

**Evaluation Manual
for the Authorisation
of plant protection products and biocides
according to Regulation (EC) No 1107/2009**

EU part

Plant protection products

Chapter 5 Residues; risk to consumers

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**Board
for the Authorisation
of Plant Protection Products and Biocides**

Chapter 5: Residues; risk to consumers

Category: Plant protection products

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GENERAL INTRODUCTION

This chapter describes the way in which the risk for consumers is estimated for the EU framework (§1 - §1.5) Regulation (EC) No 1107/2009 [1]. The risk assessment described in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorisation of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted for approval after 31 December 2013 and for plant protection products submitted for authorisation after 31 December 2015.

A concept guidance is available for the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1), it is currently still ‘to be noted’ by the Standing Committee Legislation .

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0.

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure had been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011 [3].

1.1. Introduction

The purpose of this evaluation is to establish whether the application of a plant protection product has no adverse effects on public health by consumption of treated crops, processed products, animal products or drinking water, for which the reference values ADI (Acceptable Daily Intake) and ARfD (Acute Reference Dose) as described in Chapter 4 Human toxicology; human toxicity dossier (plant protection) are compared with the exposure expected via the diet.

The analytical methods used in the residue studies and the corresponding validation for the crops or animal products in question must be described in the residue report in question or reference must be made to a separate report in which the method is described, which must then also be provided. In addition, an analytical method for enforcement must be provided (see Chapter 3 Analytical methods).

[Appendix I](#) presents the risk assessment for consumers in the form of a flow diagram.

1.2. Data requirements

The risk to consumers is assessed on the basis of the residue dossier. The data requirements are given in Chapter 5 Residues, residue dossier, §1.2.

1.3. Risk assessment

The endpoints from the toxicological dossier and the corresponding limit values (ADI, ARfD) (see Chapter 4 Human toxicology; human toxicity dossier (plant protection)) must be compared with the expected exposure to assess whether the application of a plant protection product has no adverse consequences for public health. Exposure estimation is based on data from the residue dossier (see Chapter 5 Residues, residue dossier (plant protection)).

The procedure for exposure estimation is described in this chapter.

Consumer risk assessment follows a tiered approach. The first tier is based on a worst-case situation as regards exposure estimation.

Where the criteria are not met in the first tier of the assessment, the applicant is given the opportunity to provide supplementary data and a refined risk assessment is carried out (higher tier).

Chronic intake and acute intake are calculated to assess the risk to consumers. For each product a Supervised Trial Median Residue level (STMR), a Highest Residue (HR) and a Maximum Residue Limit (MRL) are derived from the residue trials. For the derivation of STMR, HR and MRL for plant protection products we refer to §1.3.6 of Chapter 5 Residues, residue dossier. Consumer exposure to residues of plant protection products is determined on the basis of the residue data included in the list of endpoints and diet data.

The intake calculations indicate how much residue is, as result of the use of a certain active substance under GAP (Good Agricultural Practice), ingested by consumers. This intake may not exceed the value of the ADI (life-long exposure) and ARfD (single exposure).

Here, a distinction is made between health risks for the general population and for children. This distinction is made because children have a less varied consumption pattern and a higher caloric intake in comparison with adults.

For inclusion of a substance in Commission Implementing Regulation (EU) No 541/2011 [3] public health risk is only calculated for the defended uses. Member States may, however, still grant other authorisations for the substance after MRLs resulting from this application have been accepted by European Parliament and published by the European Commission. Within a year after inclusion of the substance in Commission Implementing Regulation (EU) No 541/2011, MRLs need to be harmonised in the framework of Regulation (EC) 396/2005. See also §2.3 (NL framework).

A summary of the risk assessment for consumers is in diagrammatic form presented in Appendix 1.

1.3.1 Chronic exposure calculation

As RMS, the Netherlands uses the model for assessing acute and chronic exposure for adults, children and general populations created by EFSA including all available EU Member State diets: PRIMo (Pesticide Residue Intake Model rev. 2). In 2013, a revision of EFSA PRIMo rev 3 was drafted and presented and is currently in the commenting and testing phase

First, a 'worst case scenario' is tested. Here it is assumed that all consumed products of the crops in question have been treated, a residue level will be found at the level of the MRL, and all products are consumed raw without taking the decline in residue level by processing into account.

