS numbers	III 1.4.2	Obligatory	(ISO 1750)	B/1 No. 1 B/6 No. 1-5	Obligatory	(ISO 1750)
Formulants: - Common names, IUPAC, CA names, structural formulas, EEC, EINECS, ELINCS, CAS numbers	III 1.4.3	Obligatory	(67/548/EEC Annex I)	B/1 No. 2	Obligatory	—
- Function	III 1.4.4	Obligatory	—	B/1 No. 2	Obligatory	—
Physical state and type of preparation:	III 1.5	Obligatory	—	B/1 No. 3	Obligatory	—
- Type and code of preparation	III 1.5.1	Obligatory	(GIFAP monograph No. 2)	B/1 No. 3	Obligatory	(GIFAP monograph No. 2)

Data requirements: Further information

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Active substance						
Recommended methods and precautions for handling, storage, transport, fire	II 3.7	Safety data sheet obligatory	(Art. 27 67/548/EEC)	—	Optional	(Art. 27 67/548/EEC)
Procedures for destruction or decontamination	II 3.8					
- Controlled incineration	II 3.8.1	> 60% halogens	—	—	—	—
- Other methods for disposal	II 3.8.2		—	—	—	—
Emergency measures in case of accident	II 3.9	Procedure for decontamination of water obligatory	—	—	—	—

Data requirements: Further information (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Preparation						
Packaging, compatibility with the preparation	III 4.1	Obligatory	—	A/1 No. 2 C/2 No. 3	Obligatory Type and size of packaging Domestic and allotment garden use	— —
- Description	III 4.1.1	Obligatory	(FAO packaging guidelines)	—	—	—
- Suitability	III 4.1.2	Obligatory	(ADR 3552-3556, 3558, 3560) (ISO 8317)	—	—	—
- Resistance	III 4.1.3	Obligatory	(GIFAP monograph No. 17)	—	—	—
- Cleaning procedures	III 4.2	Obligatory	—	—	—	—
Methods and precautions for handling, storage, transport, fire	III 4.4	Obligatory	(ISO TR 9122)	—	—	—

Data requirements: Further information (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Emergency measures in case of accident	III 4.5	Obligatory	—	—	—	—
Procedures for destruction or decontamination, including packaging	III 4.6					
- Possibiltiy of neutralisation	III 4.6.1	Obligatory	—	—	—	—
- Controlled incineration	III 4.6.2	> 60% halogens	—	B/2 No. 5	> 60 % halogens	Herrmann and Johnke (1992); Claussen et al. (1992)
- Other methods to dispose of	III 4.6.3	Obligatory	—	—	—	—

Data requirements:

Physico-chemical and technical data

Data requirements: Physico-chemical data

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Active substance						
Melting point and boiling point	II 2.1	Obligatory	**1** (92/69/EEC A1) **1** (92/69/EEC A2)	B/6 No. 16 B/6 No. 17	Obligatory	**1** (92/69/EEC A1) **1** (92/69/EEC A2)
Relative density	II 2.2	Obligatory	**1** (92/69/EEC A3)	B/6 No. 11	Obligatory	**1** (92/69/EEC A3)
Vapour pressure, volatility	II 2.3	Obligatory	**1** (92/69/EEC A4)	B/7 No. 23/24	Obligatory	**1** (92/69/EEC A4)
Appearance (physical state)	II 2.4	Obligatory	—	B/6 No. 13-15	Obligatory	—
Spectra (UV/visible, IR, NMR, MS), molecular extinction at relevant wavelengths	II 2.5	Obligatory	—	B/6 No. 18-21	Obligatory	—
Solubility in water, including influence of pH (4-10)	II 2.6	Obligatory	**1** (92/69/EEC A6)	B/7 No. 26	Obligatory	**1** (92/69/EEC A6)
Solubility in organic solvents	II 2.7	Obligatory	**1** (MT 181)	B/7 No. 27	Obligatory	—

Data requirements: Physico-chemical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
n-octanol/water partition coefficient, including influence of pH (4-10)	II 2.8	Obligatory	**1** (92/69/EEC A8)	B/7 No. 28	Obligatory	**1** (92/69/EEC A8)
Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of the degradation product(s), dissociation constant	II 2.9	Obligatory	**1** (92/69/EEC C7) **1** (SETAC) **1** (OECD 112)	B/7 No. 28.1 B/12 No. 2.6 B/7 No. 29	Obligatory	**1** (92/69/EEC C7) **1** (OECD Draft) **1** (OECD 112)
Stability in air, degradation, photochemical, identity of the degradation product(s)	II 2.10	Obligatory	**1** (SETAC)	B/13 No. 3.3	Volatilisation > 20%	**1** (BBA IV, 6-1)
Flammability, auto-flammability	II 2.11	Obligatory	**1** (92/69/EEC A10, A11, A12) **1** (92/69/EEC A15, A16, UN-Bowes-Cameron-Cage-Test)	— —		— —

Data requirements: Physico-chemical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Flash point	II 2.12	Obligatory	**1** (92/69/EEC A9)	—	—	—
Explosive properties	II 2.13	Obligatory	**1** (92/69/EEC A14)	—	—	—
Surface tension	II 2.14	Obligatory	**1** (92/69/EEC A5)	—	—	—
Oxidising properties	II 2.15	Obligatory	**1** (92/69/EEC A17)	—	—	—
Preparation						
Appearance (colour and odour)	III 2.1	If appropriate	—	—	—	—
Explosive and oxidising properties	III 2.2	Obligatory	**1** (92/69/EEC A14) **1** (92/69/EEC A17)	—	—	—

Data requirements: Physico-chemical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Flash point, other indications on flammability or auto-flammability	III 2.3	Obligatory	**1** (92/69/EEC A9) **1** (92/69/EEC A10, A11, A12) **1** (92/69/EEC A15, A16, UN-Bowes-Cameron-Cage-Test)	B/3 No. 4 B/3 No. 6 B/3 No. 5 + 7	Obligatory	**1** (92/69/EEC A9) **1** (92/69/EEC A10, A11, A12) **1** (92/69/EEC A15, A16, UN-Bowes-Cameron-Cage-Test)
Acidity/alkalinity, pH value if necessary	III 2.4	Obligatory	**1** (CIPAC MT 31, MT 75)	B/3 No. 1	Obligatory	**1** (CIPAC MT 31, MT75)
Viscosity and surface tension	III 2.5	Obligatory	**1** (OECD 114) **1** (92/69/EEC A5)	B/3 No. 9	Obligatory	**1** (CIPAC MT 22)
Relative density and bulk density	III 2.6	Obligatory	**1** (92/69/EEC A3) **1** (CIPAC MT 33, MT 159, MT 169)	B/3 No. 2 B/3 No. 3	Obligatory	**1** (92/69/EEC A3) **1** (CIPAC MT 33, MT 159, MT 169)/ (BBA III, 2-1/1)

Data requirements: Physico-chemical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Stability after storage	III 2.7	Obligatory	**1** (CIPAC MT 46) **1** (CIPAC MT 39, MT 48, MT 51, MT 54) **1** (GIFAP Monograph No. 17)	B/4 No. 23 B/4 No. 24 ——	Obligatory ——	**1** (CIPAC MT 46) **1** (CIPAC MT 39, MT 48, MT 51, MT 54) ——

Data requirements: Technical data

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Preparation						
Wettability	III 2.8.1	Obligatory	**1** (CIPAC MT 53.3)	B/3 No. 19	Obligatory	**1** (CIPAC MT 53.3)
Persistent foaming	III 2.8.2	Obligatory	**1** (CIPAC MT 47)	B/3 No. 12	Obligatory	**1** (CIPAC MT 47)
Suspensibility, suspension stability	III 2.8.3	Obligatory	**1** (CIPAC MT 15, MT 161, MT 168)	B/3 No. 20	Obligatory	**1** (CIPAC MT 15, MT 161, MT 168)/ (BBA III, 2-1/1)
			1 (CIPAC MT 160, MT 174, MT 180)	—	—	**1** (CIPAC MT 160, MT 174)/ (BBA III, 2-1/1)

Data requirements: Technical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Dilution stability	III 2.8.4	Obligatory	**1**(CIPAC MT 41)	——	——	——
Dry sieve test and wet sieve test	III 2.8.5	Obligatory	**1** (CIPAC MT 59.1) **1** (CIPAC MT 59.3, MT 167)	B/3 No. 13 B/3 No. 14	Obligatory	**1** (CIPAC MT 59.1) **1** (CIPAC MT 167)/ (BBA III, 2-1/1)
Size distribution of particles	III 2.8.6.1	Powders, water-dispersible granules Granules for direct application	**1**(OECD 110) **1** (CIPAC MT 58.3)	B/3 No. 15 B/3 No. 15	Powders, water-dispersible granules Granules for direct application	**1** (OECD 110) **1** (CIPAC MT 58.3)
	——	——	——	B/3 No. 15	Air jet screening (< 50 µm)	**1** (BBA III, 2-1/2)
Dust content	III 2.8.6.2	Granules	**1** (CIPAC MT 171)	B/3 No. 16	Granules	**1** (CIPAC MT 171)/ (BBA III, 2-1/2)
Friability and attrition characteristics	III 2.8.6.3	Granules	**1** (CIPAC MT 178) (Attrition characteristics)	B/3 No. 18 (Attrition characteristics)	Granules	**1** (CIPAC MT 178) (Attrition characteristics)
Emulsifiability, emulsion stability and re-emulsifiability	III 2.8.7.1	Emulsifiable preparations	**1** (CIPAC MT 36, MT 173, MT 180)	B/4 No. 21	Emulsifiable preparations	**1** (CIPAC MT 36, MT 173)

Data requirements: Technical data (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Stability	III 2.8.7.2	Diluted emulsions and preparations which are emulsions	**1** (CIPAC MT 20, MT 173)	B/4 No. 21	Diluted emulsions and preparations which are emulsions	**1** (CIPAC MT 20, MT 173)
Flowability	III 2.8.8.1	Granules	**1** (CIPAC MT 172)	B/3 No. 11	Granules	**1**(CIPAC MT 172)/ (BBA III; 2-1/ 2)
Pourability	III 2.8.8.2	Suspensions	**1** (CIPAC MT 148)	B/3 No. 10	Suspensions	**1** (CIPAC MT 148)
Dustability	III 2.8.8.3	Dustable powders	**1** (CIPAC MT 34)	B/3 No. 17	Dustable powders	**1** (CIPAC MT 34)
Physical compatibility of tank mixes	III 2.9.1	Obligatory	(company-internal method or practical trial)	——	Obligatory	(company-internal method or practical trial)
Chemical compatibility of tank mixes	III 2.9.2	Obligatory	——	——	——	——
Adhesion to and distribution on seeds	III 2.10	Seed treatment	**1** (CIPAC MT 175)	B/4 No. 22	Seed treatment	**1** (CIPAC MT 175)/ (BBA II, 4-1.1.3)
Summary and evaluation (III 2.1 - III 2.10)	III 2.11	Obligatory	——	——	——	——

