



# ENFORCEMENT ISSUES

## BPR LABELS AND P-STATEMENTS

### ARTICLE 95 LIST AND SUPPLIERS' NAME CHANGE

ECHA Forum for Exchange of Information on Enforcement and BPR Subgroup  
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# OUTLINE



- About A.I.S.E.
- BPR labels and P-statements
- Article 95 list and suppliers' name change



# A.I.S.E. NETWORK

## REPRESENTING THE DETERGENTS AND MAINTENANCE PRODUCTS INDUSTRY ACROSS EUROPE

A STRONG NETWORK of over **900** COMPANIES

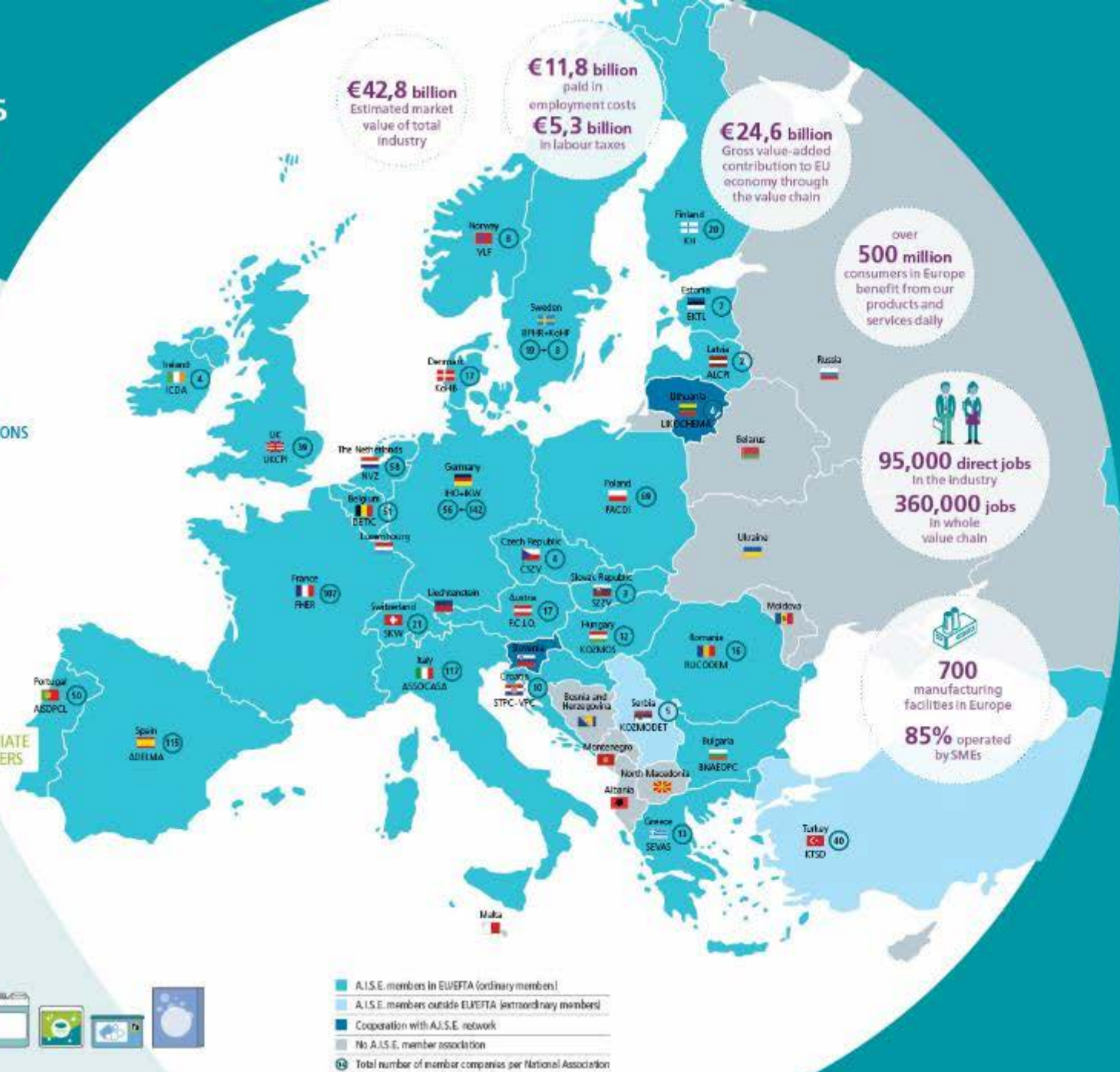
**29** NATIONAL ASSOCIATIONS

**18** CORPORATE MEMBERS

**18** ASSOCIATE MEMBERS

### A.I.S.E. REPRESENTS AN INDUSTRY THAT PROTECTS OUR EUROPEAN WAY OF LIFE

- Keeps our homes and public places clean and hygienic
- Secures patient safety in healthcare environments
- Prevents infection through good hygiene practices
- Makes our lives more pleasurable and satisfying
- Adds to our sense of wellbeing
- Facilitates convenient and modern lifestyles
- Maintains the durability of goods
- Increases productivity for companies
- Protects investments in brands
- Contributes to sustainability



# Relevance of biocides for A.I.S.E. members

- A.I.S.E. members that are active in the biocides sector are mainly biocidal products formulators:
  - Disinfectants (PT1-5)
  - Insecticides & repellents (PT18-19)
- Most A.I.S.E. members are downstream users of in-can preservatives (PT6)



# BPR labels and P-statements



# P-statement selection - legal background

- **Biocide guidance**

CA document [CA-May15-Doc.4.4](#): all P-statements that are triggered by the assigned H-statements must be listed in the SPC

- **CLP**

- CLP Article 28: principles of precedence for precautionary statements:
  - (1) Redundant or unnecessary P-statements shall be omitted from the label
  - (3) Normally, not more than 6 P-statements shall appear on the label

- [Guidance on labelling and packaging - version 4.2, March 2021](#)

- Section 7 offers assistance with the selection of the most appropriate P-statements
- Aim of the guidance: to assist in the **effective** application of CLP; information should not confuse the user



# P-statement selection - Current practice

- SPC:
  - All (so not only the most relevant) P-statements that are listed in CLP by the assigned H-statements are listed in the SPC
  - Only in exceptional cases, a P-statement is moved to the “notes section”
  - Additionally: CG document on first aid<sup>(1)</sup> causes a doubling of text in SPC section 5 (see example on following slides)
- Label:
  - Applicant select the appropriate P-statements that shall appear on the label



