Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC) (repealed)

ANNEX I

. . . .

ANNEX II

REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

PART A

Chemical substances

1. Identity of the active substance
   - 1.1. Applicant (name, address, etc.)
   - 1.2. Manufacturer (name, address, including location of plant)
   - 1.3. Common name proposed or ISO-accepted, and synonyms
   - 1.4. Chemical name (IUPAC and CA nomenclature)
   - 1.5. Manufacturer's development code number(s)
   - 1.6. CAS, EEC and CIPAC numbers (if available)

1.7. Molecular and structural formula, molecular mass
1.8. Method of manufacture (synthesis pathway) of the active substance
1.9. Specification of purity of the active substance in g/kg
1.10. Identity of isomers, impurities and additives (e.g. stabilizers), together with...
1.11. Analytical profile of batches

2. Physical and chemical properties of the active substance
2.1. Melting point and boiling point
2.1.1. . . . .
2.1.2. . . . .
2.1.3. . . . .
2.2. Relative density
2.3. Vapour pressure (in Pa), volatility (e.g. Henry's law constant)
2.3.1. . . . .
2.3.2. . . . .
2.4. Appearance (physical state, colour and odour; if known)
2.4.1. . . . .
2.4.2. . . . .
2.5. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths...
2.5.1. . . . .
2.5.2. . . . .
2.6. Solubility in water including effect of pH (4 to 10)...
2.7. Solubility in organic solvents
2.8. Partition coefficient n-octanol/water including effect of pH (4 to 10)...
2.9. Stability in water, hydrolysis rate, photochemical degradation, quantum yield and...
2.9.1. . . . .
2.9.2. . . . .
2.9.3. . . . .
2.9.4. . . . .
2.10. Stability in air, photochemical degradation, identity of breakdown product(s)
2.11. Flammability including auto-flammability
2.11.1. . . . .
2.11.2. . . . .
2.12. Flash point
2.13. Explosive properties
2.14. Surface tension
2.15 Oxidizing properties

3. Further information on the active substance
3.1. Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator
3.2. Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach...
3.2.1. . . . .
3.2.2. . . . .
3.3. Field of use envisaged, e.g. field, protected crops, storage of...
3.4. Harmful organisms controlled and crops or products protected or treated...
3.4.1. . . . .
3.4.2. . . . .
3.4.3 . . . .
3.5. Mode of action
3.5.1. . . . .
3.5.2. . . . .

Test guideline

8.2.5. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline

8.2.6. . . . .
Aim of the test
Circumstances in which required
Test guideline

8.2.7. . . . .
Aim of test
Circumstances in which required
Test conditions

8.2.8. . . . .

8.3. Effect on arthropods

8.3.1. . . . .

8.3.1.1. . . . .
Aim of the test
Circumstances in which required
Test guideline

8.3.1.2. . . . .
Aim of the test
Circumstances in which required
Test guideline

8.3.2. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline

8.4. Effects on earthworms

8.4.1. . . . .
Aim of the test
Circumstances in which required
Test guideline

8.4.2. . . . .
Aim of the test
Circumstances in which required
Test conditions

8.5. Effects on soil non-target micro-organisms
Aim of the test
Circumstances in which required
Test conditions
Test guideline

8.6. Effects on other non-target organisms (flora and fauna) believed to...

8.7. Effects on biological methods for sewage treatment

9. Summary and evaluation of points 7 and 8

10. Proposals including justification for the proposals for the classification and...

11. A dossier as referred to in Annex III, part A,...

PART B

Introduction

1. Identity of the micro-organism
   - 1.1. Applicant
   - 1.2. Producer
   - 1.3. Name and species description, strain characterisation
   - 1.4. Specification of the material used for manufacturing of formulated products...
     - 1.4.1. Content of the micro-organism
     - 1.4.2. Identity and content of impurities, additives, contaminating micro-organisms
     - 1.4.3. Analytical profile of batches

