

Draft Amendment of Agro-pesticides Labelling Management Regulations

This Draft has been translated into English according to the original Chinese version. If there is any inconsistency or ambiguity between these two versions, the Chinese version shall prevail.

Article 3 To use an agro-pesticide label or make a change to a label, an agro-pesticide manufacturer or importer must fill out an application form, attach two copies of agro-pesticide label samples, and apply to the central competent authority for approval. Within three months after approval, one copy of agro-pesticide marketing label must be submitted to the central competent authority for reference.

The sample label pursuant to the preceding paragraph must be produced through the IT tool designated by the central competent authority.

For any modification to an agro-pesticide label pursuant to Paragraph 1 relating to an item requiring an agro-pesticide permit, an application for a change to an agro-pesticide permit must be made according to the agro-pesticide permit application and approval regulations.

After the modification is made to an agro-pesticide label, the original label must be replaced within 6 months. Altering, using stickers to correct information, or repeated affixing of more than one labels are not allowed.

Article 5 The following items are required to put on the label of the formulated agro-pesticides

1. The permit number of the agro-pesticide must be specified.
2. Right holder's name, address, and telephone number of agro-pesticide permit must be specified.
3. Date of manufacture, batch number, and validity period must be specified.
4. Agro-pesticide's common name must be specified.
5. Poison prevention and detoxification methods must be specified.
6. In case of highly hazardous formulated agro-pesticides, the words "Highly Hazardous Agro-pesticides" must be specified; in case of formulated agro-pesticides with genetically engineered ingredients, the words "Genetically Engineered" must be specified; as for other formulated agro-pesticides, the words "Formulations for Agricultural-Use" must be specified.
7. Mode of action classification codes as designated by the Fungicide Resistance Action Committee (FRAC), Insecticide Resistance Action Committee (IRAC), Herbicide Resistance Action Committee (HRAC), and so forth must be specified.
8. The European Article Number (EAN) barcode must be used for product identification.
9. Hazard pictograms, precautionary pictograms, signal words and hazard statements must be specified.
10. The net weight or volume of content presented in statutory measuring units

must be specified. In case of agro-pesticides repacked into smaller package, the net weight or volume of content in the individual small package must be specified.

11. In case of imported products, the name and address of the foreign manufacturer must be specified.
12. In case of outsourced repackaging, the name and address of the outsourced factory and date of repackaging must be specified.
13. In case of outsourced processing, the name and address of the outsourced processing factory must be specified.
14. Brand name of the company must be specified, if any.
15. Formulation types, physical properties, and the contents of active ingredients and other ingredients must be specified.
16. Instructions for usage and its scope must be specified.
17. How to store product and precautions for its use must be specified.
18. Disposal and treatment of empty container must be specified.
19. Other information items designated by the central competent authority must be specified.

The label with the required information items pursuant to the preceding paragraph must be firmly attached to the agro-pesticides per retail unit. But in case that the label per retail unit cannot include all the information items, Item 1 to Item 10 pursuant to the preceding paragraph must be labelled as a minimum. Also all the information items pursuant to the preceding paragraph must be labelled in the user's manual that comes with the agro-pesticides. The user's manual must not be apart from a single retail unit.

Article 6 The following items are required on the label of the technical grade agro-pesticides.

1. The permit number of agro-pesticide must be specified.
2. Right holder's name, address, and telephone number of agro-pesticide permit must be specified.
3. In case of imported products, the name and address of the foreign manufacturer must be specified.
4. Date of manufacture and batch number must be specified.
5. Agro-pesticide's common name must be specified.
6. Brand name must be specified, if any.
7. Physical properties and the contents of active ingredients and other ingredients must be specified.
8. The net weight or volume of content presented in statutory measuring units must be specified.
9. How to store product and precaution for its use must be specified.

10. Poison prevention and detoxification methods must be specified.
11. Disposal and treatment of empty container must be specified.
12. Hazard pictograms, precautionary pictograms, signal words and hazard statement must be specified.
13. In case of technical grade agro-pesticide with genetically engineered ingredients, the words "Genetically Engineered" must be specified.
14. Other information items designated by the central competent authority must be specified.

Article 7 If the information included in an agro-pesticide label is required on an agro-pesticide permit, the items must be labelled in a manner consistent with the central competent authority's approved. For information not required on an agro-pesticide permit, the agro-pesticide manufacturer or the importer must label the information according to product's properties on their own. The Information provided from such labelling texts or images must not overlap with the information required on an agro-pesticide label. Also no false or exaggerated information is allowed.

