



Brussels, 14 July 2021

Re. Criteria for evaluation of products for cleaning and disinfection - Draft Report - discussed by Expert Group for Technical Advice on Organic Production (EGTOP) at the plenary meeting of 3 to 4 February 2020.

The Association of Manufacturers and Formulators of Enzyme Products – AMFEP and the International Association for Soaps, Detergents and Maintenance Products - A.I.S.E. support a responsible and ecological approach for cleaning and disinfection within organic operations stipulated in the draft report (hereinafter the Draft Report) provided by Expert Group for Technical Advice on Organic Production (EGTOP). It is our belief that enzymes can contribute to this approach.

Enzymes exist in all of nature – in microorganisms, plants, and animals, as well as our own bodies. They are proteins that are essential for all life. An enzyme is a catalyst which can speed up biological processes. Today, enzymes used in detergent products are produced by microorganisms in fermentation processes. The fermentation process uses sugar and other agricultural products as feedstock for the microorganisms.

Enzymes are used in detergent products to enhance the performance while decreasing the environmental impact. In terms of their functioning they help the breakdown of larger molecules into smaller fragments, that can then be removed easily by other ingredients in the formulation. Typically, enzymes are narrowly optimized molecules for their respective field of application – such as the removal of a specific protein, starch or fat – and most consumer products thus include different enzymes to work on different substrates. More commonly these substrates are referred to as “soils” or “stains” on surfaces or on fabrics. Each enzyme is good at one specific type of reaction, which results in specific enzymes being targeted to specific type of soil or stain on a surface, or on a fabric.

Enzymes break down the debris from food e.g. plant fibres and protein and they contribute to thorough and sustainable cleaning processes in the home, and in industrial processes. They offer efficient cleaning at moderate temperature, mild pH and with less water, resulting to less chemical discharge into environments and less energy and water consumption. Also, they are only needed in very low concentrations in cleaning products, to be effective. These ingredients are used in many cleaning products for consumer and industrial cleaning applications and have been safely used throughout for decades. This is also the case for dish washing detergents, and cleaning products used in food processing, and in particular Cleaning In Place (CIP). One other big advantage of enzymes is that they are readily biodegradable.

Furthermore, enzymes are recognized by both EU and Nordic Ecolabels as critical ingredients which enable cleaning products to be awarded with these Ecolabels. More than 40 years of experience in the enzyme and cleaning industries show that enzymes can be used safely at low levels in cleaning products despite their hazard classification as a respiratory sensitizer. Based on this, enzymes are derogated from the restriction of respiratory sensitizers in both EU and Nordic Ecolabel criteria for all cleaning product categories.

The Draft Report has proposed substances that cannot be considered for the inclusion in a positive list of the EU organic regulation and enzymes are listed in “Unwanted other components” in Section 2.4.5. The organic food legislation contains certain criteria that enzymes can help to fulfil, including responsible use of energy, resources, and maintenance of water quality. The ban of these ingredients can in practice result in inconsistency with the environmental goals of the legislation. Enzymes, as discussed above, offer extremely effective and safe cleaning in many applications, including food processing. Therefore, we propose that enzymes are derogated from this prohibition.

1. Enzymes used in cleaning agents for food processing - functions and benefits

The previous report “[Cleaning and disinfection, adopted in 2016](#)” delivered by EGTOP describes various cleaning products. Cleaning in place (CIP) systems in food processing is one of them and described as follows:

Cleaning in plants processing liquids such as, juice, milk, beer etc is normally done using ‘Cleaning in place’ (CIP) systems, which work in several phases. Typically used substances are: warm water; sodium hydroxide; sodium hypochlorite; heat and/or chemical sterilisation; descaling with nitric, phosphoric, sulphamic, or methanesulphonic acid.

Enzymes are not mentioned in this section; however, enzymes are important ingredients in cleaning products such as Cleaning In Place (CIP) systems. Enzymes break down the residual food debris in facilities for food processing, e.g., fibers and residue from crops, fruits, and meat etc., at moderate temperature and neutral pH. They remove the residual substrates that can contaminate production or promote biofilms within a process.