Criteria for decision-making:

Physico-chemical properties

Criteria for decision-making: Physico-chemical properties

Physico-chemical properties	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
FAO specification	Compliance with FAO specification ⇒ **Positive evaluation** ⇒ **Authorization possible*)** No FAO specification existing. The following properties are ensured: a) chemical properties (cf. Annex VI) b) physical properties (cf. Annex VI) ⇒ **Positive evaluation** ⇒ **Authorization possible*)**	Compliance with FAO specification ⇒ **Positive evaluation** ⇒ **Authorization possible*)** No FAO specification existing. The following properties are ensured: a) chemical properties (cf. Annex VI) b) physical properties (cf. Annex VI) ⇒ **Positive evaluation** ⇒ **Authorization possible*)**	Criteria identical	Not applicable

*) If one or several criteria for decision-making are not satisfied, authorization is only possible when the benefits of the plant protection product outweigh its potential side-effects provided its orderly application is ensured.
Benefits:

- Advantages and compatibility in the context of integrated plant protection or in ecological farming.
- Simplification of strategies for minimising the risk of developing resistance.
- Necessity of a larger selection of active substances or biochemical effect mechanisms, e.g. for application in connection with strategies to prevent accelerated degradation in the soil.
- Reduced risk to users and consumers.
- Reduced environmental contamination and reduced effects on non-target organisms.

Criteria for decision-making: Physico-chemical properties (continued)

Physico-chemical properties	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Tank mixes	Products or additives are chemically and physically compatible ⇒ **Positive evaluation** ⇒ **Authorization possible*)**	Products or additives are chemically and physically compatible ⇒ **Positive evaluation** ⇒ **Authorization possible*)**	Criteria identical	Development of test guidelines ⇒ **CIPAC**

*) If one or several criteria for decision-making are not satisfied, authorization is only possible when the benefits of the plant protection product outweigh its potential side-effects provided its orderly application is ensured.
Benefits:

- Advantages and compatibility in the context of integrated plant protection or in ecological farming.
- Simplification of strategies for minimising the risk of developing resistance.
- Necessity of a larger selection of active substances or biochemical effect mechanisms, e.g. for application in connection with strategies to prevent accelerated degradation in the soil.
- Reduced risk to users and consumers.
- Reduced environmental contamination and reduced effects on non-target organisms.

Data requirements:

Analytical methods (formulation/residue analysis)

Data requirements: Formulation analysis

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Method for the analysis of the technical active substance	II 4.1					
- Determination of the pure active substance in the active substance as manufactured	II 4.1.1	Obligatory	(CIPAC Handbooks etc.)	——	——	——
- Determination of significant and/or relevant impurities and additives in the technical active substance	II 4.1.2	Obligatory	——	B/2 No. 7	Optional	——
- Specificity	II 4.1.3.1	Obligatory	——	——	No special requirements	——
- Linearity	II 4.1.3.2	Obligatory	——	——	No special requirements	——
- Accuracy	II 4.1.3.3	Obligatory	——	——	No special requirements	——
- Repeatability	II 4.1.3.4	Obligatory	at least **5**	——	No special requirements	——

Data requirements: Formulation analysis (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Method for the analysis of the preparation	III 5.1					
- Determination of the active substance in the preparation	III 5.1.1	Obligatory	(CIPAC Handbooks etc.)	B/2 No. 7	Obligatory	(CIPAC Handbooks etc.)
- Determination of relevant impurities in the preparation	III 5.1.2	Obligatory	—	B/2 No. 7	Optional	—
- Determination of formulants or constituents of formulants		Optional	—	B/2 No. 7	Optional	—
- Specificity		Obligatory	—	—	—	—
- Linearity		Obligatory	—	—	—	—
- Accuracy		Obligatory	—	—	—	—
- Repeatability		Obligatory	—	—	—	—

Data requirements: Residue Analysis

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Food of plant origin, harvested products – Independent laboratory validation	II 4.2.1 III 5.2	Maximum residue level has been/is being fixed Obligatory	At least **4** **matrix types** (Draft guidance document on residue analytical methods)	B/8 No. 1.3 ——	Maximum residue level has been/is being fixed ——	Crop group-dependent (BBA I, 1 - 2) ——
Food of animal origin – Independent laboratory validation	II 4.2.1 III 5.2	Maximum residue level has been/is being fixed Obligatory	**3 - 6** **matrix types** (Draft guidance document on residue analytical methods)	B/8 No. 2.4 ——	Maximum residue level has been/is being fixed ——	**3 - 6** **matrix types** (Siebers et al. 1995) ——
Soil	II 4.2.2 III 5.2	Obligatory	**1** **matrix type** (Draft guidance document on residue analytical methods)	B/8 No. 1.1	Obligatory	**1** **matrix type** (BBA I, 1-2)
Water	II 4.2.3 III 5.2	Obligatory	**2** **matrix types** (Draft guidance document on residue analytical methods)	B/8 No. 1.2	Obligatory	**1** **matrix type** (BBA I, 1-2)

Data requirements: Residue analysis (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Air	II 4.2.4 III 5.2	Exposure of operators, workers or bystanders is likely to occur	**1 - 2 matrix types** (Draft guidance document on residue analytical methods)	B/8 No. 2.5	Obligatory	**1-2** (Blacha-Puller et al. 1994)
Body fluids and tissues	II 4.2.5 III 5.2	Active substance classification T+ or T	At least **2 matrix types** (Draft guidance document on residue analytical methods)	—	—	—

Criteria for Decision-Making:

Analytical Methods

Criteria for decision-making: Analytical methods

Analysis of Preparation	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Procedure	Determination and identification of the active substance or active substances, possibly also of toxicologically, ecotoxicologically or ecologically significant impurities and other preparation constituents ⇒ **Positive evaluation** ⇒ **Authorization possible*)**	Determination and identification of the active substance or active substances, possibly also of toxicologically, ecotoxicologically or ecologically significant impurities and other preparation constituents ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable

*) When requirements are not satisfied or not fully satisfied because this is not possible by the state of science and analytical technology, a time-limited authorization is granted when the methods can be justified regarding their suitability for the intended purpose.

Criteria for decision-making: Analytical methods (continued)

Residue analysis	EU criteria for decision-making*	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Procedure	Determination and confirmation of toxicologically, ecotoxicologically or ecologically significant residues possible	Reliable determination of residues including degradation and reaction products that may be harmful to health	Determination of additional degradation products in the EU procedure	Not applicable
- Recovery	⇒ **Positive evaluation** ⇒ **Authorization possible**	⇒ **Positive evaluation** ⇒ **Authorization possible**		
	Rate: 70-110% (average) with relative standard deviation ≤ 20% ⇒ **Positive evaluation** ⇒ **Authorization possible**	Rate: 70-110% (average) with relative standard deviation ≤ 20% ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable

*) Pursuant to Annexes II and III (Directive 96/46/EC) and Annex VI (Directive 97/57/EC) of Directive 91/414/EEC.

Criteria for decision-making: Analytical methods (continued)

Residue analysis	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– Repeatability (food)	Repeatability is smaller than or equal to concentration-dependent guideline values (cf. Annex VI) Relative standard deviation of recoveries smaller or equal 20 % at limit of determination (cf Annex II, III and VI) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Relative standard deviation of recoveries smaller or equal 20 %	Repeatability is defined on the national level only via the variance of recovery rates	Interpretation of different requirements in Annex VI (recovery/repeatability) (the necessary interpretation is given in draft guidance document on residue analytical methods)
– Reproducibility (food)	Annex VI: Reproducibility is smaller than or equal to concentration-dependent values (cf. Annex VI)	—	Larger extent of validation in the EU	Interpretation of different requirements in Annex VI and in Annexes II and III. (see draft guidance document on residue analytical methods)
	Annexes II and III: Reproducibility not necessary; instead independent laboratory validation ⇒ **Positive evaluation** ⇒ **Authorization possible**	—	Larger extent of validation in the EU	

Criteria for decision-making: Analytical methods (continued)

Residue analysis	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
- Limits of determination (sensitivity) (treated plants, plant products, food, feed or products of animal origin)	Limit of determination smaller than or equal to (proposed) maximum residue level x concentration-dependent factor (cf. Annex VI) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Limits of determination smaller than or equal to maximum residue level ⇒ **Positive evaluation** ⇒ **Authorization possible**	EU uses concentration-dependent factors	
- Soil	Limit of determination ≤ 0.05 mg/kg	Limit of determination ≤ 0.05 mg/kg	Criteria identical	Development of analytical methods for phytotoxic substances because the criteria can partly not been met ⇒ **Industry**
- Drinking water	Limit of determination ≤ 0.1 µg/l	Limit of determination ≤ 0.1 µg/l	Criteria identical	Not applicable

Criteria for decision-making: Analytical methods (continued)

Residue analysis	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
- Surface water	Limit of determination ≤ NOEC or EC_{50} (most sensitive species, not belonging to target organisms)	—	So far not necessary on the national level	Not applicable
- Air	Limit of determination smaller than or equal to toxicologically justified limit	Limit of determination smaller than or equal to toxicologically justified limit	Criteria identical	Not applicable
- Specificity	Criterion not indicated	Blank smaller than or equal to limit of determination x 0.3	EU definition is missing	Establishing a criterion (see draft guidance document on residue analytical methods)
- Analytical equipment	Annex VI: Newest state of the art Annexes II and III: Equipment in common use	Equipment in common use		Interpretation of different requirements in Annex VI and in Annexes II and III (see draft guidance document on residue analytical methods)

Data Requirements:

Fate and behaviour in soil, water, air/
Predicted environmental concentrations (PEC)

Data requirements: Fate and behaviour in soil

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Route of degradation	**II 7.1.1.1**					
Aerobic degradation	II 7.1.1.1.1	Obligatory	**1** (SETAC)	B/11 No. 1.1	Obligatory	**1** (BBA IV, 4.1)
Supplementary studies - Anaerobic degradation	II 7.1.1.1.2	Anaerobic conditions	**1** (SETAC)	—	—	—
- Soil photolysis		Obligatory	**1** (SETAC)	—	—	—
Rate of degradation	**II 7.1.1.2/ III 9.1.1**					
Laboratory	II 7.1.1.2.1/ III 9.1.1.1					
- Aerobic degradation		Obligatory (20 °C) (active substance and relevant metabolites),	**3** (SETAC)	B/11 No. 1.1	Obligatory	**3** (BBA IV, 4.1)
		obligatory (10 °C) possible calculation (active substance)	**1** (SETAC)	—	—	—
- Anaerobic degradation		Anaerobic conditions	**1** (SETAC)	—	—	—