Article 12 The classification of agro-pesticide acute toxicity shall refer to Attachment 1. The classification of agro-pesticide acute toxicity for bees shall refer to Attachment 2.
The hazard pictograms of technical grade agro-pesticides or formulated agro-pesticides shall refer to Figure 1. The hazard pictograms, signal words and hazard statements must comply with the national standard, CNS 15030, and Attachment 2.
For agro-pesticides possessing aquatic toxicity classified as Chronic Category 1, Category 2, or Acute Category 1, Category 2, according to the national standard, CNS 15030, the precautionary pictogram of dangerous/harmful to fish must be affixed.
Also, the warning "Do Not Use at Tap Water Source and Quality Protection Area, Drinking Water Source and Quality Protection Area, or Drinking Water Intake Protection Zone" must be specified.

The information items required on an agro-pesticide label shall be arranged in accordance with the following requirements:

1. Hazard pictograms, signal words, mode of actions, and the wording "Formulations for Agricultural-Use" must be located in the upper one third of a label. Precautionary pictograms with color bands must be located in the bottom of a label. The mode of action format of agro-pesticides shall refer to Figure 3.
2. The precautionary pictograms of mixing or diluting pesticide, "When handling liquid concentrate...", and "When handling dry concentrate...", must appear on the left. The precautionary pictogram, "When applying pesticide" must appear on the right.
3. The precautionary pictograms, "Danger/harmful to fish and, to animals" shall, show to the formulation's toxicity, be additionally specified to the right of all other precautionary pictograms.
4. For ready-to-use agro-pesticides which require no mixture or dilution, the precautionary pictograms, "Wear gloves," "Wear eye protection," "Wear rubber boots," "Keep locked away and out of reach of children," and "Wash

after use” must appear.

For the hazard pictograms to be printed in color, the hazard pictograms must have a black symbol on a white background with a red border frame, sufficiently wide enough to be clearly visible. The precautionary pictograms with color bands shall refer to Figure 4. The pictograms may be selected according to the safety precautions needed for that specific formulation. Depending on the level of toxicity, the precautionary pictograms with color bands must be classified as follows:

1. Extremely and highly hazardous agro-pesticides are indicated by red.
2. Moderately hazardous agro-pesticides are indicated by yellow.
3. Slightly hazardous agro-pesticides are indicated by blue.
4. Agro-pesticides unlikely to present acute hazard are indicated by green.

Attachment 1 of Article 12 - Pesticide Acute Toxicity Classification

Acute Toxicity Classification	<u>Hazard Category</u>	Oral LD ₅₀ (mg/kg body weight)	Dermal LD ₅₀ (mg/kg body weight)
Extremely hazardous	<u>Category 1</u>	≤ 5	≤ 50
Highly hazardous	<u>Category 2</u>	> 5 ~ ≤ 50	> 50 ~ ≤ 200
Moderately hazardous	<u>Category 3</u>	> 50 ~ ≤ 300	> 200 ~ ≤ 1,000
	<u>Category 4</u>	> 300 ~ ≤ 2,000	> 1,000 ~ ≤ 2,000
Slightly hazardous	<u>Category 5</u>	> 2,000 ≤ 5,000	> 2,000 ≤ 5,000
Unlikely to present acute hazard	<u>Not classified</u>	> 5,000	> 5,000

Notes:

1. Any formulated agro-pesticides must be classified based on toxicity data obtained from that formulation.
2. The acute toxicity classification in this table refers the acute toxicity classification. Hazard category refers to GHS hazard classification. (Rats are used as test animals.)

