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Introduction of CLP regulation for PPPs and yield enhancers in Hungary

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- **Implementation of CLP Regulation in the European Union**
- **CLP label elements and additional national hazardous labelling phrases**
- **CLP regulation vs. Plant Protection Product (PPP) regulation – national approach**
- **Classification of yield enhancing substances**
- **Challenges for the authority**

Globally Harmonised System (GHS = CLP) in EUROPE



GHS is the Globally Harmonised System was initiated by the United Nations in 2003 to promote:

- globally harmonized classification of chemicals
- according to their health, physical and environmental hazards, and
- to develop compatible labelling and material safety data sheets

Many countries have adopted all parts of GHS.

The EU has also adopted GHS but in modified form and called it the **Classification, Labelling and Packaging Regulation (CLP)**.

CLP Regulation (1272/2008/EC) replaces the former **Dangerous Substances Directive (DSD - 67/548/EEC)** and **Dangerous Preparations Directive (DPD - 1999/45/EC)**



CLP- Classification implementation and timeline



20. Jan. 2009

01. Dec. 2010

1. June 2015

1. June 2017

Substances

**CLP
optional**

**MSDS: CLP+EU(DSD)
Label: CLP mandatory**

**CLP in force
for substances**

Mixtures

**MSDS: Classification EU(DPD) + CLP
Label: EU(DPD)mandatory**

**2-year transitional
period for products
already
on the market**



CLP label elements



Old hazard symbols



New hazard pictograms

CLP label elements



- Signal words:

„Danger”, or „Warning”

- Hazard (H) statements:

H312 – Harmful in contact with skin.

These are replacing the old „R” phrases

- Precautionary (P) statements:

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

These are replacing the old „S” phrases.



CLP label elements



- Supplementary hazard statements:

EUH401 – To avoid risks to human health and the environment, comply with the instructions for use.

This statement is obligatory for all plant protection products

The code itself is not obligatory on the label.



Other precautionary label elements



• General/safety precautionary phrases:

- SP 1** Do not contaminate water with the product or its container. (Do not clean application equipment or its parts near surface water. / Avoid contamination via drains from farmyards and roads)
- SPe 3** To protect aquatic organisms respect an unsprayed buffer zone of **5 m** to surface water bodies.

• Waiting periods

• First aid measures

• Occupational precautions

• Other environmental provisions

• Other national precautionary phrases:

- Fire hazards classification
- Hazard to aquatic organisms
- Hazard and risk to bees



CLP Regulation VS. PPP Regulation



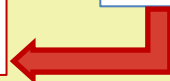
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According to Regulation 1272/2008/EC it is the responsibility of the manufacturer or importer to classify a mixture before placing the mixture on the market.



According to Regulation 1107/2009/EC the authorisation granted by the authority shall include a classification. Member States will decide on the classification when granting the authorisation.

National authorities may leave the classification to industry or they review it themselves



National procedure

Hazardous properties of all authorised products have been evaluated in Hungary.

Reasons for this decision:

- **To help smaller companies which don't have the knowledge and experience**
- **CLP statements shall correspond with the national precautionary phrases**



National procedure



- National procedure has been implemented for CLP evaluations:
 - The procedure for each product shall be initiated by the applicant
 - Applications are submitted on monthly bases
 - 90 days for assessment for the authority experts
 - All necessary data should be provided (not only the classification, but studies and reasoning as well)
 - Also non-chemical PPPs are included (P-statements)
 - The CLP (hazardous properties) part of the label is approved, **BUT authorisation certificate is not yet modified**
 - Inspectors get access to the approved CLP labels (which are not public)



National procedure - PPP



At the end of the CLP review procedure:

- The new hazardous properties including CLP, safety precautionary phrases (SP), national phrases are approved on the label, **BUT**
- **The new classification is not yet included in the authorisation certificate**
- In the future: one-by-one, the new classification will be added to the authorisation certificate of all products