Data requirements: Fate and behaviour in soil (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Field (active substance and if appropriate relevant metabolites)	II 7.1.1.2.2/ III 9.1.1.2					
- Soil degradation		$DT50_{lab}$>60d (20 °C) In case of application under "cold climatic conditions": $DT50_{lab}$>90 d (10 °C)	**4** (SETAC)	B/11 No. 1.1	$DT90_{lab}$>100d	**4** (BBA IV, 4.1)
- Soil accumulation		$DT90_f$>1a; application over several years	**2**	B/11 No. 1.1	$DT90_f$>1a	On consultation
- Soil residues		$DT50_{lab}$> 1/3 time interval between harvest and application	**1**	—	—	—

Data requirements: Fate and behaviour in soil (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Adsorption and Desorption	**II 7.1.2**	Obligatory (active substance) Obligatory (relevant metabolites)	**4** (OECD 106) **3** (OECD 106)	B7/ No. 32	Obligatory (active substance) on consultation (relevant metabolites)	**3** (OECD 106) On consultation (OECD 106)
Mobility Laboratory	**II 7.1.3/** III 9.1.2					
- Column leaching	II 7.1.3.1/ III 9.1.2.1	K_{oc} from 7.1.2 inaccurate, active substance, relevant metabolites	**4** (SETAC)	B/11 No. 1.2	Obligatory (active substance)	**3** (BBA IV, 4.2)
- Aged residue column leaching	II 7.1.3.2/ III 9.1.2.1	No K_{oc} or leaching study (only for relevant metabolites)	**1** (SETAC)	B/11 No. 1.2	> 10% in leachate (for active substance/relevant metabolites)	**3** (BBA IV, 4.2)
Field - Lysimeter trials or - Field trials on leaching	II 7.1.3.3/ III 9.1.2.2	Expert judgement or the competent authority Implementation in Germany: in case of model calculation > 0.1 µg/l in leachate	**1** (SETAC)	B/11 No. 1.2	Only lysimeter, in case of model calculation > 0.1 µg/l or aged residue column leaching >2% in leachate	**1** (BBA IV, 4.3)

Data requirements: Fate and behaviour in water

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Abiotic degradation						
– Hydrolytic degradation	II 7.2.1.1/ II 2.9.1	Obligatory (active substance/ relevant metabolites)	**3** (EEC C 7)	B/7 No. 28	Obligatory	**3** (EEC C 7)
– Photolytic degradation	II 7.2.1.2/ II 2.9.2/ II 2.9.3	Obligatory (active substance/ relevant metabolites)	**1** (SETAC)	B/12 No. 2.6	Obligatory (active substance)	**1** (OECD draft)
Biological degradation	**II 7.2.1.3**					
– Ready biodegradability	II 7.2.1.3.1	If stipulated by 67/548/EEC	**1** (EEC C 4)	B/11 No. 2.1	Water/sediment study not available	**1** (OECD 301 AE)
– Water/sediment study	II 7.2.1.3.2	Obligatory	**2** (SETAC)	B/11 No. 2.2	Active substance not readily biodegradable pursuant to B/11 No. 2.1	**2** (BBA IV, 5-1)
Degradation in the saturated zone	**II 7.2.1.4**	Expert judgement or the competent authority	**1**	—	—	—

Data requirements: Fate and behaviour in air

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Photo-chemical oxidative degradation	**II 2.10**	Obligatory	**1** (SETAC)	B/13 No. 3.3	Evaporation >20% after 24 h (calculation)	**1** (BBA VI, 6.1)
Evaporation	**II 7.2.2**	Guideline in preparation	——	B/13 No. 3.1 B/13 No. 3.2	$DT50_{hydr. + phot.}$>4d	**1-2** (BBA VI, 6.1)

Data requirements: P E C (Predicted Environmental Concentrations)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
PEC (soil)	**III 9.1.3**					
Initial, short-term, long-term PEC		Obligatory	——	E/1	Obligatory	——
PEC (groundwater)	**III 9.2.1**					
Initial, short-term, long-term PEC		Obligatory	——	B/11 No. 1.2	With K_{oc} <500, DT50 > 21 days: PELMO calculation/ lysimeter results	——
Determination of contamination paths		Obligatory	——	B/11 No. 1.4	Obligatory	——
and possible resulting additional field trials		Expert judgement or competent authority	On consultation	B/11 No. 1.2	Expert judgement or competent authority	On consultation
PEC (surface water)	**III 9.2.3**					
Initial, short-term, long-term PEC		Obligatory	——	E/2	Obligatory	——
Determination of contamination paths		Obligatory	——	B/11 No. 1.4	Obligatory	——
and possible resulting additional field trials		Expert judgement or the competent authority	On consultation	B/11 No. 1.2	Expert judgement or the competent authority	On consultation

Data requirements: P E C (Predicted Environmental Concentrations) (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
PEC (air)	**III 9.3**	Guideline in preparation	—	—	—	—

Data requirements: Monitoring (Soil, Water and Air)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Monitoring data	**III 7.4**	Presentation of data obligatory, if available	—	—	Presentation of data obligatory, if available	—

Criteria for Decision-Making:

Fate and Behaviour in Soil, Water and Air

Criteria for decision-making: Fate and Behaviour in Soil

Environmental behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
- Metabolism	Non-extractable residues >70% and mineralisation rate <5% in 100 days ⇒ **Negative evaluation** ⇒ **No authorization *)**	Non-extractable residues > 70% after 100 days ⇒ **Negative evaluation** ⇒ **No authorization **)**	Criteria quasi identical **Evaluation on the national level includes benefits**	Not appropriate Defining more precisely the criteria for persistence in the soil in the exceptional cases mentioned ⇒ **EU (Draft guidance document on soil persistence)**

* Exception - **EU: risk assessment:**
Scientific proof that
- neither accumulation of unacceptable residue levels nor observation of unacceptable phytotoxic effects resulting from accumulation in the soil, and
- no unacceptable effects on non-target organisms (pursuant to Sub-Paras 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2)

) Exception: **National: risk/benefit assessment:
Acceptable results in the following areas:
Accumulation in the soil? Residues in or phytotoxic damage to succeeding crops? Effects on soil fauna/microflora?
High probability of such effects? Lack of control mechanisms to compensate for such effects?
Only slight disadvantage when the product is not used? Other products available for the same purpose?

Criteria for decision-making: Fate and Behaviour in Soil (continued)

Environmental behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– Degradation	DT90 (field) > 1 year and DT50 (field) > 3 months	DT90 (field) > 1 year and application rate >300 (bare soil) or >600 g/ha (grown soil)	Criteria quasi identical	Development of uniform calculation methods for PEC values in the soil ⇒ **ECCO**
	⇒ **Negative evaluation** ⇒ **No authorization *)**	⇒ **Negative evaluation** ⇒ **No authorization **)**	**Evaluation on the national level includes benefits**	Preparation of standard scenarios for modelling ⇒ **FOCUS (currently developed)** Defining more precisely the criteria for persistence in the soil in the exceptional cases mentioned ⇒ **EU (Draft guidance document on soil persistence)**

* Exception - **EU: risk assessment:**
Scientific proof that
- neither accumulation of unacceptable residue levels nor observation of unacceptable phytotoxic effects resulting from accumulation in the soil, and
- no unacceptable effects on non-target organisms (pursuant to Sub-Paras 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2)

) Exception: **National: risk/benefit assessment:
Acceptable results in the following areas:
Accumulation in the soil? Residues in or phytotoxic damage to succeeding crops? Effects on soil fauna/microflora?
High probability of such effects? Lack of control mechanisms to compensate for such effects?
Only slight disadvantage when the product is not used? Other products available for the same purpose?

Criteria for decision-making: Fate and Behaviour in Soil (continued)

Environmental behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
- Leaching	Groundwater Expected concentration of the active substance or its metabolites > lowest limit value Limit values: – Maximum permissible concentration according to 80/778/EEC (0.1 µg/l) or – maximum permissible concentration laid down by the Commission when including the active substance in Annex I or where the concentration was not been laid down corresponding to the tenth of the ADI, when the active substance was included in Annex I. ⇒**Negative evaluation** ⇒**No Authorization***)	Groundwater PELMO calculation with entry of the active substance or its metabolites > 10 µg/l **) or **annual** average concentration of the active substance or its metabolites in the lysimeter ≥ 0.1 µg/l**) ⇒ **Negative evaluation** ⇒ **No authorization**	Criteria identical in principle. In both cases the evaluation for metabolites shall be made more precise .	- Preparation of criteria for carrying out lysimeter or field leaching trials (including climatic transferability) ⇒ **ECCO** - Interpretation of results (maximum annual average concentrations, ...) ⇒ **ECCO** - Weighting of monitoring data/lysimeter or field leaching data ⇒ **ECCO** Preparation of standard scenarios for modelling ⇒ **FOCUS (currently developed)**

*) Exception: scientific proof that the lower concentration is not exceeded under relevant field conditions.
**) The same criteria apply to metabolites in addition to proof of harmful effects on the groundwater.