2. Biological properties of the micro-organism
   - 2.1. History of the micro-organism and its uses. Natural occurrence and...
     - 2.1.1. Historical background
     - 2.1.2. Origin and natural occurrence
   - 2.2. Information on target organism(s)
     - 2.2.1. Description of the target organism(s)
     - 2.2.2. Mode of action
   - 2.3. Host specificity range and effects on species other than the...
   - 2.4. Development stages/life cycle of the micro-organism
   - 2.5. Infectiveness, dispersal and colonisation ability
   - 2.6. Relationships to known plant or animal or human pathogens
   - 2.7. Genetic stability and factors affecting it
   - 2.8. Information on the production of metabolites (especially toxins)
   - 2.9. Antibiotics and other anti-microbial agents

3. Further information on the micro-organism
   - Introduction
   - 3.1. Function
   - 3.2. Field of use envisaged
   - 3.3. Crops or products protected or treated
   - 3.4. Method of production and quality control
   - 3.5. Information on the occurrence or possible occurrence of the development...
   - 3.6. Methods to prevent loss of virulence of seed stock of...
   - 3.7. Recommended methods and precautions concerning handling, storage, transport or fire...
   - 3.8. Procedures for destruction or decontamination
   - 3.9. Measures in case of an accident

4. Analytical methods
   - Introduction
   - 4.1. Methods for the analysis of the micro-organism as manufactured
   - 4.2. Methods to determine and quantify residues (viable or non-viable)

5. Effects on human health
   - Introduction
   - TIER I
   - 5.1. Basic information
     - 5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel
5.1.3. Sensitisation/allergenicity observations, if appropriate
5.1.4. Direct observation, e.g. clinical cases
5.2. Basic studies
5.2.1. Sensitisation
Aim of the test
Circumstances in which required
5.2.2. Acute toxicity, pathogenicity and infectiveness
5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness
Circumstances in which required
5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness
Circumstances in which required
5.2.2.3. Intraperitoneal/subcutaneous single dose
Circumstances in which required
5.2.3. Genotoxicity testing
Circumstances in which required
Aim of the test
Test conditions
5.2.3.1. In vitro studies
Circumstances in which required
5.2.4. Cell culture study
5.2.5. Information on short-term toxicity and pathogenicity
Aim of the test
Circumstances in which required
5.2.5.1. Health effects after repeated inhalatory exposure
Circumstances in which required
5.2.6. Proposed treatment: first aid measures, medical treatment
TIER II
5.3. Specific toxicity, pathogenicity and infectiveness studies
5.4. In vivo studies in somatic cells
Circumstances in which required
5.5. Genotoxicity — In vivo studies in germ cells
Aim of the test and test conditions
Circumstances in which required
5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation...

6. Residues in or on treated products, food and feed
Introduction
6.1. Persistance and likelihood of multiplication in or on crops, feedingstuffs...
6.2. Further information required
6.2.1. Non-viable residues
6.2.2. Viable residues
6.3. Summary and evaluation of residue behaviour resulting from data submitted...

7. Fate and behaviour in the environment
Introduction
7.1. Persistence and multiplication
7.1.1. Soil
7.1.2. Water
7.1.3. Air
7.2. Mobility

8. Effects on non-target organisms
   - Introduction
   - 8.1. Effects on birds
     - Aim of the test
   - 8.2. Effects on aquatic organisms
     - Aim of the test
     - 8.2.1. Effects on fish
       - Aim of the test
     - 8.2.2. Effects on freshwater invertebrates
       - Aim of the test
     - 8.2.3. Effects on algae growth
       - Aim of the test
     - 8.2.4. Effects on plants other than algae
       - Aim of the test
   - 8.3. Effects on bees
     - Aim of the test
   - 8.4. Effects on arthropods other than bees
     - Aim of the test
   - 8.5. Effects on earthworms
     - Aim of the test
   - 8.6. Effects on non-target soil micro-organisms
   - 8.7. Additional studies

9. Summary and evaluation of environmental impact

ANNEX III

REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE AUTHORIZATION OF A PLANT PROTECTION PRODUCT

INTRODUCTION

1.1. . . . .
1.2. . . . .
1.3. . . . .
1.4. . . . .
1.5. . . . .
1.6. . . . .
2.1. . . . .
2.2. . . . .
2.3. . . . .
2.4. . . . .
2.5. . . . .
2.6. . . . .
3. . . . .
4. . . . .

PART A

Chemical preparations

1. Identity of the plant protection product
   - 1.1. Applicant (name and address, etc.)
   - 1.2. Manufacturer of the preparation and the active substance(s) (names and...