This worst case scenario is also called the International Theoretical Maximum Daily Intake (ITMDI) calculation:

$$\text{TMDI} = \sum \text{MRL}_i \times \text{F}_i$$

MRL_i = Maximum Residue Level of a certain product (mg/kg)

F_i = corresponding national consumption of the product in question per person (kg/day)

The TMDI is calculated for all EU regional diets. When the TMDI is found to exceed the ADI of one or more diets, an IEDI (International Estimated Daily Intake) calculation is carried out in which processing data are included and the STMR (median) is applied as residue level instead of the MRL.

$$\text{IEDI} = \sum \text{STMR}_i \times \text{E}_i \times \text{P}_i \times \text{F}_i$$

STMR = Supervised trial median residue level of a certain product (mg/kg)

E = factor for the edible part of the particular product

P = processing factor of the particular product

F = corresponding national consumption of the particular product per person (kg/day)

1.3.2 Acute exposure calculation

As RMS, the Netherlands uses the model for assessing acute and chronic exposure created by EFSA including all available EU Member State diets: PRIMo (Pesticide Residue Intake Model rev 2). In Europe, the consumption of primary agricultural products by all European regional populations is derived for acute exposure estimation, also referred to as 'large portion'. All national diets (97.5 percentile of consumption data) and national unit weights are included. Where no national unit weights are presented, the mean value of the other national data are used.

The point estimate is a worst case scenario and is also referred to as the International Estimate of Short-Term Intake (IESTI) calculation. The internationally developed methodology [4, 5, 6] is followed for point estimation; this assumes that a person is eating a large portion ('Large Portion' = LP), which by coincidence also contains a very high residue level (expressed by the variability factor = v). Currently, four different situations are distinguished for the IESTI-calculation, each with a specific mathematical method, for which the following parameters are used [6]:

U = unit weight (g)

LP = highest available 'large portion' (97.5 percentile from consumption data) (kg/day)

v = variability factor

HR = highest residue level in composite samples of the edible portion, found in the residue trials (mg/kg)

HR-P = highest residue level, where processing of the crop (mg/kg) is taken into account

STMR = Supervised Trial Median Residue (mg/kg)

STMR-P = Supervised Trial Median Residue, where processing of the crop (mg/kg) is taken into account

bw = body weight

Case 1:

The residue concentration in composite samples from residue trials (raw or processed) more or less corresponds with the residue in a portion (meal size) of the product; a portion consists of several units (unit weight is < 25 g):

$$\text{IESTI} = [\text{LP} \times (\text{HR or HR-P})] / \text{bw}$$

For case 2a as well as 2b:

The portion (meal size), e.g. a piece of fruit or vegetable, may contain a higher residue than composite samples from residue trials (unit weight > 25 g).

A variability factor is therefore introduced (a standard factor or based on available residue data in separate pieces of fruit or vegetable).

Depending on the properties of a product, the following standard variability factors are applied:

Product property	v
Unit weight of head lettuce	3
Unit weight of the whole portion > 250 g	5
Unit weight of the whole portion ≤ 250 g	7
Unit weight of the whole portion ≤ 250 g, and the pesticide is granule for soil treatment	10
Leafy vegetables where the unit weight of the whole portion ≤ 250 g	10

Specific for case 2a:

This concerns the unit weights that are smaller than the large portion (LP):

$$\text{IESTI} = \{U \times (\text{HR of HR-P}) \times v\} + \{(LP-U) \times (\text{HR of HR-P})\} / \text{bw}$$

Where sufficient residue data in separate units are available to derive a HR for separate units, this value should be entered in the first part of the equation, without variability factor. The HR value derived from composite samples should then be used in the second part.

Specific for case 2b:

Concerns unit weights larger than the large portion:

$$\text{IESTI} = \text{LP} \times (\text{HR or HR-P}) \times v / \text{bw}$$

Where sufficient residue data in separate units are available to derive a HR for separate units, this value should be entered into the equation, without variability factor.

