

### New authorization process for plant protection products

Label text changes to the

Usage and restrictions annex



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### Reform of the authorization process for plant protection products from 1 May 2025

The authorization process for plant protection products is changing on 1 May 2025. Tukes is replacing written instructions with a table to facilitate authorization processing and improve the clarity of the instructions. The instructions for use -table can be downloaded from the Tukes website at: [link]

### What is changing?

### 1. Written usage instructions are no longer included in authorizations

Tukes will no longer include written instructions with the authorizations. The written usage instructions are replaced with a table that serves as the official instructions.

#### 2. The usage instructions are presented as a table

The applicant must fill in the instructions for use -table in both Finnish and Swedish. Tukes uses this table in the authorization process and attaches it to the official authorization, i.e. the so-called Usage and Restrictions Annex.



### What is changing?

### 3. Label texts are no longer published on KemiDigi

Tukes no longer publishes the complete label text in the KemiDigi register. Instead, we only publish the Usage and Restrictions Annex, which includes the conditions in a table. The authorization holder will be responsible for ensuring that the final label text corresponds to this annex and publishes it on its own website, for example.

#### 4. These changes apply to all new applications and amendments after 1 May 2025.

As of 1 May 2025, all approvals and amendments will follow the new policy. Previously approved label texts will remain in KemiDigi. The authorization holder is responsible for ensuring that the packaging instructions correspond to the approved text. Amendments require an authorization, that is applied from Tukes.



### **Responsibilities and roles in the new authorization process**

### **Applicant:**

- Fills in the instructions for use -table in Finnish and Swedish.
- Attaches the table to the application.
- Prepares the final label text that matches the table attached to the decision.
- Publishes the full label text on its own website.
- Ensures that the label complies with the EU labelling regulation.

### Finnish Safety and Chemicals Agency (Tukes):

- Provides the final approved user instructions table.
- Makes use of user instructions provided by the applicant in the application process.
- Prepares the decision and attaches the Usage and Restrictions annex to it.
- Publishes the Annex in the KemiDigi register of plant protection products.

### tukes

# Instructions for filling in the instructions for use -table :

- Fill in all the white fields in the Excel table. The blue help text will disappear when the field is correctly filled in.
- Remember to fill in the same table in Swedish as well. The numbers are automatically copied from the Finnish fields.
- Click on the title cells to see additional instructions for filling a particular field.
- There is a pre-filled example table on the Example tab.
- Examples of different use areas are available in the Use area examples tab.

#### taulukko suomeksi | Instuctions for use- table in Finnish | Bi Pes Area/place of use Crop/use ber CO Viljelykasvi / käyttökohde Paikka/alue Torjur ero $\mathbf{w}$ T. $\mathbf{T}$ leveäleh porkkana [DAUCA] kasvihuone rikkakas leveäleh kevätvehnä [EPPO-koodi] avomaa rikkakas leveäleh kurkku [EPPO-koodi] kasvihuone rikkakas Area of use examples mple (+)6

23.5.2025



# What is required information in the label text?

# The label text must include the following information as provided by Tukes:

- Basic product information
- CLP classification
- Usage restrictions and other instructions

This information may not be changed without authorization from Tukes.





# How is the information from the instructions for use -table transferred to the label?

The conditions in the Tukes-approved user instruction table must be included in the label text.

• The information can be presented as a table or in written form.

The authorization holder may choose the presentation method and may add additional instructions as long as they:

- do not conflict with the table.
- do not change approved use areas or quantities.





# What can be changed on a label without an authorization?

## Items that can be changed without a separate application:

- Wording of the user instructions.
- Addition of clarifying instructions for use.
- Update the style and formatting

### As long as the following do not change:

- Use of the product (GAP)
- CLP classification
- Restrictions on use



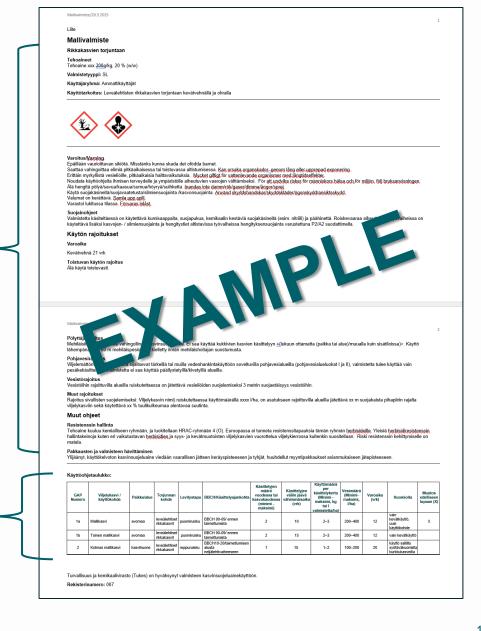
### **New Usage and Restrictions annex**

The Usage and Restrictions annex includes the basic information of the product, as classifications and labels set by the authorities, as well as restrictions on use and other instructions. This information must be included in the label text as provided by the authority. This part of the label may not be changed in the final label without a separate application.

#### **User instructions table**

The terms of use contained in the instructions for use must be included in the label text either as a table or in written form. The authorization holder may define the final format and include additional instructions to the label as necessary, as long as they do not conflict with the Tukes-provided user instructions table.

In the future, the authorization holder may modify this label section without approval from Tukes as long as the approved use areas and quantities are not changed.





### Effects on the user

In the future, the label text of the package will no longer be available in the KemiDigi register of plant protection products.

During the transition period, the register shows both old-style label texts and the new Usage and Restrictions Annexes, in which the instructions for use are presented as a table.

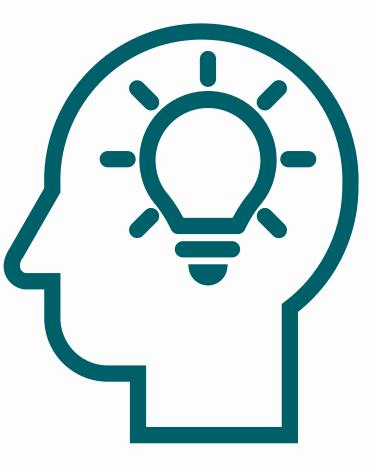
Many retailers publish the complete label texts on their websites. If necessary, the user should request an electronic version of the label text from the authorization holder or the product representative.





# Applicant's checklist from 1 May 2025:

- Download the instructions for use -table from the Tukes website at: [link]
- Fill in the user instructions table in Finnish and Swedish.
- Attach the table to the application.
- Format the label in accordance with the EU regulation.
- Make sure that the label corresponds with the table.
- Publish the complete label texts online.
- If necessary, submit an application to Tukes to make changes.





# What does Tukes supervise on the market?

Tukes market surveillance makes sure that the label texts:

- Comply with the EU Labelling Regulation (547/2011)
- Include the CLP classification and restrictions provided in the product authorisation decision
- Conforms to the information on user instructions table





### **Further information**

www.tukes.fi/kasvinsuojeluaineet www.kemidigi.fi/kasvinsuojeluainerekisteri Email questions to: ppp@tukes.fi

### **Related legislation:**

EU Regulation on Plant Protection Products 1107/2009/EC Act on Plant Protection Products 1563/2011 EU Regulation labelling requirements for plant protection products 547/2011/EU CLP Regulation 1272/2008/EC