# Example

## “Nonanoic Acid Algaecides” Biocidal Product Family<sup>(1)</sup>



An algaecide based on nonanoic acid for professional and non-professional use

Meta SPC1 - classification Eye irrit. 2, H319

### P-statements:

P101 - If medical advice is needed, have product container or label at hand.

P102 - Keep out of reach of children

P103 - Read label before use.

P264 - Wash hands thoroughly after handling.

P280 - Wear eye protection (for professional users only, a special packaging is obligatory for the general public)

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical advice/attention.

P501 - Dispose of contents/container in accordance with local regulations.

### First aid instructions for this product:

General: If medical advice is needed, have product container or label at hand. IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.



# Continued Example: Nonanoic Acid Algaecides

P-statement	Applicability for general public	Applicability for professional users
P101	Duplication of the first aid instructions - not applicable according to CLP article 28.1 - should be removed	Duplication and additionally only intended for consumer products - should be removed
P102	Applicable	Only intended for consumer products - should be removed
P103	CLP labelling guidance: optional - should be removed	Only intended for consumer product - should be removed
P264	CLP labelling guidance: Recommended for the general public	CLP labelling guidance: optional for the industrial/professional users - - should be removed
P280	CLP labelling guidance: recommended but for this product other RMM are in place - should be removed	CLP labelling guidance: recommended
P305 + P351 + P338	Duplication of the first aid instructions CLP labelling guidance: recommended Should be removed according to article 28.1	Duplication of the first aid instructions CLP labelling guidance: recommended Should be removed according to article 28.1
P337 + P313	CLP labelling guidance: recommended	CLP labelling guidance: recommended
P501 9	Not a P-statement that is allocated to H319 but according to CLP Art. 28(2), a statement regarding disposal of the product is necessary on consumer products	Not a P-statement that is allocated to H319

# Applying “normal CLP” to the label - For Meta-SPC 1 Nonanoic Acid Algaecides



For non-professional use

Meta SPC1 - classification Eye irrit. 2, H319

P-statements:

Keep out of reach of children.

Wash hands thoroughly after handling.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local regulations.

First aid instructions for this product:

General: If medical advice is needed, have product container or label at hand. IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.