Attachment 2 of Article 12 –Classification of Pesticide Acute Toxicity to Bees



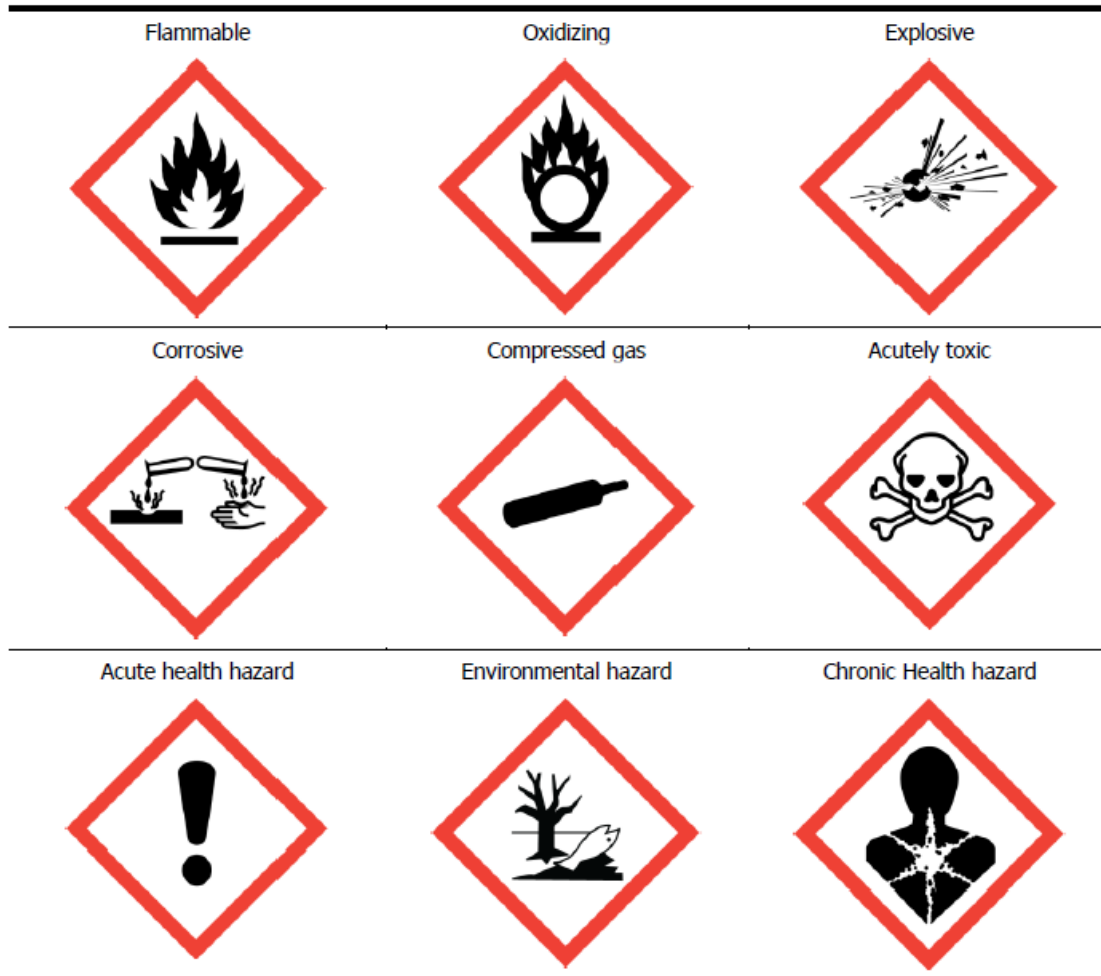
Hazard Category	Thresholds of Acute Contact Toxicity to Bees	Hazard Pictograms	Signal Words	Hazard Statement
Category 1	$LD_{50} \leq 2 \mu\text{g}/\text{bee}$		Warning	Highly toxic to bees
Category 2	$2 \mu\text{g}/\text{bee} < LD_{50} \leq 11 \mu\text{g}/\text{bee}$		Warning	Moderately toxic to bees
Category 3	$LD_{50} > 11 \mu\text{g}/\text{bee}$	No	No	Practically non-toxic to bees

Figure 1 of Article 12- Hazard pictograms



Bee Hazard



Figure 2 of Article 12- Precautionary pictograms















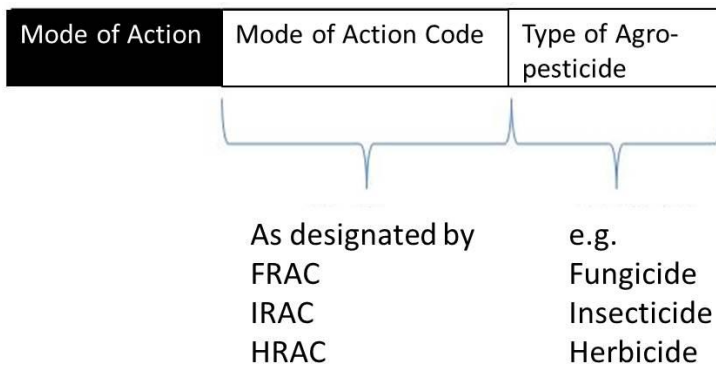
 <p>Keep locked away and out of reach of children</p>		
 <p>When handling liquid concentrate ...</p>	 <p>When handling dry concentrate ...</p>	 <p>When applying pesticide ...</p>
 <p>Wear gloves</p>	 <p>Wear eye protection</p>	 <p>Wear rubber boots</p>
 <p>Wear protection over nose and mouth</p>	 <p>Wear respirator</p>	
 <p>Wear overalls</p>	 <p>Wear apron</p>	 <p>Wash after use</p>
 <p>Dangerous/harmful to animals</p>	 <p>Dangerous/harmful to fish – do not contaminate lakes, rivers, ponds or streams</p>	