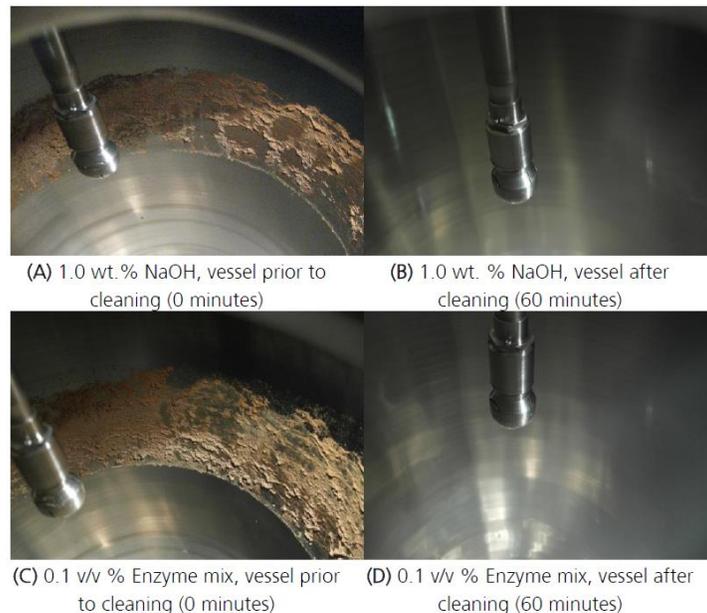


Figure 1: Cleaning performance of 1.0 wt.% NaOH and 0.1 v/v % enzyme mix illustrated on yeast soil ring located on the surface of a stainless steel fermentation vessel.

When utilising enzyme containing cleaning products, the facilities can be easily cleaned with milder chemicals and vigorous mechanical actions. The cleaning can take place at moderate temperature and with less water in the rinsing process (Figure 1). Thus, enzymes can reduce the chemical load to the environments, and water and energy consumption whilst contributing to thorough cleaning.

Enzymes are proteins and readily biodegradable. A study on enzyme exposure created for REACH Chemical Safety Assessment showed that enzyme exposure to the environment is negligible.

The use of enzymes within the cleaning process thus fits into the environmental aims of efficient use of resources and energy.

2. CLP Classification of enzymes and risk evaluation

Enzymes are proteins and as such can cause respiratory sensitization. The enzymes used for cleaning products are classified as Respiratory Sensitizer Category 1 under the CLP Regulation.

Safe use of enzymes is of utmost importance for the enzyme and the detergent industry. Some of the enzymes commonly used in cleaning for food processing (Table) 1 are also used widely for consumer laundry products. Derived Minimal Effect Levels (DMEL) have been set at 60 ng/m³ for workers and at 15 ng/m³ for consumers based on the data generated over the years.

Enzymes used as ingredients for cleaning products are subject to REACH obligations. The enzymes in Table 1 are registered under REACH with solid documentation through Chemical Safety Assessment, demonstrating that enzyme exposure for workers during a CIP cleaning process is well below the DMEL.

Table 1. Typical enzymes used in cleaning agents for food processing

Enzyme	CAS number	CLP classification relevant for Ecolabelling	Cleaning function
Cellulase	9012-54-8	H334 ¹	Degrade and remove plant debris (fibers)
Glucoamylase	9032-08-0	H334	Degrade and remove plant debris (fibers)
Polygalacturonase	9032-75-1	H334	Degrade and remove plant debris (fibers)
Protease (Subtilisin)	9014-01-1	H334 H400 ² H411 ³	Degrade and remove meat and plant debris (protein)

The enzyme and the detergent industry have 40+ years of experience on safety of enzymes and have co-created ample material on the safe use of these ingredients, including guidance, webinars, posters for professional worker (Ref: www.aise.eu/enzymes).

3. Ecolabelling and enzymes

As an additional point, the Draft Report stipulates that cleaning products should comply with the criteria set in EU Ecolabel on hard surface cleaning products.