Criteria for decision-making: Fate and Behaviour in Water

Environmental behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– Entry in surface waters	Surface water Values for individual active substances according to Directive 75/440/EEC exceeded in surface water intended for the abstraction of drinking water or not acceptable effects on non-target organisms including animals (cf. ecotoxicology) ⇒ **Negative evaluation** ⇒ **No authorization**	Surface water Persistence in <u>water</u> ⇒ **Negative evaluation** ⇒ **Further evaluation cf. toxicology or ecotoxicology** Accumulation in the <u>sediment</u> ⇒ **Negative evaluation** ⇒ **Further evaluation cf. ecotoxicology**	Directive 75/440/EEC stipulates only values for a reduced number of active substances. Cf. ecotoxicology	Development of uniform calculation methods for PEC values for water and sediment ⇒ **ECCO** Preparation of standard scenarios for modelling ⇒ **FOCUS (currently developed)**

Criteria for decision-making: Fate and Behaviour in Air

Environmental behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– Concentration in air	Concentration of the active substance in air exceeds the AOEL values or the limit values for operators, workers and bystanders ⇒ **Negative evaluation** ⇒ **No authorization**	Evaporation and persistence in the troposphere and no lasting degradation in/on plants, in the soil and in the water, or trend to accumulation ⇒ **Negative evaluation** ⇒ **Decision on authorization dependent on risk/benefit assessment**	EU considers in the uniform principles only human exposure **Evaluation on the national level includes benefits**	Development of guidelines for risk assessment ⇒ **EPPO/CoE or OECD (currently developed)**

Data Requirements and Criteria for Decision-Making:

Effects on Non-Target Organisms

Data Requirements:

Soil Micro-Organisms

Data requirements: Soil Micro-Organisms

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory Microbial activity (especially carbon mineralisation and nitrogen transformation)	Active substance II 8.5	Obligatory	**1** (SETAC*)	—	—	—
	Preparation III 10.7.1	Obligatory, if persistent active substances (DT 90 > 100 days) have long-lasting negative effects on the studied activity (> 25% compared with the control)	**1** (SETAC*)	Preparation E/1 No. 1.1	Obligatory	**1** (BBA Teil VI, 1-1, EPPO, SETAC*)
Supplementary studies in the laboratory, semi-field or field Details not yet defined	Preparation III 10.7.2	Obligatory, if difference > 25% of the studied activity compared with the control at the trial end in the laboratory	**1** (SETAC*)	Preparation E/1 No. 1.1	Obligatory, if difference >15% of the studied activity compared with the control at the trial end in the laboratory	**1** (BBA Teil VI, 1-1, EPPO, SETAC*)

* similar as with EPPO Guideline

Criteria for Decision-Making:

Soil Micro-Organisms

Criteria for decision-making: Soil Micro-Organisms

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Microbial activity (especially carbon mineralisation and nitrogen transformation)	Active substance Difference of > 25% of studied activity compared with the control at the trial end (max. 100 days) ⇒ **Negative evaluation**	—	– In contrast to the German procedure the EU procedure concentrates on active substance testing – Reduced EU trial programme	– Shift of emphasis on the test of preparations in order to cover at the same time the effects of active substances and formulants – Revision of Directive 96/12/EC ⇒ **EU**
	Preparation Difference > 25% of studied activity compared with the control at the trial end (max. 100 days) ⇒ **Negative evaluation***	Preparation Difference > 15% of studied activity compared with the control at the trial end (max. 100 days) ⇒ **Negative evaluation usually leading to further studies**	– Higher tolerance value for the negative evaluation of results in the EU (> 25% instead of > 15%) – Objective risk evaluation is not possible because of data according to EU procedure	– Revision of EPPO/SETAC Guideline (OECD Guidelines are in preparation) ⇒ **OECD/EPPO/CoE** – Defining more precisely the term "suitable risk assessment" ("Unless ... sentence") ⇒ **EU**

Criteria for decision-making: Soil Micro-Organisms (continued)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
				– Development of more sensitive and more meaningful methods for covering of effects ⇒ **National/international**
Data from supplementary studies in the laboratory, semi-field or field	Details not yet defined	Details not yet defined	Not possible for the time being because of insufficient experience	Definition of details for such trials as well as decision criteria or principles of evaluation ⇒ **BBA/EU**
Risk minimisation by:	Conditions at the discretion of Member States	Conditions: currently none	—	—

* Authorization possibly after in-depth risk assessment and evaluation (pursuant to Annex VI, 2.5.2.6. of Directive 91/414/EEC).

Data Requirements:

Earthworms

Data requirements: Earthworms

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory – Acute toxicity	Active substance II 8.4.1	Obligatory	**1** (OECD 207)	—	—	—
	Preparation III 10.6.1.1	– Preparation contains more than 1 active substance – Toxicity cannot be derived from already tested preparation	**1** (OECD 207)	Preparation E/1 No. 1.2.1	Obligatory	**1** (OECD 207)
– Reproduction toxicity	Active substance II 8.4.2	Expert decision: – DT 90 > 100 days – Multiple application	**1** (ISO DIS 11268-2)	—	—	—
	Preparation III 10.6.1.2	– Preparation contains more than 1 active substance – Toxicity cannot be derived from already tested preparation – Increased dose rate	**1** (ISO DIS 11268-2)	Preparation E/1 No. 1.2.1	– Risk assessment not possible from the study on acute toxicity – High persistence of the active substance in the soil – Multiple application	**1** (BBA Teil VI, 2-2, ISO DIS 11268-2)

Data requirements: Earthworms (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Field						
– Effects on populations	Preparation III 10.6.1.3	TER long-term < 5	**1** (ISO Draft 11268-3)	Preparation E/1 No. 1.2.1	Laboratory data do not allow final evaluation	**1** (BBA Teil VI, 2-3, ISO Draft 11268-3)
– Residues in earthworms	Preparation III 10.6.1.3	Expert judgement: only in combination with field trial	No information	—	—	—

Criteria for Decision-Making:

Earthworms

Criteria for decision-making: Earthworms

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Acute toxicity	TER < 10 ⇒ **Negative evaluation***	TER	Partly shift to active substance examination in the EU, as a result possible reduction of requirements	Improvement and validation of models for exposure assessment ⇒ **EPPO/CoE**
Reproduction toxicity	TER < 5 ⇒ **Negative evaluation***	TER	Partly shift to active substance examination in the EU and dose/response test, as a result possible reduction of requirements	Clarify data requirements about persistent active substances ⇒ **BBA/EU**
Other trials with earthworms, e.g. field	Risk to populations ⇒ **Negative evaluation***	Risk to populations ⇒ **Negative evaluation****	Fixed trigger value in the EU for field trials, as a result possibly more field trials necessary	– Risk assessment and – Mitigation strategies for non-target areas ⇒ **BBA/EU** – Defining more precisely the term "suitable risk assessment" ("Unless ...sentence") ⇒ **EU**
Risk minimisation by:	Conditions at the discretion of Member States	Conditions	—	Revision of conditions ⇒ **BBA**

* Authorization possibly after detailed risk assessment and evaluation (pursuant to Annex VI, 2.5.2.5. of Directive 91/414/EEC)

** Authorization with conditions

Data Requirements and Criteria for Decision-Making:

Soil Macro-Organisms (Organic Matter Breakdown)

Data requirements: Other non-target organisms (flora and fauna)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Other non-target organisms (flora and fauna)	Active substance II 8.6 Preparation III 10.8	Evaluation of existing data on biological activity regarding effects	Not yet defined (——)	——	——	——

Criteria for decision-making: Other non-target organisms (flora and fauna)

Effects	**EU criteria for decision-making**	**BBA principles of evaluation**	**Comparison EU / national procedure**	**Necessary action / research**
Other non-target organisms (flora and fauna)	No detailed information	No information	Additionally in the EU procedure	– Preparation of guidelines and evaluation principles ⇒ **OECD/EU**

Data Requirements and Criteria for Decision-Making:

Other non-target organisms
(flora and fauna)

Data requirements: Soil macro-organisms (organic matter breakdown)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Field Soil macro-organisms (organic matter breakdown)	Preparation III 10.6.2	Obligatory, if DT 90 > 365 days	**1** (-)	—	—	—

Criteria for decision-making: Soil macro-organisms (organic matter breakdown)

Effects	**EU criteria for decision-making**	**BBA principles of evaluation**	**Comparison EU / national procedure**	**Necessary action / research**
Soil macro-organisms (organic matter breakdown)	No detailed information	No information	Additionally in the EU procedure	– Preparation of guidelines and evaluation principles ⇒ **OECD/EU**

Data Requirements:

Honey bees

Data requirements: Honey bees

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory – Acute toxicity Determination of LD_{50} values with oral intake and contact exposure	Active substance* II 8.3.1.1 *except for microbial active substances	Obligatory	**1** each (EPPO No. 170, OECD TG/9655. DOC, OECD TG/9656.DOC)	—	—	—
– Acute toxicity Determination of LD_{50} values with oral intake and contact exposure	Preparation III 10.4.1	Exposure possible	**1** each (EPPO No. 170, OECD TG/9655. DOC, OECD TG/9656.DOC)	Preparation E/4 No. 5	Exposure possible	**3** each (BBA VI, 23-1, EPPO No. 170, OECD TG/9655. DOC, OECD TG/9656.DOC)
– Residues after bees exposure in the field (deposit or residual toxicity)	Preparation III.10.4.2	Risk to foraging bees	Cannot be carried out for the time being because no method available	Preparation E/4 No. 5	Exposure possible	**3** studies on bee poisoning by BBA
– Effects on bee brood	Preparation II 8.3.1.2	Obligatory for insect growth regulators	**1 - 3** (Oomen-de-Ruijter test)	Preparation E/4 No. 5	Obligatory for insect growth regulators	**3** (Apis larvae test according to Wittmann)

Data requirements: Honey bees (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Semi-field – Cage tests Determination of the risks for the survival and behaviour of bees and development of colonies	Preparation III 10.4.3	– Exposure possible – Damage ratios QH_0 and QH_c between 50 and 2500	**2** (EPPO No. 170)	Preparation E/4 No. 5	– Exposure possible – LD_{50} oral < 100 µg/bee or mortality in the other test species (residual toxicity, topical application and inhalation) > 15%	**3** (BBA VI, 23-1, EPPO No. 170)
Semi-field – Tunnel tests Only for certain issues such as the determination of risks by intake of contaminated honey dew	Preparation III 10.4.5	Exposure possible	**2** (EPPO No. 170 as far as possible)	Preparation E/4 No. 5	Exposure possible	**2** On consultation
Field Determination of the risks for the survival and behaviour of bees and development of colonies	Preparation III 10.4.4	Exposure possible	**2** (EPPO No. 170 as far as possible)	Preparation E/4 No. 5	Exposure possible	**3** (BBA VI, 23-1, EPPO No. 170 as far as possible)

Criteria for Decision-Making:

Honey Bees

Criteria for decision-making: Honey bees

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Acute toxicity	Active substance Calculation of the damage potential on the basis of the LD_{50} values and the highest active substance level in g/ha planned for the application QH_0 or $QH_c > 50$ ⇒ **Negative evaluation***	—	—	– Revision of EPPO guideline No. 170 which is being done ⇒ **EPPO** – Standardisation of test methods for bee larvae ⇒ **EPPO**
Acute toxicity	Preparation See active substance ⇒ **Negative evaluation***	Preparation LD_{50} oral < 100 µg bee; and damage to the other test species ⇒ **Negative evaluation****	No essential differences in the evaluation of results	
Residues in bees	No information	Frequent evidence of bee damage can lead to more negative classification	—	– Development of test methods for other bee species ⇒ **BBA/EU**

Criteria for decision-making: Honey bees (continued)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Cage or tent tests	Serious disturbance of the behaviour of bees and negative effects on the development of colonies ⇒ **Negative evaluation***	See EU ⇒ **Negative evaluation****	Criteria identical	– Inclusion of other bee species in provisions of protection ⇒ **BBA/EU**
Tunnel tests	See cage or tent tests	See EU	Criteria identical	– Research demand for all the other study types mentioned ⇒ **BBA/EU**
Risk for survival and behaviour of bees and the development of colonies	Permanent disturbance of flight activity, behaviour and development of colonies in consideration of the bee brood ⇒ **Negative evaluation***	See EU	Criteria identical	– Defining more precisely the term "suitable risk assessment " ("Unless ... sentence") ⇒ **EU**
Risk minimisation by:	Conditions: In most EU states plant protection products that are harmful to bees are labelled meaning that they are subject to corresponding restrictions of use.	Conditions of the Bees Protection Regulation dated 22nd July 1992	——	Revision of conditions ⇒ **BBA**

* Authorization possibly after detailed risk assessment and evaluation and with classification as harmful to bees (pursuant to Annex VI, 2.5.2.3. of Directive 91/414/EEC).