# Example Nonanoic Acid Algaecides



## SPC

### P-statements:

If medical advice is needed, have product container or label at hand.

Keep out of reach of children

Read label before use.

Wash hands thoroughly after handling.

Wear eye protection (for professional users only, a special packaging is obligatory for the general public)

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local regulations.

### First aid instructions for this product:

General: If medical advice is needed, have product container or label at hand. IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

## Applying CLP rules for the label

### P-statements:

Keep out of reach of children. Wash hands thoroughly after handling. If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local regulations.

### First aid instructions for this product:

General: If medical advice is needed, have product container or label at hand. IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor. IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.



# Example: Nonanoic Acid Algaecides

## Conclusion



- The SPC lists 8 P-statements (only for 1 H-statement)
- Part of the text is duplicated in other SPC sections
- Can lead to :
  - Lengthy SPC
  - Long unclear text on the label



# General conclusion and consequences

- The SPC does not guide enforcement authorities to identify what should be on the label (= what is most important for the users)
  - Biocidal authorisation is based on risk assessment: it is not obvious which P-statements are the most critical during use based on the classification of the product
  - Authorisation holder should select the most appropriate statements

⇒ Could be challenging for enforcement authorities to judge, without reading the full risk assessment, whether the authorisation holder properly selected the P-statements



# Way forward?

- A.I.S.E. is reflecting on possible ways forward
- Enforcement authorities should get more direct guidance from the experts that have assessed the full dossier
  - Competent Authorities' experts know the full PAR => summarised into the SPC
  - SPC shall contain the relevant P-statements => can be used for inspections without the need for additional assessment



# Another example: CG-51\_e-c Guidance for first aid instructions - Adapt a confusing sentence

- The guidance states that all biocides classified as H314 and/or H318 should be labelled with the sentence:

*Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid*

- This phrase is also included on products with low pH (pH < 2) (Example EU [2023/1758](#))
- For the label solely “Rinse eyes repeatedly on the way to the doctor” is needed
- Reasons:
  - The current phrase is long and not easy to understand
  - Only mentioning pH > 11 on a product that is the opposite (pH < 2) may lead to the wrong treatment. Causing more harm
  - Healthcare personnel/doctor may not be present while on the way to the doctor. Repeated rinsing is still important in that case

⇒ Another example where the SPC would not lead to a clear label for users and enforcement authorities

# Article 95 list and suppliers' name change





- Nowadays it is common that companies active in the biocides supply chain are changing names, mainly due to acquisitions/merges
- When an active substance supplier changes name :
  - The supplier informs its customers
  - SDS are updated with new name
  - ECHA updates Art. 95 list of approved suppliers
  - The supplier's customers update :
    - the relevant BPR products' authorisation (administrative change which can be notified after implementation (within 12 months) – as per Title 1 section 2 of the Annex of the “Change Regulation”<sup>(1)</sup>)
    - the relevant local products' authorisation (if the name of the AS manufacturer is part of the authorisation under the national regime for BP's under transitional period)



- This creates lots of administrative work to update BPR and local authorisations
- Potential issue at enforcement level : discrepancy between the Article 95 list and the authorisation of the BP
- Example :
  - A BP formulator is buying its AS from a company “A”
  - the name of company “A” is changing to “B”, the change is implemented in the SDS, and on Art 95 list
  - inspection takes place before the authorisation of the BP is updated (e.g. in case the company has not submitted yet the admin. change, or the MS has not amended yet the authorisation)



# Proposals

- Some AS Suppliers indicate on their documentation (e.g. Art 95 statement, LoA, etc...) the current and previous name (e.g. “Company B, previously named company A”)



# Proposals

- A.I.S.E. contacted ECHA to ask that Article 95 list reflects name change, for instance: list both names for a certain period, such as:

*“company B, formerly listed as company A (name changed on DD-MM-YYYY)”*

- ECHA indicated it is not possible :
  - the list reflects the current situation and does not report changes occurred in the past
  - Would require changing the structure of the list => considerable administrative work for ECHA



The screenshot shows the ECHA website interface. At the top, the ECHA logo is visible. Below it, there is a search bar and a table of chemical substances. The table has several columns, including 'CAS No.', 'Name', and 'Status'. The table contains several rows of data, with some cells highlighted in blue. The text is small and difficult to read, but the structure of the table is clear.



**Thank you for your attention**