1.3. Trade name or proposed trade name, and manufacturer's development code...
1.4. Detailed quantitative and qualitative information on the composition of the...
1.4.1. . . . .
1.4.2. . . . .
1.4.3. . . . .
1.4.4. . . . .
1.5. Physical state and nature of the preparation (emulsifiable concentrate, wettable...
1.5.1. . . . .
1.6. Function (herbicide, insecticide, etc.)

2. Physical, chemical and technical properties of the plant protection product...
2.1. Appearance (colour and odour)
2.2. Explosivity and oxidizing properties
2.2.1. . . . .
2.2.2. . . . .
2.3. Flash point and other indications of flammability or spontaneous ignition...
2.4. Acidity/alkalinity and if necessary pH value
2.4.1. . . . .
2.4.2. . . . .
2.5. Viscosity and surface tension
2.5.1. . . . .
2.5.2. . . . .
2.5.3. . . . .
2.6. Relative density and bulk density
2.6.1. . . . .
2.6.2. . . . .
2.7. Storage — stability and shelf-life: Effects of light, temperature and...
2.7.1. . . . .
2.7.2. . . . .
2.7.3. . . . .
2.8. Technical characteristics of the plant protection product
2.8.1. Wettability
2.8.2. Persistent foaming
2.8.3. Suspensibility and suspension stability
2.8.4. Dilution stability
2.8.5. Dry sieve test and wet sieve test
2.8.6. Particle size distribution (dustable and wettable powders, granules), content of...
2.8.6.1. . . . .
2.8.6.2. . . . .
2.8.6.3. . . . .
2.8.7. Emulsifiability, Re-emulsifiability, emulsion stability
2.8.7.1. . . . .
2.8.7.2. . . . .
2.8.8. Flowability, pourability (rinsability) and dustability
2.8.8.1. . . . .
2.8.8.2. . . . .
2.8.8.3. . . . .
2.9. Physical and chemical compatibility with other products including plant protection...
2.9.1. . . . .
2.9.2. . . . .

2.10. Adherence and distribution to seeds
2.11. Summary and evaluation of data presented under points 2.1. to...

3. Data on application
3.1. Field of use envisaged, e.g. field, protected crops, storage of...
3.2. Effects on harmful organisms, e.g. contact, inhalation or stomach poison,...
3.3. Details of intended use e.g. types of harmful organisms controlled...
3.4. Application rate
3.5. Concentration of active substance in material used (e.g. in the...
3.6. Method of application
3.7. Number and timing of applications and duration of protection
3.8. Necessary waiting periods or other precautions to avoid phytotoxic effects...
3.9. Proposed instructions for use

4. Further information on the plant protection product
4.1. Packaging (type, materials, size etc.), compatibility of the preparation with...
4.1.1. . . . .
4.1.2. . . . .
4.1.3. . . . .
4.2. Procedures for cleaning application equipment
4.3. Re-entry periods, necessary waiting periods or other precautions to protect...
4.3.1. . . . .
4.3.2. . . . .
4.4. Recommended methods and precautions concerning: handling, storage, transport or fire...
4.5. Emergency measures in the case of an accident
4.6. Procedures for destruction or decontamination of the plant protection product...
4.6.1. Possibility of neutralization
4.6.2. Controlled incineration
4.6.3. Others

5. Analytical methods
Introduction
5.1. Methods for the analysis of the preparation
5.1.1. . . . .
5.1.2. . . . .
5.1.3. . . . .
5.1.3.1. . . . .
5.1.3.2. . . . .
5.1.3.3. . . . .
5.1.3.4. . . . .
5.2. Analytical methods for the determination of residues

6. Efficacy data
General
6.1. Preliminary tests
6.2. Testing effectiveness
Aim of the tests
Test conditions
Test guideline
6.3. Information on the occurrence or possible occurrence of the development...
6.4. Effects on the yield of treated plants or plant products...
6.4.1. Effects on the quality of plants or plant product