** Further testing or authorization with classification as harmful to bees.

Data Requirements:

Beneficial Arthropods (other than honey bees)

Data requirements: Beneficial Arthropods (other than honey bees)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory According to species: – Mortality – Parasitation rate – Feeding rate	Active substance or representative preparation II 8.3.2	Obligatory	at least **4** from 13 species (IOBC 1988 and 1992, EPPO No. 142, No. 151, No. 180, SETAC 1994)	—	—	—
– Fertility – Behavioural disorders	Preparation III 10.5	Obligatory if – preparation contains more than 1 active substance – toxicity cannot be reliably predicted from the preparation already tested	If necessary: at least **2** (guidelines see active substance)	Preparation E/4 No. 6	Obligatory	at least **2** from more than 20 species according to the field of use (BBA 23-2.1.1 BBA 23-2.1.2 BBA 23-2.1.3 BBA 23-2.1.4. BBA 23-2.1.5 BBA 23-2.1.6 BBA 23-2.1.7 BBA 23-2.1.8 BBA 23-2.1.9 IOBC, 1988 EPPO No. 142, No. 151, No. 180, SETAC 1994)

Data requirements: Beneficial Arthropods (other than honey bees) (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Supplementary studies in the laboratory, semi-field or field According to species: Test parameters: see laboratory and in addition abundance	Active substance or representative preparation II 8.3.2 Preparation III 10.5	– Effects in the laboratory > 30% – Multiple application	If necessary: in general no more than **4** (guidelines: see active substance)	Preparation E/4 No. 6	**Field:** Only viticulture: Typhlodromus pyri obligatory for multiple application; other fields of use (e.g. fruit and vegetable cultivation) voluntary, if effects in the laboratory > 30%	At least **3 - 5** (BBA 23-2.3.4) At least **1** per species (IOBC 1988, 1992, if applicable BBA 23-2.3.3)

Criteria for Decision-Making:

Beneficial Arthropods (other than honey bees)

Criteria for decision-making: Beneficial Arthropods (other than honey bees)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Mortality Parasitation rate Feeding rate Fertility Behavioural disorders	Active substance and preparation Classification of lethal and sub-lethal effects based on IOBC criteria: > 30% harmful ⇒ **Negative evaluation***	Preparation Classification of lethal and sub-lethal effects based on IOBC criteria: < 30% not harmful 30 - 80% slightly harmful > 80% harmful ⇒ **Labelling regarding possible risk****	Partial shift to active substance examination in the EU, possibly resulting in a reduction of requirements In the national procedure unrealistic evaluation is possible on the basis of laboratory trials: a) Overestimation of the effects of toxic preparations b) Underestimation of less toxic preparations in case of multiple application The extent of effects on non-target arthropods is relevant for the autho-rization in the EU procedure in contrast to the national procedure	– Improvement and validation of test methods ⇒ **International initiative with the involvement of IOBC, EPPO, BART and COMET (started)** – Exposure assessment ⇒ **International initiative with the involvement of IOBC, EPPO, BART and COMET** – Risk assessment ⇒ **EU, international initiative with the involvement of IOBC, EPPO, BART and COMET**

Criteria for decision-making: Beneficial Arthropods (other than honey bees) (continued)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Data from supplementary studies in the laboratory, semi-field or field	Classification of effects based on IOBC criteria: < 25% not harmful 25 - 50% slightly harmful 51 - 75% moderately harmful > 75% harmful ⇒ **Negative evaluation, if unacceptable effects**	Based on IOBC criteria: < 25% not harmful 25 - 50% slightly harmful > 50% harmful Classification of effects according to BBA 23-2.3.4 (only Typhlodromus pyri, viticulture): < 40% not harmful 40 - 80% slightly harmful > 80% harmful ⇒ **Labelling regarding possible risks****	Possibly more higher-level trials necessary in consideration of multiple applications and trigger values pursuant to Annex VI. In the future prevention of "unnecessary" field trials by the use of dose/response data from laboratory trials.	– Risk assessment and risk minimisation for non-target areas ⇒ **EU, international initiative with the involvement of IOBC, EPPO, BART and COMET** – Defining more precisely the term "suitable risk assessment" ("Unless ...sentence") ⇒ **EU, international initiative with the involvement of IOBC, EPPO, BART and COMET**

Criteria for decision-making: Beneficial Arthropods (other than honey bees) (continued)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
General			All in all, comparable methods for testing and evaluation of preparations. National procedure is not suitable for confirming that the authorization requirements are satisfied for certain product groups according to Annex VI (e.g. insecticides, acaricides). Annex VI requires consistent further testing for some product groups (e.g. insecticides, acaricides), among others also the use of other methods (dose/ response tests) and the use of risk minimisation strategies.	General revision of the testing strategy is necessary for evaluating the effects of preparations on non-target arthropods in the authorization procedure regarding risk assessment, evaluation and mitigation because the test requirements and the extent of testing must be oriented according to the provisions of Annex VI in order to confirm that the authorization requirements are met. ⇒ **BBA and the above international organisations**
Risk minimisation by:	Labelling requirements based on EPPO and SETAC proposals at the discretion of the Member States	Labelling regarding possible risks	Appropriate restrictions shall be imposed with the authorization according to Directive 91/414/EEC	Revision of labelling ⇒ **BBA**

* Authorization possibly after detailed risk assessment and evaluation (pursuant to Annex VI, 2.5.2.4. of Directive 91/414/EEC)

** Authorization with labelling

Data Requirements:

Birds and Mammals

Data requirements: Birds and Mammals

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory – Acute oral toxicity to birds	Active substance II 8.1.1 Preparation III 10.1.1	Obligatory Exposure possible and TER acute or TER short-term between 10 and 100	**1** (——) **1** (——)	Active substance E/3 No. 4.1 Preparation E/3 No. 4.2	Obligatory If risk possible	**1 - 2** (——) **1** (——)
– Avian short-term dietary toxicity to birds	Active subst. II 8.1.2	Obligatory	**1 - 2** (OECD 205)	——	——	——
– Reproduction trial with birds	Active subst. II 8.1.3	– prolonged or – repeated exposure	**1** (OECD 206)	Active subst. E/3 No. 4	– prolonged or – repeated exposure	**1** (OECD 206)
Cage Acceptance trial with birds	Preparation III 10.1.3	Treated seed, baits or granules and TER acute < 10	**1** (——)	Preparation E/3 No. 4.3.3	Treated seed, baits or granules and risk possible	**1** (BBA Teil VI, 25-1)
Field Other trials with birds	Preparation III 10.1.2 III 10.1.4	TER acute < 10 TER short-term < 10 TER long-term < 5	**1** (——)	Preparation E/3 No. 4	If necessary for conclusive evaluation	**1** (——)
Cage or field Trials with wild mammals	Preparation III 10.3	TER acute < 10 TER long-term < 5	**1** (——)	Preparation E/3 No. 3	Only in exceptional cases	(——)

Criteria for Decision-Making:

Birds and Mammals

Criteria for decision-making: Birds and Mammals

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Acute oral toxicity to birds and mammals	TER acute < 10 ⇒ **Negative evaluation***	TER	Criteria identical	Preparation of a guideline with reduced use of experimental animals ⇒ **OECD**
Sub-acute toxicity to birds	TER short-term < 10 ⇒ **Negative evaluation***	——	So far not explicitly required by BBA, but has been common for a long period of time on the international level	——
Reproduction toxicity to birds	TER long-term < 5 ⇒ **Negative evaluation***	TER	Criteria identical	Revision of guideline ⇒ **OECD**
Other trials with birds and mammals	Populations at risk ⇒ **Negative evaluation***	Populations at risk ⇒ **Negative evaluation****	Criteria identical	– Preparation of a "guidance paper" on trigger values and suitable methods ⇒ **EPPO/EU** – Defining more precisely the term "suitable risk assessment" ("Unless ...sentence") ⇒ **EU**
Bio-accumulation factor (BCF)	BCF > 1 ⇒ **Negative evaluation***	BCF > 1 ⇒ **Negative evaluation****	Criteria identical	——
Risk minimisation by:	Conditions at the discretion of the Member States	Conditions	——	Revision of conditions ⇒ **BBA**

* Authorization possibly after detailed risk assessment and evaluation (according to Annex VI, 2.5.2.1. of Directive 91/414/EEC)

** Authorization possibly after risk/benefit assessment

Data Requirements:

Aquatic Organisms

Data requirements: Aquatic Organisms

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory						
– Toxicity to algae	Active subst. II 8.2.6 Preparation III 10.2.1	Obligatory Preparation contains formulants increasing the toxicity or several active substances	**1,** herbicides **2** (OECD 201) **1** (OECD 201)	Active subst. E/2 No. 2.2 Preparation E/2 No. 2.2	See EU	See EU
– Acute toxicity to fish	Active subst. II 8.2.1 Preparation III 10.2.1	Obligatory Preparation contains formulants increasing the toxicity or several active substances	**2** (OECD 203) **1** (OECD 203)	Active subst. E/2 No. 2.5 Preparation E/2 No. 2.5	See EU	See EU
– Acute toxicity to daphnia	Active subst. II 8.2.4 Preparation III 10.2.1	Obligatory Preparation contains formulants increasing the toxicity or several active substances	**1** (OECD 202 I) **1** (OECD 202 I)	Active subst. E/2 No. 2.3 Preparation E/2 No. 2.3	See EU	See EU
– Chronic toxicity to daphnia	Active subst. II 8.2.5 Preparation III 10.2.4	Chronic exposure Preparation more toxic than active substance	**1** (OECD 202 II) **1** (OECD 202 II)	Active subst. E/2 No. 2.4 Preparation E/2 No. 2.4	See EU	See EU