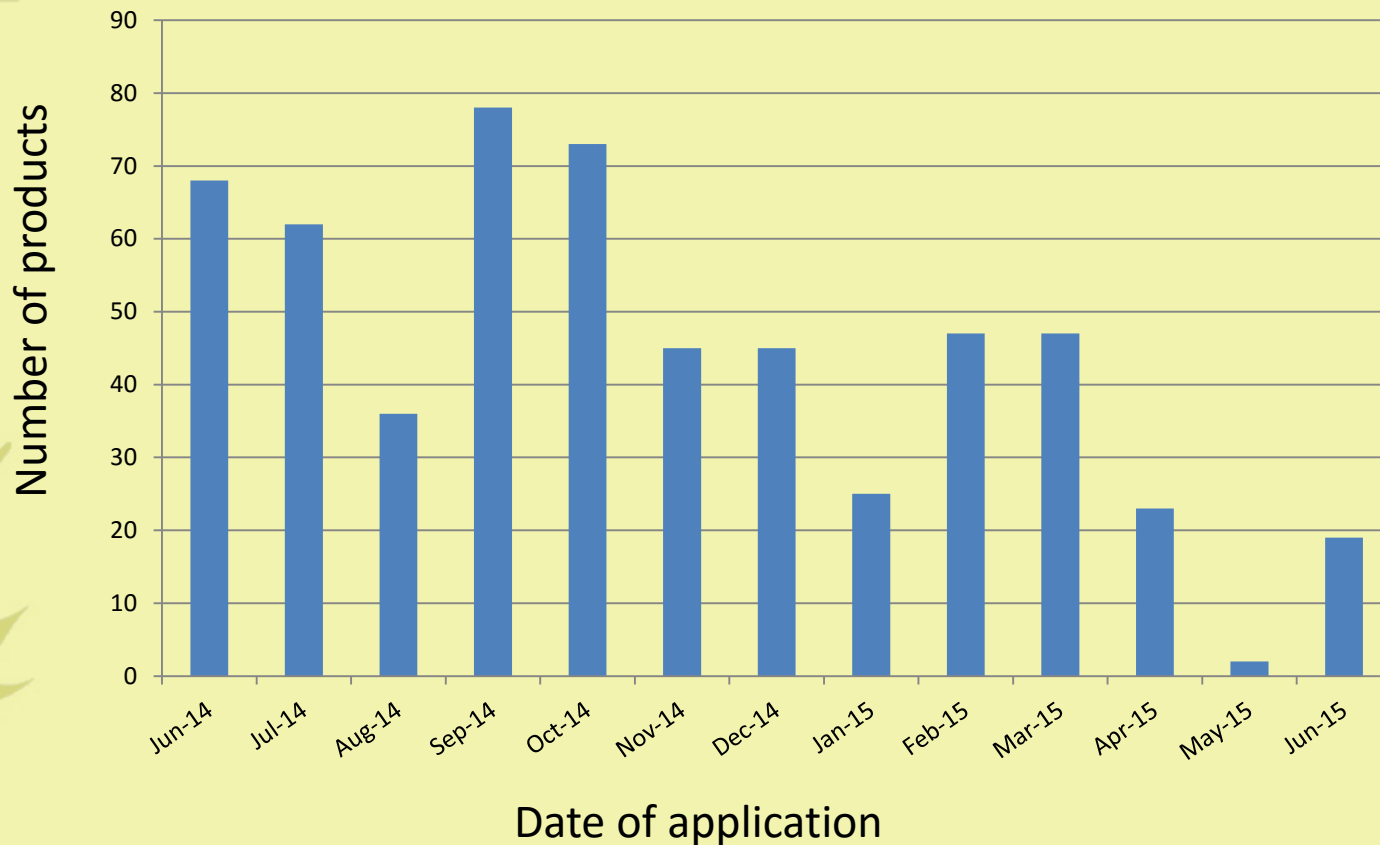


National Procedure - PPP

~ 700 CLP applications received in 1 year



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Applications have been received for 85% of all authorised PPPs.

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National procedure –YES

(yield enhancing substances)



- **Almost the same procedure as for PPPs**
- **30 days for evaluation**
- **CLP is included into the registration, labelling is the responsibility of the authorisation holder**
- **Authorisation holders must apply for CLP modification (only 30% have done so) – many small companies**



National procedure -YES



As a rule of thumb:

- **Industrial by-products (soil conditioners, liming material) get H-statements**
- **70% of the products get only P statements (e.g. compost, wastewater sludge)**
- **Soil conditioners containing biostimulants also get H-statements**



Future challenges

MSDS (CLP) is frequently updated by authorisation holders → MSDS and label do not always comply:

- If CLP is still only approved on the label – 90 days review
- If CLP is included in the registration document – normal amendment timeline (label must not be amended) → In case of any inspection the company can refer to the application for updated CLP

Future challenges



- **OLD (R and S phrases) and NEW (H and P statements) classification can not be placed together on the label of one product!**
- **Until 1 June 2017 (transitional period) the same product may be on the shelves of a shop with old and new label in case of:**
 - **different packaging sizes**
 - **different batches**

All depends on the date of manufacture!





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Thank you for your attention!

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