7.2.1. Operator exposure
7.2.1.1. Estimation of operator exposure
Aim of the estimation
Circumstances in which required
Estimation conditions
7.2.1.2. Measurement of operator exposure
Aim of the test
Circumstances in which required
Test conditions
7.2.2. Bystander exposure
Aim of the estimation
Circumstances in which required
Estimation conditions
7.2.3. Worker exposure
7.2.3.1. Estimation of worker exposure
Aim of the estimation
Circumstances in which required
Estimation conditions
7.2.3.2. Measurement of worker exposure
Aim of the test
Circumstances in which required
Test conditions

7.3. Dermal absorption
Aim of the test
Circumstances in which required
Test conditions
Test guideline

7.4. Available toxicological data relating to non-active substances

8. Residues in or on treated products, food and feed
Introduction

8.1. Metabolism, distribution and expression of residue in plants or livestock...
Aim of the tests
Circumstances in which required
Test conditions

8.2. Residue trials
Aim of the tests
Circumstances in which required
Test conditions

8.3. Livestock feeding studies
Aim of the tests
Circumstances in which required
Test conditions

8.4. Effects of industrial processing and/or household preparations
Aim of the tests
Circumstances in which required
Test conditions

8.5. Residues in succeeding crops
Aim of the test
Circumstances in which required
Test conditions

8.6. Proposed maximum residue levels (MRLs) and residue definition

8.7. Proposed pre-harvest intervals for envisaged uses, or withholding periods or...

10.4.1. . . . .
Aim of the test
Circumstances in which required
Test guideline
10.4.2. . . . .
Aim of the test
Circumstances in which required
Test conditions
10.4.3. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline
10.4.4. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline
10.4.5. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline

10.5. Effects on arthropods other than bees
10.5.1. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline
10.5.2. . . . .
Aim of the test
Circumstances in which required
Test conditions
Test guideline

10.6. Effects on earthworms and other soil non-target macro-organisms, believed to...
10.6.1. . . . .
10.6.1.1. . . . .
Aim of the test
Circumstances in which required
Test guideline
10.6.1.2. . . . .
Aim of the test
Circumstances in which required
Test conditions
10.6.1.3. . . . .
Aim of the test
Circumstances in which required
Test conditions
10.6.2. . . . .
Aim of the test
Circumstances in which required

10.7. Effects on soil non-target micro-organisms
10.7.1. . . . .

Aim of the test
Circumstances in which required
Test guideline

10.7.2. . . . .
Aim of the test
Circumstances in which required

10.8. Available data from biological primary screening in summary form

11. Summary and evaluation of points 9 and 10

12. Further information
12.1. . . . .
12.2. . . . .
12.3. . . . .
12.4. . . . .
12.5. . . . .

PART B

Introduction

1. IDENTITY OF THE PLANT PROTECTION PRODUCT
1.1. Applicant
1.2. Manufacturer of the preparation and the micro-organism(s)
1.3. Trade name or proposed trade name, and manufacturer's development code...
1.4. Detailed quantitative and qualitative information on the composition of the...
1.5. Physical state and nature of the preparation
1.6. Function

2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT...
2.1. Appearance (colour and odour)
2.2. Storage stability and shelf-life
2.2.1. Effects of light, temperature and humidity on technical characteristics of...
2.2.2. Other factors affecting stability
2.3. Explosivity and oxidising properties
2.4. Flash point and other indications of flammability or spontaneous ignition...
2.5. Acidity, alkalinity and if necessary pH value
2.6. Viscosity and surface tension
2.7. Technical characteristics of the plant protection product
2.7.1. Wettability
2.7.2. Persistent foaming
2.7.3. Suspensibility and suspension stability
2.7.4. Dry sieve test and wet sieve test
2.7.5. Particle size distribution (dustable and wettable powders, granules), content of...
2.7.6. Emulsifiability, re-emulsifiability, emulsion stability
2.7.7. Flowability, pourability (rinsability) and dustability
2.8. Physical, chemical and biological compatibility with other products including plant...
2.8.1. Physical compatibility
2.8.2. Chemical compatibility