Data requirements: Aquatic Organisms (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Laboratory						
– Chronic toxicity to aquatic insects and aquatic gastropod molluscs	Active subst. II 8.2.5	– Direct application in waters – Insects more sensitive than daphnia	**1** each (——)	Active subst. E/2 No. 2.7	See EU except for direct application in waters	See EU
– Prolonged/chronic toxicity to fish	Active subst. II 8.2.2 Preparation III 10.2.4	Chronic exposure Preparation more toxic than active substance	**1** (OECD 204 and other methods) **1** (OECD 204)	Active subst. E/2 No. 2.6 Preparation E/2 No. 2.6	See EU	See EU
– Prolonged toxicity to sediment organisms	Active subst. II 8.2.7	– High daphnia toxicity – Persistence of the active substance in the sediment	**1** (e.g. BBA Publication 315)	Active subst. E/2 No. 2.7	See EU	See EU
– Toxicity to higher aquatic plants (e.g. 1 Lemna species)	Active subst. II 8.2.8	for herbicides	**1** (——)	Active subst. E/2 No. 2.7	See EU	See EU
– Microcosm	Preparation III 10.2.2	TER < 10/100 and special trigger values	**1** (SETAC)	Preparation E/2 No. 2.7	See EU	See EU
– Bioconcentration in fish	Active subst. II 8.2.3	log Pow > 3	**1** (OECD 305 E)	Active subst. B/12 No. 2.3	See EU	See EU
Field Mesocosm	Preparation III 10.2.2	TER < 10/100 and special trigger values	**1** (SETAC)	Preparation E/2 No. 2.7	See EU	See EU

Criteria for Decision-Making:

Aquatic Organisms

Criteria for decision-making: Aquatic Organisms

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Toxicity to algae	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	——
Acute toxicity to fish	TER < 100 ⇒ **Negative evaluation***	See EU	Criteria identical	——
Acute toxicity to daphnia	TER < 100 ⇒ **Negative evaluation***	See EU	Criteria identical	——
Chronic toxicity to daphnia	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	Interpretation of the phrase "chronic exposure" for aquatic organisms ⇒ **BBA/EU**
Chronic toxicity to aquatic insects and gastropod molluscs	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	——
Prolonged/chronic toxicity to fish	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	Preparation of a guideline for studying the chronic toxicity to fish ⇒ **OECD**

Criteria for decision-making: Aquatic Organisms (continued)

Effects	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Prolonged toxicity to sediment organisms	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	– Preparation of a guideline ⇒ **OECD** – Inclusion of reproduction in the existing method ⇒ **BBA**
Toxicity to higher aquatic plants	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	– Preparation of a guideline ⇒ **OECD** – Preparation of a method for rooted plants ⇒ **BBA**
Microcosm	TER < 10 ⇒ **Negative evaluation***	See EU	Criteria identical	Preparation of standard methods ⇒ **BBA**
Bioconcentration in fish	BCF > 100 or 1000 ⇒ **Negative evaluation***	See EU	Criteria identical	——
Mesocosm	TER < 1 - 10 ⇒ **Negative evaluation***	See EU	Criteria identical	– Uniform data evaluation ⇒ **SETAC** – Preparation of a "guidance paper" ⇒ **OECD**
Risk minimisation by:	Conditions at the discretion of the member states	Conditions**	——	Revision of conditions ⇒ **BBA**

* Authorization possibly after detailed risk assessment and evaluation (according to Annex VI, 2.5.2.2. of Directive 91/414/EEC).
Defining more precisely the term "suitable risk assessment" ("Unless ... sentence") for all aquatic organisms and test stages.

** Authorization possibly with conditions; in special cases no-authorization

Data Requirements

Residue Behaviour in or on treated Products, Food and Feed

Data requirements: Residue Behaviour in or on treated Products, Food and Feed

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Storage stability	II 6 III 8	Obligatory, unless the analysis is carried out within 30 days after sampling	maximum **4** different plant matrices	B/9 No. 3 - 5	Storage period > 6 months	——
			maximum **4** different animal matrices (Guidance Document - Appendix H)	B/10 No. 7 - 8		——
Metabolism, distribution and expression of residues in plants	II 6.1 III 8.1	Obligatory	at least **3** crop groups (Guidance Document - Appendix A)	B/9 No. 1	Obligatory	At least **3** crop groups (BBA IV, 3-2, 3-2/1)
		Desirable: Information on uptake, distribution and mode of action	——	B/9 No. 2	Obligatory: Information on uptake, distribution and mode of action	——

Data requirements: Residue Behaviour in or on treated Products, Food and Feed (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Metabolism, distribution and expression of residues in livestock	II 6.2 III 8.1	Residues in livestock feed ≥ 0.1 mg/kg	**1 - 3** (Guidance Document - Appendix F)	D/1 No. 5.2	In case of significant residues in feed	**1 - 3** (OECD 417)
Residue trials (crops)	II 6.3 III 8.2	Obligatory In general harvest values; half of them as residue decline studies, if edible parts are concerned; 2 vegetation periods, in major crops more trials than in minor crops; extrapolation of results; results of European countries with comparable climates acceptable	**4** or **8** per crop (Guidance Document - Appendix B/D)	B/9 No. 3 B/9 No. 4	Obligatory In general residue decline studies, seldom values at harvest 2 vegetation periods; extrapolation is possible with restrictions; results from European countries with comparable climates are acceptable	**8** per crop (BBA IV, 3-3, BBA IV, 3-3.1.1, BBA IV, 3-8)
Livestock feeding studies	II 6.4 III 8.3	Residues in feed ≥ 0.1 mg/kg and residues in food of animal origin > 0.01 mg/kg or > limit of determination	**1 - 3** (Guidance Document - Appendix G)	B/10 No. 8 D/1 No. 5.1 D/1 No. 5.2	Residues in food of animal origin above the limit of determination	**1 - 3** (OECD 417)

Data requirements: Residue Behaviour in or on treated Products, Food and Feed (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (directive)**	**Assignment**	**Reasons/conditions**	**Number of trials (directive)**
Effects of industrial processing and/or household preparations	II 6.5/ III 8.4					
– Effects on the nature of residue	II 6.5.1	Significant residues in plants to be processed or plant products or total TMDI larger than 10% of the ADI	maximum **3** hydrolysis studies for identifying metabolisation (Guidance Document - Appendix E)	—	—	—
– Effects on the level of residue	II 6.5.2	Significant residues in plants or plant products to be processed or total TMDI larger than 10% of the ADI, and	maximum **13** studies (corresponding process types) as balance studies	B/10 No. 7	Residues in the raw product (at the latest when TMDI for this product is above 10% of the ADI) and processing takes place and	**2** per selected crop of a crop group (basic studies)

Data requirements: Residue Behaviour in or on treated Products, Food and Feed (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (directive)**	**Assignment**	**Reasons/conditions**	**Number of trials (directive)**
– Effects on the level of residue (continued)	II 6.5.2	the processed plant product plays an important part in nutrition or - by way of exception - maximum residue levels for processed products shall be fixed. Further studies, if necessary. Main purpose: setting of transfer factors	**3** Follow-up studies (Guidance Document - Appendix E)	B/10 No. 7	residues in the processed product and importance of the product for human or animal nutrition	**4** Follow-up studies (BBA IV, 3-4, BBA IV, 3-3.4)

Data requirements: Residue Behaviour in or on treated Products, Food and Feed (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Residues in succeeding crops	II 6.6 III 8.5	Significant residues in the soil or plant material until drilling or until planting of succeeding crop	Stepwise: minimum **1** estimation, metabolism maximum **8** residue trials with in general 3 crops (Guidance Document - Appendix C)	B/9 No. 5	Significant residues in the soil	Stepwise: minimum **1** estimation, no metabolism, maximum **8** residue trials per crop (BBA IV, 3-10)
Proposed maximum residue levels (MRL's) and residue definition	II 6.7 III 8.6	Obligatory residue definition once per active substance as a result of metabolism studies	**1** per crop (Guidance Document - Appendix I)	B/10 No. 10 D/2 No. 14	Obligatory residue definition once per active substance as a result of metabolism studies	**1** per crop (BBA IV, 3-6) BBA IV, 3-8)
Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods in case of post harvest use	II 6.8 III 8.7	Obligatory	**1** per intended use (Guidance Document - Appendix I)	B/10 No. 11	Obligatory	**1** per envisaged use (BBA IV, 3-6)

Data requirements: Residue Behaviour in or on treated Products, Food and Feed (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Estimation of the potential and actual exposure through diet and other means	II 6.9 III 8.8	Obligatory	**1** (WHO Guideline)	B/10 No. 10	Obligatory	**1** (BBA IV, 3-7) (WHO Guideline)
Summary and evaluation of residue behaviour	II 6.10 III 8.9	Obligatory	**1**	B/9 No. 6 B/10 No. 9	Obligatory Obligatory	**1** **1**

Criteria for Decision-Making:

Residue Behaviour in or on treated Products, Food and Feed

Criteria for decision-making: Residue Behaviour in or on treated Products, Food and Feed

Residue behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– Proper application	Residues not higher than necessary according to Good Agricultural Practice ⇒ **Positive evaluation** ⇒ **Authorization possible**	Residues not higher than necessary according to Good Agricultural Practice ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable
– There is neither a Community nor a preliminary maximum residue level	Fixing of a preliminary maximum residue level according to Article 4.1 f Consumer exposure below the ADI value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	A nationally fixed maximum residue level is not exceeded or elaboration of a proposal for a maximum residue level*) Consumer exposure below the ADI or DTA value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable

* Authorization can only be granted when the necessary maximum residue level has been fixed in the Maximum Residue Level Regulation (RHmV).

Criteria for decision-making: Residue Behaviour in or on treated Products, Food and Feed (continued)

Residue behaviour	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– There is a preliminary maximum residue level	Level is not exceeded or fixing of a new preliminary maximum residue level according to Article 4.1 f Consumer exposure below the ADI value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Level is not exceeded or elaboration of a proposal for a maximum residue level*) Consumer exposure below the ADI value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable

* Authorization can only be granted when the necessary maximum residue level has been fixed in the Maximum Residue Level Regulation (RHmV).