Figure 3 of Article 12 Agro-pesticide mode of action information box format

Products containing a single active ingredient



Products containing more than one active ingredient

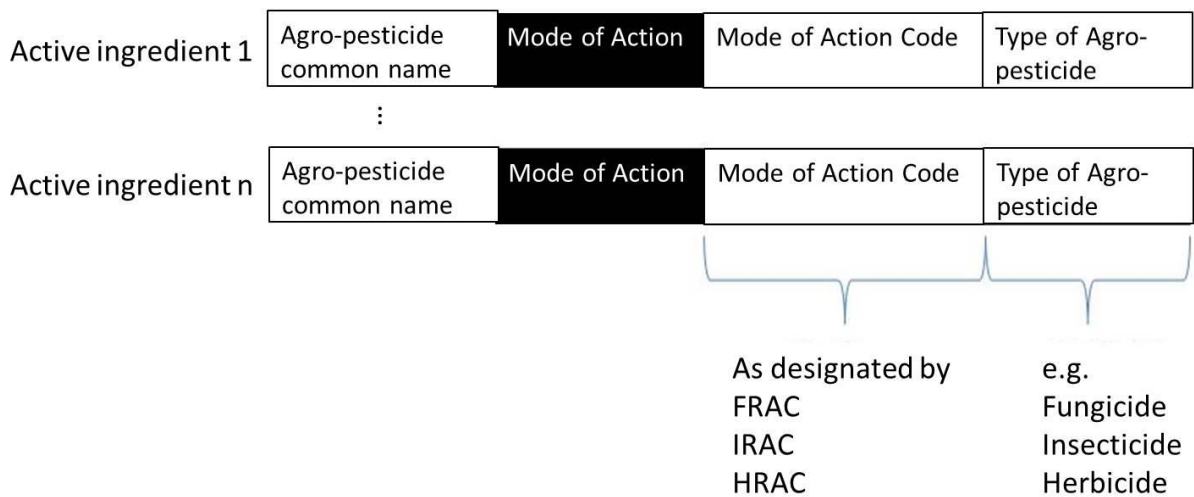
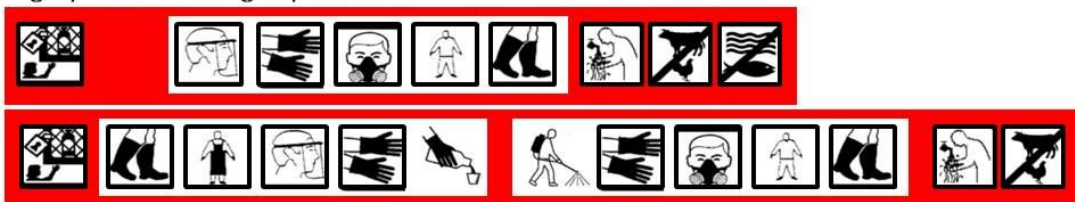
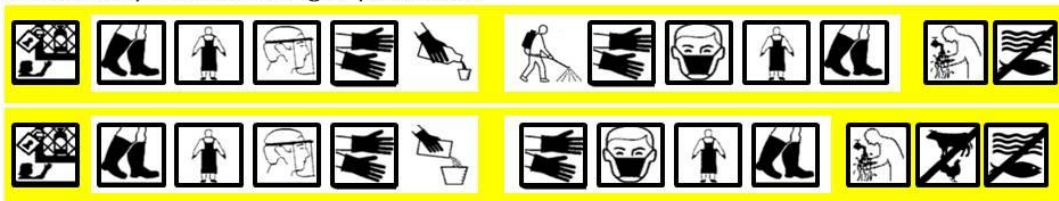


Figure 4 of Article 12 Examples of precautionary pictograms with color bands

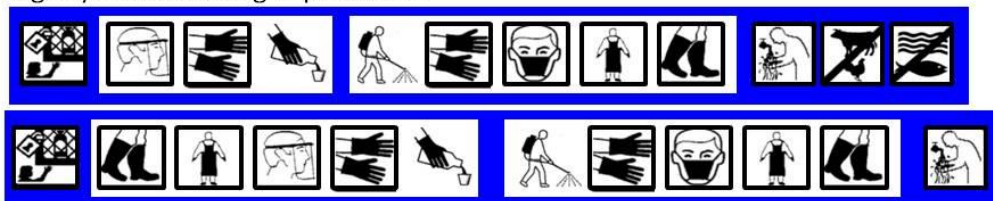
Highly Hazardous Agro-pesticides



Moderately Hazardous Agro-pesticides



Slightly Hazardous Agro-pesticides



Unlikely to present acute hazard