ANNEX IV

STANDARD PHRASES FOR SPECIAL RISKS FOR HUMANS OR THE ENVIRONMENT AS REFERRED TO IN ARTICLE 16

INTRODUCTION

ANNEX V

STANDARD PHRASES FOR SAFETY PRECAUTIONS FOR THE PROTECTION OF HUMANS OR THE ENVIRONMENT AS REFERRED TO IN ARTICLE 16

INTRODUCTION

1. General provisions
   - SP 1

2. Specific safety precautions
   - 2.1. Safety precautions for operators (SPo)
     - General provisions
       - 1. . . . .
       - 2. . . . .
       - 3. Member States may add specifications of engineering controls, such as:...
     - Specific provisions
       - SPo 1
       - SPo 2
       - SPo 3
       - SPo 4
       - SPo 5
   - 2.2. Safety precautions related to the environment (SPe)
     - SPe 1
     - SPe 2
     - SPe 3
     - SPe 4
     - SPe 5
     - SPe 6
     - SPe 7
     - SPe 8
   - 2.3. Safety precautions related to good agricultural practice
     - SPa 1
   - 2.4. Specific safety precautions for rodenticides (SPr)
     - SPr 1
     - SPr 2
     - SPr 3

3. Attribution criteria for standard phrases for specific safety precautions
   - 3.1. INTRODUCTION
   - 3.2. Attribution criteria for standard phrases for safety precautions for operators...
     - SPo 1
     - SPo 2
     - SPo 3
     - SPo 4
     - SPo 5
   - 3.3. Attribution criteria for standard phrases for safety precautions for the...
     - SPe 1
     - SPe 2
     - SPe 3
     - SPe 4
     - SPe 5

ANNEX VI

PART I

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF CHEMICAL PLANT PROTECTION PRODUCTS

CONTENTS

A. INTRODUCTION

3. . . . .
4. . . . .
5. . . . .
6. . . . .

B. EVALUATION

1. General principles
   1. . . . .
   2. . . . .
   3. . . . .
   4. . . . .
   5. . . . .
   6. . . . .
2. Specific priciples
   - 2.1. Efficacy
     - 2.1.1. . . . .
     - 2.1.2. . . . .
     - 2.1.3. . . . .
     - 2.1.4. . . . .
     - 2.1.5. . . . .
   - 2.2. Absence of unacceptable effects on plants or plant products
     - 2.2.1. . . . .
     - 2.2.2. . . . .
     - 2.2.3. . . . .
   - 2.3. Impact on vertebrates to be controlled
   - 2.4. Impact on human or animal health
     - 2.4.1. arising from the plant protection product
       - 2.4.1.1. . . . .
       - 2.4.1.2. . . . .
       - 2.4.1.3. . . . .
       - 2.4.1.4. . . . .
     - 2.4.2. Arising from residues
       - 2.4.2.1. . . . .
       - 2.4.2.2. . . . .
       - 2.4.2.3. . . . .
       - 2.4.2.4. . . . .
       - 2.4.2.5. . . . .
       - 2.4.2.6. . . . .
   - 2.5. Influence on the environment
     - 2.5.1. Fate and distribution in the environment
       - 2.5.1.1. . . . .
       - 2.5.1.2. . . . .
       - 2.5.1.3. . . . .
       - 2.5.1.4. . . . .
       - 2.5.1.5. . . . .
     - 2.5.2. Impact on non-target species
       - 2.5.2.1. . . . .
       - 2.5.2.2. . . . .
       - 2.5.2.3. . . . .
       - 2.5.2.4. . . . .
       - 2.5.2.5. . . . .
       - 2.5.2.6. . . . .
   - 2.6. Analytical methods

2.6.1. for formulation analysis:
2.6.2. for residue analysis:
2.7. Physical and chemical properties
2.7.1. . . . .
2.7.2. . . . .
2.7.3. . . . .

C. DECISION-MAKING
1. General principles
1. . . . .
2. . . . .
3. . . . .
4. . . . .
5. . . . .
6. . . . .
7. . . . .
8. . . . .
9. . . . .
2. Specific principles
2.1. Efficacy
2.1.1. . . . .
2.1.2. . . . .
2.1.3. . . . .
2.1.4. . . . .
2.1.5. . . . .
2.2. Absence of unacceptable effects on plants or plant products
2.2.1. . . . .
2.2.2. . . . .
2.2.3. . . . .
2.2.4. . . . .
2.2.5. . . . .
2.2.6. . . . .
2.2.7. . . . .
2.2.8. . . . .
2.3. Impact on vertebrates to be controlled
2.4. Impact on human or animal health
2.4.1. arising from the plant protection product
2.4.1.1. . . . .
2.4.1.2. . . . .
2.4.1.3. . . . .
2.4.1.4. . . . .
2.4.1.5. . . . .
2.4.1.6. . . . .
2.4.2. arising from residues
2.4.2.1. . . . .
2.4.2.2. . . . .
2.4.2.3. . . . .
2.4.2.4. . . . .
2.4.2.5. . . . .
2.4.2.6. . . . .
2.4.2.7. . . . .
2.5. Influence on the environment
2.5.1. Fate and distribution in the environment