Case 3:

Concerns processed products that have been combined or mixed; the STMR-P value represents the highest residue concentration:

$$\text{IESTI} = \text{LP} \times \text{STMR-P} / \text{bw}$$

The calculations above are carried out by using the UK consumption data (large portion sizes) and Unit Weights [7] and with the NL large portion sizes where the Netherlands is rapporteur, as described in Appendix 3, and residue data.

Supplementary data may be required for a further refinement of the exposure calculation

(for further details about risk estimation for acutely toxic substances see the methodology as applied by JMPR [6].

The mentioned variability factors (v) are standard factors. Generally, these are conservative values, i.e., they are overestimates. Variability can therefore also be calculated from field measurements of a large number of samples taken of the crop in question which has in accordance with GAP been treated with the pesticide in question. The mathematical procedure for calculating the variability factor is still under debate in the EU but a draft proposal has been made by the IUPAC Advisory Committee on Crop Protection Chemistry [8].

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances, a representative formulation has to be included in the dossier. Therefore, section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products, only section 1.4.2 and 1.4.3 apply.

1.4.1 Approval of the active substance

Regulation (EC) No 1107/2009 Annex II provides the procedure and criteria for the approval of an active substances, safeners and synergists pursuant to Chapter II of Regulation (EC) No 1107/2009.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance. The texts specifically applicable to the Risk to consumers are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossiers submitted pursuant to Article 7(1) shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD). In the case of an active substance, safener or synergist for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed, the dossier submitted pursuant to Article 7(1) shall contain the information necessary to carry out a risk assessment and for enforcement purposes.

The dossier shall in particular:

- (a) permit any residue of concern to be defined;
- (b) reliably predict the residues in food and feed, including succeeding crops; L 309/40 EN Official Journal of the European Union 24.11.2009
- (c) reliably predict, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;
- (d) permit a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;
- (e) permit, where relevant, concentration or dilution factors due to processing and/or mixing to be defined. The dossier submitted pursuant to Article 7(1) shall be sufficient

to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.6. Impact on human health

3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population. When the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.

3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

3.9. Residue definition

An active substance, safener or synergist shall only be approved if, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.

Point 4 of Annex II of Regulation (EC) No 1107/2009 gives criteria for substitution. The texts specifically applicable to the aspect 'risk to consumers' are presented below. In the chapter "Generic aspects" of this Evaluation Manual, more information is provided on criteria for substitution.

4. Candidate for substitution

An active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met:

- its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,

Point 5 of Annex II of Regulation (EC) No 1107/2009 gives information on low risk substances. In the chapter "Generic aspects" of this Evaluation Manual, more information is provided on low risk substances.

For the criteria for drinking water we refer to Council Directive 98/83/EEC [9] where a maximum drinking water concentration of 0.1 µg/kg is permitted. Generally, this upper limit means that the ITMDI for drinking water is so low (mostly less than 1% of the ADI) that this is not separately included in the chronic diet calculation.

1.4.2 Evaluation

1.4.2.1. Residue dossier

The principles for the evaluation (the Uniform Principles) regarding residues and consumer safety are presented in Commission Regulation (EU) No 546/2011 [10]. These concern the relevant sections of the introductory principles, the general principles, and the specific principles Effect of the residues.

The specific principles Effect of the residues are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.4.2. Impact on human or animal health arising from residues

2.4.2.1. Member States shall evaluate the specific information on toxicology as provided for in the Annex to Regulation (EU) No 544/2011 and in particular:

- the determination of an acceptable daily intake (ADI),
- the identification of metabolites, degradation and reaction products in treated plants or plant products,
- behaviour of residues of the active substance and its metabolites from the time of application until harvest, or in the case of post-harvest uses, until unloading of stored plant products.

2.4.2.2. Prior to evaluating the residue levels in the reported trials or in products of animal origin Member States shall examine the following information:

- data on the proposed good agricultural practice, including data on application as provided for in the Annex to Regulation (EU) No 545/2011 and proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses,
- nature of the preparation,
- analytical methods and the residue definition.