Criteria for decision-making: Residue Behaviour in or on treated Products, Food and Feed (continued)

Residue analysis	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
– There exists a Community maximum level	Level is not exceeded or fixing of a new preliminary maximum residue level according to Article 4.1 f Consumer exposure below the ADI value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Level is not exceeded or elaboration of a proposal for a maximum residue level Consumer exposure below the ADI value (including processing) ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable
– Use as feed	No detrimental effects on animal health ⇒ **Positive evaluation** ⇒ **Authorization possible**	No detrimental effects on animal health ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria identical	Not applicable

Data Requirements:

Toxicology

Data requirements: Toxicology

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Active substance						
Absorption, distribution, metabolism and excretion	II 5.1	Obligatory	**2** (87/302/EEC) (96/54/EEC B36)	D/1-7	Obligatory	**1** (OECD 451)
Acute toxicity	II 5.2			D/1-1		
– oral (rat)	II 5.2.1	Obligatory	**1** (92/69/EEC B1, B1 bis.) (96/54/EEC B1 tris.)	D/1-1.1	Obligatory	**1** (OECD 401)
– dermal (rat)	II 5.2.2	Obligatory	**1** (92/69/EEC B3)	D/1-1.2	Obligatory	**1** (OECD 402)
– inhalative (rat)	II 5.2.3	Obligatory, unless animal experiment is not justified	**1** (92/69/EEC B2)	D/1-1.3	Obligatory	**1** (OECD 403)

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
– intraperitoneal (rat)	—	—	—	D/1-1.4	Obligatory	**1** (OECD 401)
– oral (other animal species)	—	—	—	D/1-1.5	Obligatory	**1** (OECD 401)
– skin irritation	II 5.2.4	Obligatory, unless strong skin irritation to be expected	**1** (92/69/EEC B4)	D/1-1.6	Obligatory	**1** (OECD 404)
– eye irritation	II 5.2.5	Obligatory, unless strong eye irritation to be expected	**1** (92/69/EEC B5)	D/1-1.7	Obligatory	**1** (OECD 405)
– skin sensitisation	II 5.2.6	Obligatory	**1** (92/69/EEC B6) (96/54/EEC B6)	D/1-1.8	Obligatory	**1** (OECD 406)
Short-term toxicity	II 5.3			D/1-3 D/1-4		
– oral study over 28 days	II 5.3.1	Not obligatory (to be reported when carried out for range finding)	(92/69/EEC B7) (96/54/EEC B7)	D/1-3	Obligatory	**1** (OECD 407)

Data requirements: Toxicology (continued)

Study	European Union			Germany		
	Assignment	Reasons/conditions	Number of trials (guideline)	Assignment	Reasons/conditions	Number of trials (guideline)
– oral study over 90 days	II 5.3.2	Obligatory dog (90 days) rat (dog (1 year), if significant for extra-polating results to man)	**2 - 3** (87/302/EEC) (96/54/EEC B26) (96/54/EEC B27)	D/1-4.1 D/1-4.2	Obligatory (rat, further animal species, as a rule dog)	**2** (OECD 408)
– other exposure routes	II 5.3.3					
dermal 28 days		Optional	(92/69/EEC B9)	—	—	—
dermal 90 days		Optional	(87/302/EEC) (96/54/EEC B28)	—	—	—
inhalative 28 days		Optional	(92/69/EEC B8)	—	—	—
inhalative 90 days		Optional	(87/302/EEC) (96/54/EEC B29)	—	—	—

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Genotoxicity	II 5.4			D/2-9		
– In vitro studies	II 5.4.1	Obligatory	(87/302/EEC) (92/69/EEC B10, B14) (96/54/EEC B15-21)	D/2-9.1	Obligatory	(DFG Report)
– In vivo studies with somatic cells	II 5.4.2	Obligatory depended on 5.4.1	(87/302/EEC) (92/69/EEC B12, B11) (96/54/EEC B22, 24, 25)	D/2-9.2	Obligatory	(DFG Report)
– In vivo studies with germ cells	II 5.4.3	Obligatory depended on 5.4.1	(87/302/EEC) (96/54/EEC B23)	—	—	—
Livestock						
– Livestock feeding studies	II 6.4 III 8.3	See also residue trials	—	D/1-5.1	Obligatory in case of occurrence of residues in feed	—
– Metabolism studies in livestock	II 6.2 III 8.1	See also residue trials	—	D/1-5.2	Obligatory in case of occurrence of residues in feed	—

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Long-term toxicity and carcinogenicity	II 5.5	Obligatory Long-term toxicity and carcinogenicity, rat Carcinogenicity, mouse	**2 - 3** (87/302/EEC) (96/54/EEC B33) (96/54/EEC B/32)	D/1-6.1 D/2-8.1 D/2-8.2	Obligatory rat, long-term toxicity rat, carcinogenicity carcinogenicity (in general mouse)	**2 - 3** (OECD 452) or (OECD 453) (OECD 451)
Reproduction toxicity	II 5.6			D/2-10		
– Multi-generation studies	II 5.6.1	Obligatory	**1** (87/302/EEC) (96/54/EEC B35)	D/2-10.1	Obligatory	(OECD 416)
– Test for developmental toxicity						
oral	II 5.6.2	Obligatory rat and rabbit	**2** (87/302/EEC) (96/54/EEC B31)	D/2-11.1/ D/2-11.2	Obligatory rat and rabbit	**2 - 4** (OECD 414)
dermal	—	—	—	—	In case of oral teratogenicity in rat and rabbit, additionally dermal teratogenicity	(OECD 414)

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Delayed neurotoxicity	II 5.7	Obligatory for certain substances (e.g. in case of phosphorous-organic compounds)	**1** (96/54/EEC B37, 38)	—	—	—
Other toxicological studies	II 5.8			D/2-12		
– Toxicological study in metabolites	II 5.8.1	if necessary	—	D/1-7	if necessary	e.g. (OECD 417)
– Additional active substance tests	II 5.8.2	if necessary (neuro-toxicity, immuno-toxicity, ADME)	—	D/2-12	if necessary	—
Medical data	II 5.9	to be reported as far as available	—	D/1-2	to be reported as far as available	—
– Medical surveillance of manufacturing plant personnel	II 5.9.1	to be reported as far as available	—	D/1-2.1 D/1-2.2	to be reported as far as available	—
– Direct observation (clinical cases, accident-related poisoning)	II 5.9.2	to be reported as far as available	—	D/2-2.3	to be reported as far as available	—

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
– Observations on exposure of the population in general and possibly epidemiological tests	II 5.9.3	to be reported as far as available	——	D/2-2	to be reported as far as available	——
– Poisoning diagnosis (determination of active substances and metabolites), specific poisoning symptoms, clinical trials	II 5.9.4	to be reported as far as available	——	——	——	——
– Proposed treatment: First Aid, antidotes, medical treatment	II 5.9.5	Obligatory	——	——	——	——
– Poisoning symptoms to be expected	II 5.9.6	If known	——	——	——	——
Summary of toxicity in mammals and general evaluation	II 5.10	Obligatory	——	Annex D/2 and D/2-14	Obligatory	——

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
Preparation						
Acute toxicity	III 7.1			D/2-15		
– oral (rat)	III 7.1.1	Obligatory	**1** (92/69/EEC B1, B1 bis.) (96/54/EEC B1 tris)	D/2-15.1	Obligatory	**1** (OECD 401) or calculation method
– dermal (rat)	III 7.1.2	Obligatory	**1** (92/69/EEC B3)	D/2-15.2	Obligatory	**1** (OECD 402) or calculation method
– inhalative (rat)	III 7.1.3	Obligatory, unless animal experiment is not justified	**1** (92/69/EEC B2)	D/2-15.3	Obligatory in case of possible exposure to undiluted preparation	**1** (OECD 403)
– skin irritation	III 7.1.4	Obligatory, unless strong skin irritation has to be expected	**1** (92/69/EEC B4)	D/2-15.4	Obligatory	**1** (OECD 404)

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
– Eye irritation	III 7.1.5	Obligatory, unless strong eye irritation has to be expected	**1** (92/69/EEC B5)	D/2-15.5	Obligatory	**1** (OECD 405)
– Skin sensitisation	III 7.1.6	Obligatory	**1** (92/69/EEC B6) (96/54/EEC B6)	—	—	—
– Supplementary studies for combination of plant protection products	III 7.1.7	If necessary	—	—	—	—
Exposure data	III 7.2			A/2		
– Operator exposure	III 7.2.1					
Evaluation of operator exposure	III 7.2.1.1	Obligatory	—	A/2-2	Obligatory	(BBA I, 3-3)
Measurement of user exposure	III 7.2.1.2	Obligatory, when health-relevant limit values are exceeded	Data or calculation model	A/2-2.1	Obligatory	(BBA I, 3-3)

Data requirements: Toxicology (continued)

	European Union			Germany		
Study	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**	**Assignment**	**Reasons/conditions**	**Number of trials (guideline)**
– Exposure of bystanders	III 7.2.2	Obligatory	Calculation model	—	—	—
– Exposure of workers	III 7.2.3	Obligatory	—	—	—	—
Evaluation of workers exposure	III 7.2.3.1	Obligatory	—	—	—	—
Measurement of workers exposure	III 7.2.3.2	Obligatory, when limit values are exceeded	Data or calculation model	—	—	—
Skin absorption	III 7.3	Obligatory in case of main exposure route	(OECD 417)	—	—	—
Available toxicological data about substances which are no active substances	III 7.4	As far as available	Safety data sheet	D/2-15	Obligatory (all information available)	—

Criteria for Decision-Making:

Toxicology

Criteria for decision-making: Toxicology

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Operator exposure	Exposure > AOEL value ⇒ **Negative evaluation** ⇒**No authorization** Limit value for the active substance and/or toxicologically relevant compound(s) not exceeded - Pursuant to 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work and – pursuant to 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work ⇒ **Positive evaluation** ⇒ **Authorization possible**	Exposure > tolerable exposure ⇒ **Negative evaluation** ⇒**No authorization** Plant protection product contains carcinogenic substances of category 1 or 2 (pursuant to 91/325/EEC) ⇒ **Negative evaluation** ⇒ **No authorization**	Calculation method on an identical basis. Difference mainly in terms of use and justification of safety factors Criteria in principle identical EU: Definition of limit values for the active substances National: no definition of limit values	Harmonisation of AOEL value calculation ⇒ **ECCO**

Criteria for decision-making: Toxicology (continued)

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Protective clothing or equipment	Equipment – is effective – corresponds with the relevant Community regulations – is easy to procure and – use is possible under the indicated conditions of application ⇒ **Positive evaluation** ⇒ **Authorization possible**	Handling and application of the plant protection product are possible with acceptable personal protective equipment Requirements made on personal protective equipment are defined by BBA Guideline. The level of protection to be reached can be calculated. ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria in principle identical but no EU specification for special personal protective equipment in plant protection	Harmonisation of personal protective equipment in plant protection ⇒ **EU**
Consumer exposure	See also residue behaviour	See also residue behaviour		

Criteria for decision-making: Toxicology (continued)

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Plant protection product		Plant protection product shows an essential uncontrollable health hazard during usual handling and storage or unintentional exposure. ⇒ **Negative evaluation** ⇒ **No authorization**	Criteria in principle identical	Not applicable
	Plant protection product may be harmful due to its properties or improper handling or use ⇒ **Special restrictions for packaging size, type of preparation, marketing, instructions for and conditions of use**			