2.5.1.1. . . . .
2.5.1.2. . . . .
2.5.1.3. . . . .
2.5.1.4. . . . .
2.5.2. Impact on non-target species
2.5.2.1. . . . .
2.5.2.2. . . . .
2.5.2.3. . . . .
2.5.2.4. . . . .
2.5.2.5. . . . .
2.5.2.6. . . . .
2.6. Analytical methods
2.6.1. for formulation analysis:
2.6.2. for residue analysis:
2.7. Physical and chemical properties
2.7.1. . . . .
2.7.2. . . . .
2.7.3. . . . .

PART II

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS

A. INTRODUCTION
1. . . . .
2. In evaluating applications for granting authorisations Member States shall:
3. . . . .
4. Where the data and information provided are sufficient to permit...
5. During the process of evaluation and decision-making, the Member State...
6. . . . .
7. . . . .
8. . . . .
9. . . . .
10. Definitions and explanations of microbiological terms

B. EVALUATION
1. General principles
1.1. Having regard to current scientific and technical knowledge, Member States...
1.2. The quality/methodology of tests, where there are no standardised test...
1.3. In interpreting the results of evaluations, Member States shall take...
1.4. . . . .
1.5. . . . .
1.6. . . . .
1.7. Where specific principles in Section 2 provide for the use of...
1.8. . . . .
2. Specific principles
2.1. Identity
2.1.1. Identity of the micro-organism in the plant protection product

2.1.2. Identity of the plant protection product

2.2. Biological, physical, chemical, and technical properties

2.2.1. Biological properties of the micro-organism in the plant protection product...

2.2.1.1. . . . .

2.2.1.2. The ability of micro-organisms to adapt to the environment must...

2.2.1.3. The mode of action of the micro-organism should be evaluated...

2.2.1.4. In order to evaluate possible effects on non-target organisms, information...

2.2.1.5. . . . .

2.2.2. Physical, chemical and technical properties of the plant protection product...

2.2.2.1. . . . .

2.2.2.2. . . . .

2.2.2.3. Member States shall evaluate the physical and chemical properties of...

2.2.2.4. . . . .

2.3. Further information

2.3.1. Quality control of the production of the micro-organism in the...

2.3.2. Quality control of the plant protection product

2.4. Efficacy

2.4.1. . . . .

2.4.2. . . . .

2.4.3. Member States shall evaluate the efficacy data provided for in...

2.4.4. Member States shall evaluate the performance of the plant protection...

2.4.5. Member States shall evaluate the degree of adverse effects on...

2.4.6. Where the plant protection product label includes requirements for use...

2.4.7. . . . .

2.4.8. Where the proposed use of a plant protection product is...

2.5. Identification/detection and quantification methods

2.5.1. Analytical methods for the plant protection product

2.5.1.1. Non-viable components

2.5.1.2. Viable components

2.5.2. Analytical methods for the determination of residues

2.5.2.1. Non-viable residues

2.5.2.2. Viable residues

2.6. Impact on human or animal health

2.6.1. Effects on human or animal health arising from the plant...

2.6.1.1. Member States shall evaluate operator exposure to the micro-organism, and/or...

2.6.1.2. Member States shall examine information relating to the nature and...

2.6.1.3. Member States shall examine the nature and characteristics of the...

2.6.1.4. Member States shall evaluate the possibility of exposure of other...

2.6.2. Effects on human or animal health arising from residues

2.6.2.1. Non-viable residues
2.6.2.2. Viable residues

2.7. Fate and behaviour in the environment
2.7.1. Member States shall evaluate the possibility of contamination of ground...
2.7.2. Member States shall evaluate the risk for the aquatic compartment...
2.7.3. . . . .
2.7.4. Member States shall evaluate the possibility of exposure of organisms...

