Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 547/2011

of 8 June 2011

implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Article 65(1) thereof,

Whereas:

(1) In accordance with Regulation (EC) No 1107/2009 the labelling requirements set out in Article 16 of Directive 91/414/EEC of the Council of 15 July 1991 concerning the placing of plant protection products on the market[(2)] and in Annexes IV and V thereto, are to continue to apply under Regulation (EC) No 1107/2009.

(2) It is therefore necessary for the implementation of Regulation (EC) No 1107/2009 to adopt a regulation incorporating those labelling requirements for plant protection products with any necessary modifications, such as updating references.

(3) Provisions should be included concerning re-use of packaging and concerning plant protection products which are to be used for experiments or tests for research or development purposes.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The labelling of plant protection products shall comply with the requirements, as set out in Annex I, and contain, where approriate, the standard phrases for special risks to human or animal health or to the environment, as set out in Annex II, and the standard phrases for safety precautions for the protection of human or animal health or of the environment, as set out in Annex III.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 547/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 June 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

LABELLING REQUIREMENTS AS REFERRED TO IN ARTICLE 1

(1) The following information shall be included clearly and indelibly on the packaging of plant protection products:

(a) the trade name or designation of the plant protection product;

(b) the name and address of the holder of the authorisation and the authorisation number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;

(c) the name of each active substance expressed as provided for in Article 10 (2.3) of Directive 1999/45/EC of the European Parliament and of the Council[(3)] with clear indication of the chemical form. The name must be as given in the list contained in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(4)] or, if not included therein, its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC rules;

(d) the concentration of each active substance expressed as follows:

(i) for solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C), as % w/w and g/kg,

(ii) for other liquids/gel formulations, as % w/w and g/l,

(iii) for gases, as% v/v and % w/w.

If the active substance is a micro-organism, its content shall be expressed as the number of active units per volume or weight or any other matter that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g);

(e) the net quantity of plant protection product given in: g or kg for solid formulations, g, kg, ml or l for gases and ml or l for liquid formulations;

(f) the formulation batch number and production date;

(g) information on first aid;

(h) the nature of any special risks to human or animal health or to the environment, by means of standard phrases selected by the competent authority, as appropriate, from those set out in Annex II;

(i) safety precautions for the protection of human or animal health or of the environment, in the form of standard phrases selected by the competent authority, as appropriate, from those set out in Annex III;

(j) the type of action of the plant protection product (e.g. insecticide, growth regulator, herbicide, fungicide, etc.) and the mode of action;

(k) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);

(l) the uses for which the plant protection product has been authorised and any specific agricultural, plant health and environmental conditions under which the product may be used or shall not be used;

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(m) directions for and conditions of use and the dose rate including where appropriate the maximum dose per hectare per application and the maximum number of applications per year. The dose rate is expressed in metric units, for each use provided for under the terms of the authorisation;

(n) where appropriate, the safety interval for each use between the last application and:

(i) sowing or planting of the crop to be protected,

(ii) sowing or planting of succeeding crops,

(iii) access by humans or animals,

(iv) harvesting,

(v) use or consumption;

(o) particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:

— the crop in question, or

— subsequent and adjacent crops;

(p) if accompanied by a leaflet, as set out in point 2, the sentence ‘Read accompanying instructions before use’;

(q) directions for appropriate conditions of storage, safe disposal of the plant protection product and of the packaging;

(r) where necessary, the expiry date for normal conditions of storage;

(s) a prohibition concerning the re-use of packaging, except by the authorisation holder and on condition that packaging has been specifically designed in order to allow re-use by the authorisation holder;

(t) any information required by the authorisation in accordance with Articles 31, 36(3), 51(5) or 54 of Regulation (EC) No 1107/2009;

(u) the categories of users allowed to use the plant protection product, where use is limited to certain categories.

(2) The information required by points 1-(m), (n), (o), (q), (r) and (t) may be indicated on a separate leaflet accompanying the package if the space available on the package is too small. Such a leaflet shall be regarded as part of the label.

(3) In no circumstances may the label of the packaging of a plant protection product bear the indications ‘non-toxic’, ‘harmless’, or similar indications. However, information that the plant protection product may be used when bees or other non target species are active, or when crops or weeds are in flower or other such phrases to protect bees, or phrases with similar information concerning the protection of bees or of other non-target species, may be included in the label, if the authorisation explicitly allows use under such conditions.

(4) Member States may make the placing of plant protection products on the market in their territories subject to their being labelled in their national language or languages.

(5) By way of derogation from point (1), labelling and packaging of plant protection products to be used for experiments or tests for research or development purposes, as provided for in Article 54 of Regulation (EC) No 1107/2009, need only comply with points (1)(b), (c),

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(d), (j), (k) of this Annex. The label shall include information required by the permit for trial purposes, provided for in Article 54(1) of Regulation (EC) No 1107/2009 and the words 'product intended for experimental use, not fully characterised, handle with extreme care'.

ANNEX II

STANDARD PHRASES FOR SPECIAL RISKS TO HUMAN OR ANIMAL HEALTH OR TO THE ENVIRONMENT AS REFERRED TO IN ARTICLE 1

INTRODUCTION

The following additional standard phrases are defined to supplement the phrases provided for by Directive 1999/45/EC, which applies to plant protection products. The provisions of that Directive shall also be used for plant protection products containing micro-organisms, including viruses, as active substances. The labelling of products containing micro-organisms, including viruses, as active substances shall also reflect the provisions concerning dermal and respiratory sensitisation testing which are laid down in part B of the Annex to Commission Regulation (EU) No 544/2011[(5)] and part B of the Annex to Commission Regulation (EU) No 545/2011[(6)].

The standard phrases for special risks are without prejudice to Annex I.

1. **Standard phrases for special risks**

1.1. *Special risks related to humans (RSh)*

RSh 1

BG	:	Токсичен при контакт с очите.
ES	:	Tóxico en contacto con los ojos.
CS	:	Toxický při styku s očima.
DA	:	Giftig ved kontakt med øjnene.
DE	:	Giftig bei Kontakt mit den Augen.
ET	:	Mürgine silma sattumisel.
EL	:	Τοξικό όταν έρθει σε επαφή με τα μάτια.
EN	:	Toxic by eye contact.
FR	:	Toxique par contact oculaire.
[[F1]HR	:	Otrovno u dodiru s očima.**]**
IT	:	Tossico per contatto oculare.
LV	:	Toksisks nonākot saskarē ar acīm.
LT	:	Toksiška patekus į akis.
HU	:	Szemmel érintkezve mérgező.
MT	:	Tossiku meta jmiss ma' l-għajnejn.
NL	:	Giftig bij oogcontact.
PL	:	Działa toksycznie w kontakcie z oczami.
PT	:	Tóxico por contacto com os olhos.
RO	:	Toxic în contact cu ochii!
SK	:	Jedovatý pri kontakte s očami.
SL	:	Strupeno v stiku z očmi.
FI	:	Myrkyllistä joutuessaan silmään.
SV	:	Giftigt vid kontakt med ögonen.