*“the use of ecolabelled products should be preferred to other products, where possible.
In the new structure for Annex VII ecolabelled products should be included in the basic*

¹ May cause allergy or asthma symptoms or breathing difficulties if inhaled

² Very toxic to aquatic life

³ Toxic to aquatic life with long-lasting effects

*lists, while non-ecolabelled cleaning products should be included in the restricted lists.”
(Executive Summary)*

In order to be awarded the EU Ecolabel, a cleaning product, which fall within the product group ‘hard surface cleaning products’, shall comply with the criteria, as well as the related assessment and verification requirements, set out in the Annex of the Commission Decision (EU) 2017/1217. (2.4.4)

Both EU and Nordic Ecolabels do not permit H334 substances [Respiratory Sensitizers] in Ecolabel products. However, enzymes are derogated from this restriction due to their safety profile and the benefits they bring and they are ingredients of many cleaning products awarded with Ecolabels.

In particular, the background document to the Nordic Ecolabel for "[Cleaning Agents For Use in the Food Industry](#)" summarize enzymes as follows.

The substances that are often classified as sensitising are fragrance substances, preservatives and enzymes. [...] Enzymes are exempted here as there is a need for enzymes in a number of types of cleaning agents in order to degrade proteins, etc. [...]

Enzymes are used in a number of cleaning agents for use in the food industry, such as products for membrane cleaning. [...] Another new aspect is the requirement for the enzymes to be encapsulated (in solid form) or liquids/slurries. This requirement is to prevent the people who work in cleaning agent production from being exposed to the enzymes' potential sensitisation of the respiratory system.

Thus, enzymes are well recognized in Ecolabel schemes as critical ingredients that enable cleaning products to be awarded for Ecolabels.

Conclusion

The use of enzymes within the cleaning process helps to achieve the environmental aims of efficient use of resources and energy. This is due to the properties of enzymes allowing them to work effectively in low concentration, at low temperatures, mild pH and can minimize water use. In addition, these ingredients are readily biodegradable. A study on enzyme exposure created for REACH Chemical Safety Assessment showed that enzyme exposure to the environment is negligible.

The enzyme and the detergent industry have 40+ years of experience on safety of enzymes, thus action has been taken to responsibly use these products in consumer and industrial products and mitigate the risks associated with the hazard classification.

Enzymes have also been accepted within Ecolabel products, and we thus propose that enzymes also be derogated from this prohibition.

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AMFEP

AMFEP, is a non-profit European industry association created in 1977. AMFEP currently has 31 members, representing over 90% of the European and over 80% of the world enzyme market. AMFEP serves as a hub for information exchange and dialogue between enzymes producers and formulators, industry organisations, the scientific community and policy makers and promotes co-operation on regulatory and safety aspects of enzymes. AMFEP informs its customers and other interested parties on the efficacy and safety aspects of its enzyme products and defends and promotes the enzyme industry. Members of AMFEP produce and sell enzymes for use in food, feed, detergents and other non-food industries, excluding enzymes for pharmaceutical and diagnostic use. AMFEP fruitfully co-operates with European institutions and partner associations worldwide, has observer status in Codex Alimentarius, is Member of the EFSA Stakeholders Consultative platform, and is one of ECHA's accredited stakeholder organisations.

A.I.S.E.

A.I.S.E. is the International Association for Soaps, Detergents and Maintenance Products. Based in Brussels, A.I.S.E. has been the voice of the industry to EU regulators for nearly 70 years. Membership consists of 29 national associations across Europe, 17 corporate members and 14 value chain partners. Through this extensive network, A.I.S.E. represents over 900 companies supplying household and professional cleaning products and services across Europe.

The industry is a substantial contributor to the European economy with an annual market value of €41,2 billion, directly employing 95 000 and 360 000 throughout the value chain. A.I.S.E. has a long history in leading voluntary industry initiatives that focus on sustainable design, manufacturing and consumption, product safety and safe use of products by consumers and professional customers.