2.8. Effects on and exposure of non-target organisms
2.8.1. Member States shall evaluate the possibility of exposure of and...
2.8.1.1. A micro-organism may give rise to risks because of its...
2.8.1.2. A plant protection product may give rise to toxic effects...
2.8.2. Member States shall evaluate the possibility of exposure of and...
2.8.2.1. A micro-organism may give rise to risks because of its...
2.8.2.2. A plant protection product may give rise to toxic effects...
2.8.3. Member States shall evaluate the possibility of exposure of and...
2.8.3.1. A micro-organism may give rise to risks because of its...
2.8.3.2. A plant protection product may give rise to toxic effects...
2.8.4. Member States shall evaluate the possibility of exposure of and...
2.8.4.1. A micro-organism may give rise to risks because of its...
2.8.4.2. A plant protection product may give rise to toxic effects...
2.8.5. Member States shall evaluate the possibility of exposure of and...
2.8.5.1. A micro-organism may give rise to risks because of its...
2.8.5.2. A plant protection product may give rise to toxic effects...
2.8.6. Member States shall evaluate the possibility of exposure of and...
2.8.6.1. A micro-organism may give rise to risks because of its...
2.8.6.2. . . . .
2.8.6.3. A plant protection product may give rise to toxic effects...

2.9. Conclusions and proposals

C. DECISION-MAKING
1. General principles
1.1. . . . .

1.2. . . . .
1.3. . . . .
1.4. . . . .
1.5. . . . .
1.6. Before issuing an authorisation, Member States shall ensure that the...
1.7. Before issuing authorisations, Member States shall:
1.8. No authorisation shall be granted unless all the requirements referred...
1.9. Where an authorisation has been granted according to the requirements...
1.10. . . . .
1.11. . . . .
1.12. . . . .
1.13. . . . .
1.14. . . . .

2. Specific principles
2.1. Identity
2.2. Biological and technical properties
2.2.1. . . . .
2.2.2. . . . .
2.3. Further information
2.4. Efficacy
2.4.1. Performance
2.4.1.1. . . . .
2.4.1.2. . . . .
2.4.1.3. . . . .
2.4.1.4. . . . .
2.4.1.5. Where proposed label claims include requirements for use of the...
2.4.1.6. . . . .
2.4.1.7. . . . .
2.4.2. Absence of unacceptable effects on plants and plant products
2.4.2.1. . . . .
2.4.2.2. . . . .
2.4.2.3. . . . .
2.4.2.4. . . . .
2.4.2.5. . . . .
2.4.2.6. . . . .
2.4.2.7. . . . .
2.4.2.8. . . . .
2.5. Identification/detection and quantification methods
2.5.1. . . . .
2.5.2. No authorisation shall be granted unless there are adequate methods...
2.6. Impact on human and animal health
2.6.1. Effects on human and animal health arising from the plant...
2.6.1.1. . . . .
2.6.1.2. No authorisation shall be granted if the micro-organism and/or the...
2.6.1.3. All micro-organisms should be regarded as potential sensitisers, unless it...
2.6.1.4. . . . .
2.6.1.5. . . . .
2.6.1.6. . . . .

2.6.1.7. . . . .
2.6.1.8. . . . .
2.6.1.9. . . . .
2.6.2. Effects on human and animal health arising from residues
2.6.2.1. . . . .
2.6.2.2. . . . .
2.7. Fate and behaviour in the environment
2.7.1. . . . .
2.7.2. . . . .
2.7.3. No authorisation shall be granted if the contamination of groundwater...
2.7.4. No authorisation shall be granted if the contamination of surface...
2.7.5. . . . .
2.7.6. . . . .
2.7.7. . . . .
2.8. Effects on non-target organisms
2.8.1. Where there is a possibility of birds and other non-target...
2.8.2. Where there is a possibility of aquatic organisms being exposed,...
2.8.3. Where there is a possibility of bees being exposed, no...
2.8.4. Where there is a possibility of arthropods other than bees...
2.8.5. . . . .
2.8.6. . . . .