Criteria for decision-making: Toxicology (continued)

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Plant protection product	Plant protection product classified as very toxic ⇒ **No authorization for use by non-commercial users**	Upon single exposure, the plant protection product causes: – Death or serious health damage or – strong allergic reactions ⇒ **Negative evaluation** ⇒ **No authorization** Hazard potential(s) (active substance/preparation) exist during common handling and use of hazardous substances and preparations ⇒ **Labelling** (warning symbol according to Hazardous Substance Regulation (GefStoffV), reference to special risk and safety phrases)	Criteria in principle identical	Not applicable Harmonisation of classification/labelling ⇒ **EU**

Criteria for decision-making: Toxicology (continued)

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Exposure of bystanders and workers after application	Exposure < AOEL value (for active substance or toxicologically relevant compound(s)) ensured by safety waiting periods and other precautions **and** limit values for the active substance and/or the toxicologically relevant compound(s) not exceeded - pursuant to 80/1107/EEC for the protection of workers from the risks related to exposure to chemical, physical and biological agents at work and - pursuant to 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work ⇒ **Positive evaluation** ⇒ **Authorization possible**	Exposure < tolerable exposure ⇒ **Positive evaluation** ⇒ **Authorization possible** (With specific information in the instructions for use)	More detailed evaluation approaches on the EU level	Harmonisation of specifications for re-entry conditions ⇒ **OECD Pesticide Forum**

Criteria for decision-making: Toxicology (continued)

Human and animal health	EU criteria for decision-making	BBA principles of evaluation	Comparison EU / national procedure	Necessary action / research
Effects on animals	Definition of safety waiting periods and other precautions ensuring no detrimental effects on animals ⇒ **Positive evaluation** ⇒ **Authorization possible**	Plant protection product residues will lead to irreversible damage or mortality among wild animals immediately after application or later ⇒ **Negative evaluation** ⇒ **No authorization** Adherence to safety waiting periods for livestock ⇒ **Positive evaluation** ⇒ **Authorization possible**	Criteria in principle identical	Not applicable
Adherence to AOEL values and limit values	Safety waiting periods and other precautions must be realistic; special precautions must be taken, if necessary.			

Glossary and explanations

a	year
ADI	Acceptable daily intake
ADME	Absorption, Distribution, Metabolism, Excretion
ADR	Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif au transport international des marchandises dangereuses par route) (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
AOEL	Acceptable operator exposure level
BART	Beneficial Arthropod Regulatory Testing Group
BCF	Bioconcentration factor
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council
CIPAC MT	Collaborative International Pesticides Analytical Council Miscellaneous Techniques
COMET	Commercial Ecotoxicological Testing Group
d	day(s)
DFG	Deutsche Forschungsgemeinschaft (German Research Foundation)
DTA	Duldbare tägliche Aufnahmemenge (Acceptable daily intake)
$DT50/90_{lab/f}$	Disappearance time in laboratory/field studies (Time period after which 50/90 % of the active substance is no further detected in laboratory/field studies)
$DT50_{hydr.+phot.}$	Disappearance time hydrolysis and photolysis (Time period after which 50 % of the active substance is no further detected in hydrolytic and photolytic studies)
EC50	Effective concentration

ECCO	European Commission Coordination/EU Review Programme
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of new chemical substances
EPPO/CoE	European and Mediterranean Plant Protection Organization/Council of Europe
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing (Workshop)
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the co-ordination of pesticide fate models and their use
GefStoffV	Verordnung zum Schutz vor gefährlichen Stoffen (Hazardous Substance Regulation)
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques, Brussels
IOBC	International Organization for Biological and Integrated Control of Noxious Animals and Plants-Working Group "Pesticides and Beneficial Organisms"
IR	Infrared spectrum
ISO	International Organisation for Standardisation
ISO DIS	International Standard Organisation Draft International Standard
ISTA	International Seed Testing Association
IUPAC	International Organization of Pure and Applied Chemistry
Koc	Linear partition coefficient related to the organic carbon content
LD 50	Lethal dose of a substance killing 50 % of individuals of one test species
LOEC	Lowest observable effect concentration
log Pow	Logarithmic partition coefficient of an active substance (n-octanol/ water)
MS	Mass spectrum

NMR	Nuclear magnetic resonance
OECD	Organization for Economic Co-operation and Development
PEC	Predicted Environmental Concentration
PELMO	Pesticide Leaching Model
QHc	Risikoquotient bei Kontaktexposition (Quotient of Hazard contact)
QHo	Risikoquotient bei oraler Aufnahme (Quotient of Hazard oral)
Screening	Initial efficacy testing of new substances
SETAC	Society of Environmental Toxicology and Chemistry
T	Warning symbol: toxic
T+	Warning symbol: very toxic
TER	Toxicity Exposure Ratio
TMDI	Theoretical maximum daily intake
Trigger value	Value for the decision on the execution of trials or on evaluation
UN	UN-Recommendations on the transport of dangerous goods (United Nations)
WHO	World Health Organization of the United Nations

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- A.1 Melting/freezing temperature

- A.2 Boiling temperature

- A.3 Relative density

- A.4 Vapour pressure

- A.5 Surface tension

- A.6 Water solubility

- A.8 Partition coefficient

- A.9 Flash-point

- A.10 Flammability (solids)

- A.11 Flammability (gases)

- A.12 Flammability (contact with water)

- A.13 Pyrophoric properties of solids and liquids

- A.14 Explosive properties

- A.15 Auto-ignition temperature (liquids and gases)

- A.16 Relative self-ignition temperature for solids

- A.17 Oxidizing properties (solids)

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- C.4 Biodegradation: determination of the 'ready' biodegradability; C.4-A: Dissolved organic carbon (DOC) die-away; C.4-B: Modified OECD screening test; C.4-C: Carbon dioxide (CO_2) evolution; C.4-D: Manometric respirometry; C.4-E: Closed bottle; C.4-F: MITI (Ministry of International Trade and Industry - Japan).

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- MT 34 Dustability tests after tropical storage

- MT 36 Emulsion characteristics of emulsifiable concentrates

- MT 39 Emulsifiable concentrates and solutions

- MT 41 Dilution stability of herbicide aqueous solutions

- MT 46 Accelerated storage procedure
- MT 47 Persistent foaming
- MT 48 Stability of tar oil products
- MT 51 Stability of undiluted tar-petroleum and petroleum oil products
- MT 53.3 Wetting of wettable powders
- MT 54 Stability of undiluted petroleum oil formulations, including those containing DNOC and tar products
- MT 58.3 Apparent density after compaction without pressure
- MT 59.1 Dry sieving-dusts
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- MT 75 Determination of pH values
- MT 148 Pourability of suspension concentrates
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- MT 157.2 Column elution method (solubility less than 10-2 g/l)
- MT 159 Pour and tap bulk density of granular materials
- MT 160 Spontaneity of dispersion of suspension concentrates
- MT 161 Suspensibility of aqueous suspension concentrates
- MT 167 Wet sieving after dispersion of water dispersible granules
- MT 168 Determination of the suspension stability of water dispersible granules
- MT 169 Tap density of water dispersible granules
- MT 171 Dustiness of granular products
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Sub-chronic oral toxicity test: 90-day repeated oral dose using rodent species

Sub-chronic oral toxicity test: 90-day repeated oral dose using non-rodent species

Sub-chronic dermal toxicity study: 90-day repeated dermal dose study using rodent species

Sub-chronic inhalation toxicity study: 90-day repeated inhalation dose study using rodent species

Teratogenicity test - rodent and non-rodent

Chronic toxicity test

Carcinogenicity test

Combined chronic toxicity/carcinogenicity test

One-generation reproduction toxicity test

Two-generation reproduction toxicity test

Toxicokinetics

Mutagenicity testing and screening for carcinogenicity:

- Gene mutation - Saccharomyces cerevisiae

- Mitotic recombination - Saccharomyces cerevisiae

- In vitro mammalian cell gene mutation test

- DNA damage and repair - unscheduled DNA synthesis - mammalian cells in vitro

- Sister chromatid exchange assay in vitro

- Sex-linked recessive lethal test in Drosophila melanogaster

- In vitro mammalian cell transformation tests

- Rodent dominant lethal test

- In vivo mammalian germ-cell cytogenetics

- Mouse spot test

- Mouse heritable translocation.

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- B.1 Acute toxicity (oral)

- B.1 bis. Acute toxicity (oral) Fixed Dose Method

- B.2 Acute toxicity (inhalation)

- B.3 Acute toxicity (dermal)

- B.4 Acute toxicity (skin irritation)

- B.5 Acute toxicity (eye irritation)

- B.6 Skin sensitization

- B.7 Repeated dose (28 days) toxicity (oral)

- B.8 Repeated dose (28 days) toxicity (inhalation)

- B.9 Repeated dose (28 days) toxicity (dermal)

- B.10 Mutagenicity (in vitro mammalian cytogenetic test)

- B.11 Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)

- B.12 Mutagenicity (micronucleus test)

- B.13 Mutagenicity (Escherichia coli - reverse mutation assay)

- B.14 Mutagenicity (Salmonella typhimurium - reverse mutation assay).

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- B.15 Gene mutation - Saccharomyces cerevisiae

- B.16 Mitotic recombination - Saccharomyces cerevisiae

- B.17 In vitro mammalian cell gene mutation test

- B.18 DNA damage and repair - unscheduled DNA synthesis - mammalian cells in vitro

- B.19 Sister chromatid exchange assay in vitro

- B.20 Sex-linked recessive lethal test in Drosophila melanogaster

- B.21 In vitro mammalian cell transformation test

- B.22 Rodent dominant lethal test

- B.23 In vivo mammalian germ-cell cytogenetics

- B.24 Mouse spot test

- B.25 Mouse heritable translocation

- B.26 Sub-chronic oral toxicity test: 90-day repeated oral dose using rodent species

- B.27 Sub-chronic oral toxicity test: 90-day repeated oral dose using non-rodent species

- B.28 Sub-chronic dermal toxicity study: 90-day repeated dermal dose study using rodent species

- B.29 Sub-chronic inhalation toxicity study: 90-day repeated inhalation dose study using rodent species

- B.30 Chronic toxicity test

- B.31 Teratogenicity test - rodent and non-rodent

- B.32 Carcinogenicity test

- B.33 Combined chronic toxicity/carcinogenicity test

- B.34 One-generation reproduction toxicity test

- B.35 Two-generation reproduction toxicity test

- B.36 Toxicokinetics

- B.37 Delayed neurotoxicity of organophosphorous substances after acute exposure

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