2.4.2.3. On the basis of suitable statistical models Member States shall evaluate the residue levels observed in the reported trials. This evaluation shall be made for each proposed use and shall take into consideration:

- (i) the proposed conditions of use of the plant protection product;
- (ii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in the Annex to Regulation (EU) No 545/2011 and the distribution of residues between edible and non-edible parts;
- (iii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
- (iv) the realistic possibilities of extrapolating data from one crop to another.

2.4.2.4. Member States shall evaluate the residue levels observed in products of animal origin, taking into consideration the information provided for in point 8.4 of Part A of the Annex to Regulation (EU) No 545/2011 and residues resulting from other uses.

2.4.2.5. Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using a suitable calculation model. This evaluation will take account, where relevant, of other sources of information such as other authorized uses of plant protection products containing the same active substance or which give rise to the same residues.

2.4.2.6. Member States shall, where relevant, estimate the exposure of animals, taking into account the residue levels observed in treated plants or plant products intended to be fed to animals.

1.4.2.2. MRL setting

With regard to setting of MRLs, risk assessment and decision making Regulation (EC) No 1107/2009 refers to Regulation (EC) 396/2005 [11].

MRLs might be connected to national applications, zonal applications or import tolerances according to the following procedure:

1. Any party, interested in public health can request the setting of an MRL. An MRL request should be submitted to a member state.
2. The member state shall evaluate the request, and forward an Evaluation Report to EFSA.
3. EFSA performs a risk assessment and publish it's opinion
4. The Standing Committee on Food Chain and Animal Health (SCoFCAH) working group residues votes about the proposal
5. The proposal enters the so called scrutiny procedure at the EU parliament
6. The commission publishes the new MRL as an amendment to Regulation (EC) 396/2005.

The timelines are specified in Regulation (EC) 396/2005:

Article 8

Evaluation of applications

1. A Member State to which an application complying with Article 7 is submitted pursuant to Article 6 shall immediately forward a copy to the Authority and the Commission and draw up an evaluation report without undue delay.

Article 9

Submission of evaluated applications to the Commission and the Authority

1. After completion of the evaluation report, the Member State shall forward it to the Commission. The Commission shall without delay inform the Member States and forward the application, the evaluation report and the supporting dossier to the Authority.
2. The Authority shall acknowledge in writing receipt of the application to the applicant, the evaluating Member State and the Commission without delay. The acknowledgement shall state the date of receipt of the application and the accompanying documents.

Article 11

Time limits for the Authority's opinion on applications concerning MRLs

1. The Authority shall give its reasoned opinion as provided for in Article 10 as soon as possible and at the latest within three months from the date of receipt of the application. In exceptional cases where more detailed evaluations need to be carried out, the time limit laid down in the first subparagraph may be extended to six months from the date of receipt of the valid application.

Article 14

Decisions on applications concerning MRLs

1. Upon receipt of the opinion of the Authority and taking into account that opinion, a Regulation on the setting, modification or deletion of an MRL or a Decision rejecting the application shall be prepared by the Commission without delay and at the latest within three months, and submitted for adoption in accordance with the procedure referred to in Article 45(2).

(...)

3. The Commission may request at any time that supplementary information be provided by the applicant or by the Authority. The Commission shall make available any supplementary information received to the Member States and the Authority.

1.4.3 Decision making

The principles for decision making regarding residues are presented in the Commission Regulation (EU) No 546/2011[10]. These concern the relevant sections of the introductory principles, the general principles, and the specific principles Effect of the residues.

The specific principles Effect of the residues are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.4.2. Impact on human or animal health arising from residues

2.4.2.1. Authorisations must ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.

Estimation of the acute risk of exposure to residues of plant protection products via food is not as such included in the text above, but it is already carried out in practice (see

also 1.4).

