



Extension of the GRA

AMFEP & A.I.S.E. example

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Enzymes are...

- **biological proteins** produced by fermentation.
- **act as catalysts** - make and improve nearly 400 everyday consumer and commercial products (food and beverage, animal nutrition and textiles through to household cleaning, biofuels and energy generation).
- **readily biodegradable**
- exhibit no specific environmental toxicity - **not classified for the environment**
- **have an excellent safety profile** - no risk of acute toxicity, repeat dose toxicity, genotoxicity, carcinogenicity or reproductive and developmental toxicity



The safety of enzymes

- Enzymes are classified as Respiratory Sensitizer Category 1
- Despite this intrinsic hazard, **the use of enzymes has been documented safe:**
 - No reporting of enzyme allergies to consumers for 50+ years*
 - Occupational exposure leads to very limited number of enzyme allergies. Few incidents have been reported where exposure control has not been in place.
 - **REACH evaluation** conducted (CoRAP and RMOA) for all technical applications of alpha-amylase 2015-2018. **Concluded that the uses of enzymes are safe to both consumers and workers, and that this conclusion can cover all enzyme classes.**

*) Prevalence of sensitization in population very rare, 0.126% in 1977-2010

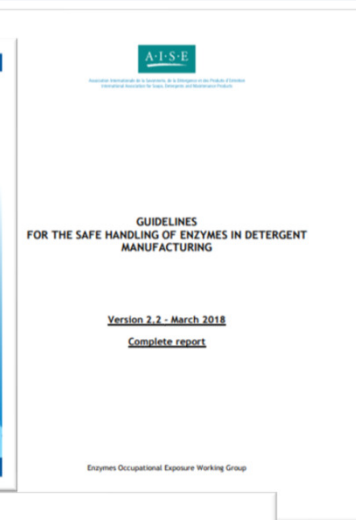
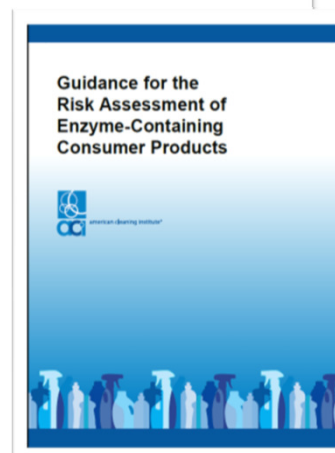


Product Stewardship

- A Derived Minimal Effect Level (**DMEL**) has been set for **all enzymes**, e.g. in the cleaning & laundry uses:
 - 60 ng/m³ for workers
 - 15 ng/m³ for consumers

Based on published clinical studies, and data generated for decades*

- Focus on product design, low-dusting and non-volatile
- Development of publicly available guidance material:
 - Comprehensive guidance document
 - Webinars introducing specific subjects
 - Posters for professional workers (17 languages)
 - Guidance document for risk assessment of enzyme-containing consumer products



*) 40 years at the time of establishing the DMELs



Sustainability benefits of enzymes in cleaning products

Highly targeted bio-catalysts used in detergents for **better** stain removal, whiteness, fabric and colour care and overall cleaning performance

Significant environmental benefits

Washing at low temperatures

Innovating compact products

Alternative technology to phosphates

Readily biodegradable-
no environmental impact



... **9 g per wash CO₂ reduction per wash (11 time lower)***

... **1.4 million tonnes CO₂ reduction due to compaction**

* If surfactants are replaced with enzymes

... **2,300 GWh/year in Europe – Cold wash**

equivalent to the electricity consumption of more than 300,000 inhabitants

... **5.2 m3 CDV** reduction per wash**

**CDV = the critical dilution volume, used for Ecolabel criteria

... **30 million tonne saving due to compaction**

... **3.8 g surfactant saving per wash (30% reduction)*****

*** if surfactants are replaced with enzymes

Source: A.I.S.E. Fact sheet 2019 [20190410111600-aise_factsheet-2019_compaction_def.pdf](#)
[Surfactant replacement with enzymes](#) | Whitepaper by Novozymes (2020)
[I Prefer 30 - Home](#)



GRA extension and enzymes

The issue:

- The Chemicals Strategy for Sustainability (CSS) - Proposal to **extend the current GRA** to uses by professionals and to additional chemicals e.g. those affecting the respiratory system.
- Enzymes are classified as **Respiratory Sensitizers Category 1** under the CLP Regulation.

Our view:

- It is a **far reaching extension of the GRA**, based only on the intrinsic properties of substances, without consideration of risk assessment and proven safe use
- a blanket ban on these ingredients simply due to their hazard would have a **huge impact** on the enzyme industry and its downstream users (the detergent industry) – **depriving them of important environmental, societal and technological benefits.**
- The sector would need a workable procedure with a meaningful derogation process to be designed and implemented.



In conclusion

- **Enzymes:** a successful example - ahead of its time (1960s) - of innovative ingredients in cleaning products, with wide-ranging functionalities and significant sustainability benefits
- **Opportunity:** Enzymes – enablers for multiple sectors to become aligned with EU sustainability policy ambitions:
 - Green Deal, EU Taxonomy, CSS, Farm to Fork, Zero Pollution, ESPR
- **Risk:** if GRA is extended to include respiratory sensitizers used in consumer (and professional) uses:
 - Sustainability benefits will be lost for the Cleaning sector – after decades of safe and sustainable performance
 - Leaves the sector with no other sustainable alternatives for their products, thereby impacting consumers' demands.
- **Our Ask:** **Carefully assess** the demonstrated safe use and sustainability benefits of substances, such as enzymes, prior to inclusion in the scope of the GRA.