1.5. Developments

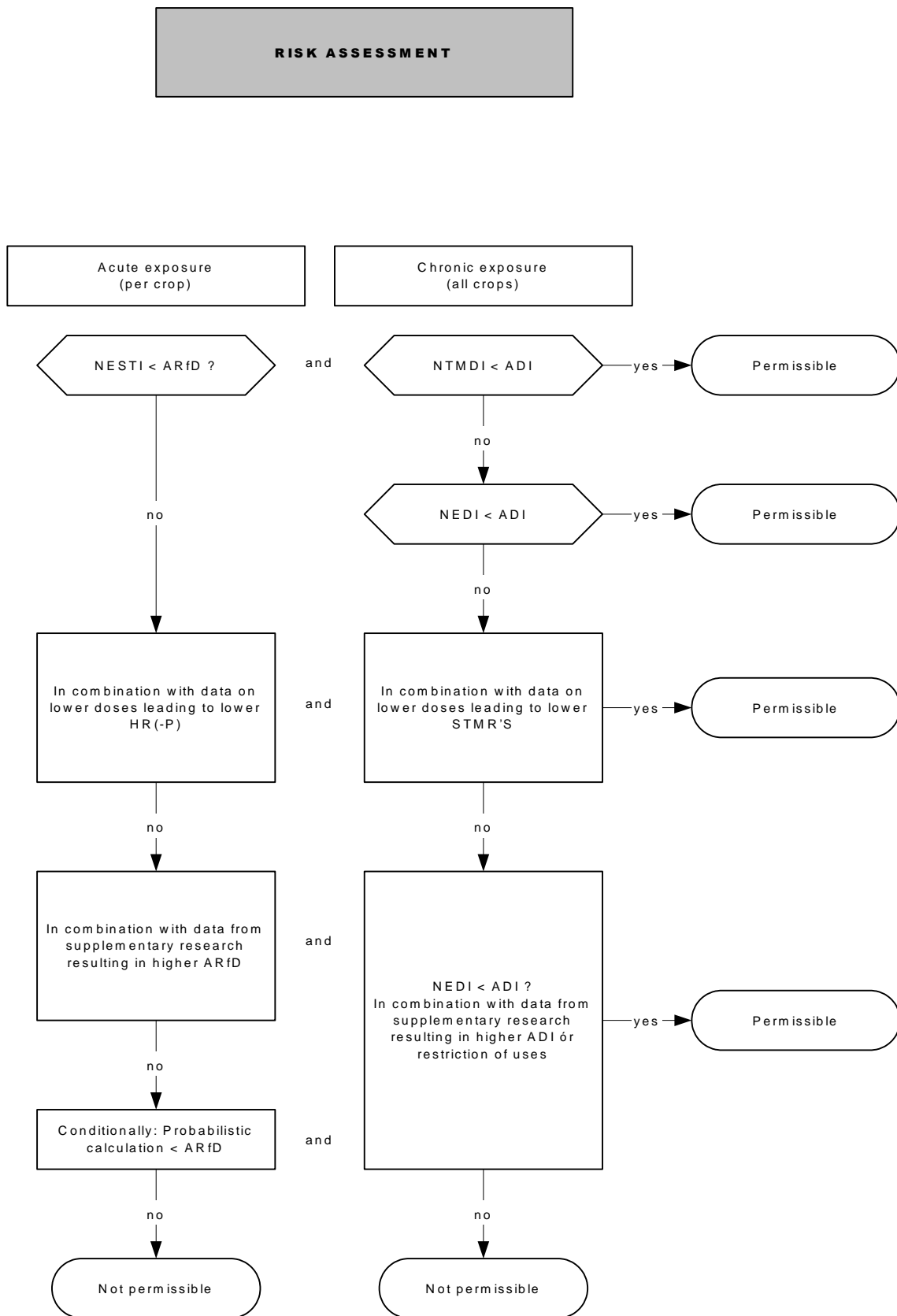
In the context of the far-reaching integration of the NL and EU evaluation of chemical plant protection products, NL developments are entered into the EU circuit. As regards risk assessment for consumers, new methodologies are on their way. There currently is a strong international development in the area of the estimation of the acute risk of exposure to residues of plant protection products via food (JMPR/EU/EPA/CCPR [12]). Implementation of Directives at EU level is expected after agreement between Member States. This concerns the following developments:

- A working programme is running in which the advantages and disadvantages of the probabilistic approach are weighed and the starting points for such a calculation are formulated, such as: are calculations based on the total population or only on consumers of a certain product, are all consumable products included or is the calculation carried out per product.
In 2012 EFSA has published Guidance on Probabilistic Modelling: Guidance on the Use of Probabilistic Methodology for Modelling Dietary Exposure to Pesticide As a result of a brought cooperation between Residue (EFSA Journal 2012; 10(10): 2839). The Acropolis (Aggregate and Cumulative Risk of Pesticides: an On-Line Integrated Strategy) project was started as a multi-stakeholders initiative. As an output of the project an integrated online tool was developed to model dietary exposure: MCRA 8 (Monte Carlo Risk Assessment). Currently the Acropolis online model tool is being tested and different groups of the stakeholders are being trained to use it in practice.
- There is debate about the variability factor (v) in the IESTI calculation. Currently, different variability factors (3, 5, 7 and 10) are used in the EU [6]. The JMPR (2003) [13] has advised to apply the value of 3 for all cases in which the Unit Weight is > 25 g. The Codex Alimentarius has meanwhile adopted this advice. In the EU, the debate about adjustment of the variability factor must still be held
- A model for assessing acute and chronic exposure including all available EU Member State diets has been created by EFSA: PRIMo (Pesticide Residue Intake Model rev 2). In 2013, model EFSA PRIMo rev 3 was drafted and is currently in the commenting and testing phase.

3. APPENDICES

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Appendix 1 Flow diagram risk assessment for consumers



Appendix 2 EFSA PRIMo consumer exposure model

The TMDI calculation is for inclusion of a substance in 540/2011 carried out by using a spreadsheet (see also §1.3.1 of this chapter).

This can be found on the EFSA website under the name:

EFSA calculation model “PRIMO” or revision 2. (Model EFSA PRIMo rev 3 was drafted and is currently in the commenting and testing phase)

The IEDI calculation is for inclusion of a substance in 540/2011 carried out by using the same spreadsheet (see also §1.3.1 of this chapter) not using MRL values but STMR and/or P-factors when available.

Appendix 3 EFSA PRIMo consumer exposure model

The IESTI calculation is for inclusion of a substance in 540/2011 carried out by using a spreadsheet (see also §1.3.2 of this chapter).

This can be found on the EFSA website under the name:

EFSA calculation model “PRIMO” or revision 2 . (Model EFSA PRIMO rev 3 was drafted and is currently in the commenting and testing phase)

4. REFERENCES

- 1 Regulation (EC) No 1107/2009, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 2 Directive 91/414/EEC, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 3 Commission Implementing Regulation (EU) No 540/2011, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 4 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, 1999.
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- 7 New UK technical policy on the estimation of dietary intakes of pesticide residues, PSD Jan. 1997, AAHL/3/97 (unit weights)
- 8 Hamilton, D., Ambrus, A., Dieterle, R., Felsot, A., Harris, C., Petersen, B., Racke, K., Wong, S.-S., Gonzalez, R., Tanaka, K., Earl, M., Roberts, G., and Bhula, R. Pesticide residues in food – Acute dietary exposure. *Pest. Manag. Sci.* **60**: 311-339 (2004). Generated by: members of the Advisory Committee on Crop Protection Chemistry, Division of Chemistry and the Environment of the International Union of Pure and Applied Chemistry (IUPAC).
- 9 Council Directive 98/83/EEC , <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=248712%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=7&list=248712%3Acs%2C234420%3Acs%2C234419%3Acs%2C226566%3Acs%2C225836%3Acs%2C225835%3Acs%2C226845%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 10 Commission Regulation (EU) No 546/2011, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574598%3Acs&pos=2&page=1&lang=en&pgs=10&nbl=2&list=607713%3Acs%2C574598%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 11 Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food of plant and animal origin and amending Council Directive 91/414/EEC, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=400226%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=2&list=400226%3Acs%2C400559%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 12 De CCPR is the Codex Committee on Pesticide Residues of the Codex Alimentarius. <http://www.codexalimentarius.net>
- 13 Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, 2003.