# Industry Guidelines on the Safe Handling of Enzymes in the Textile Industry Supply Chain

## Part II: Textile Finishing & Garment Finishing Industry

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This paper has been developed by the joint Enzymes Safety Working Group with members of:

AMFEP – Association of Manufacturers and Formulators of Enzyme Products www.amfep.org

EURATEX – The European Apparel and Textile Confederation euratex.eu

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**List of Abbreviations**

**ACGIH**: American Conference of Governmental Industrial Hygienists

**ADR**: European Agreement concerning the International Carriage of Dangerous Goods by Road (Accord Européen Relatif au Transport International des Marchandises Dangereuses par Route)

**aep**: active enzyme protein

**AISE**: International Association for Soaps, Detergents and Maintenance Products (Association Internationale de l'industrie du Savon, des Détergents et des Produits d'Entretien)

**AMFEP**: Association of Manufacturers and Formulators of Enzyme Products

**APF**: Assigned Protection Factor

**CAD**: Chemical Agent Directive

**CLP**: Classification, Labelling and Packaging (Regulation)

**CSA**: Chemical Safety Assessment

**DMEL**: Derived Minimal Effect Level

**ECHA**: European Chemicals Agency

**ELISA**: Enzyme-linked immunosorbent assay

**ERC**: Enzyme REACH Consortium

**ES**: Exposure Scenario(s)

**eSDS**: extended SDS

**EU**: European Union

**EURATEX**: The European Apparel and Textile Confederation

**FEV1**: Forced Expiratory Volume in one second

**FVC**: Forced Vital Capacity

**GES**: Generic Exposure Scenarios

**GHS**: Globally Harmonised System

**HEPA**: High Efficiency Particulate Air Filters

**HRA**: Health Risk Assessment

**HSE**: Health and Safety Executive

**IBC**: Intermediate Bulk Containers

**IgE**: Immunoglobulin E

**IUBMB**: International Union of Biochemistry and Molecular Biology (Enzyme Nomenclature Committee)

**LEV**: Local Exhaust Ventilation

**LMRA**: Last Minute Risk Analysis

**MAK**: German Occupational Exposure Limit (Maximale Arbeitsplatz Konzentration)

**MS**: Member States

**NIOSH**: The National Institute for Occupational Safety and Health

**OC**: Operational Condition

**OEL**: Occupational Exposure Limit

**OSH**: Occupational Safety and Health

**PAPR**: Powered Air Purifying Respirators

**PEFR**: Peak Expiratory Flow Rate

**PPE**: Personal Protective Equipment

**RAST**: Radioallergosorbent Test

**RCR:** Risk Characterisation Ratio

**REACH**: Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation)

**RMM**: Risk Management Measure

**RPE**: Respiratory Protective Equipment

**SDS**: Safety Data Sheet

**SDIA**: Soap and Detergent Industry Association (UK)

**SOP**: Standard Operating Procedure

**STEL**: Short Term Exposure Limit

**TCF**: Textile Chemical Formulators

**TLV**: Threshold Limit Value

**TWA**: Time-Weighted Average

## Foreword

For decades, enzymes have been widely used in the textile industry supply chain due to their unique properties that facilitate the production of high-quality textile products and, at the same time, significantly improve the ecological footprint of the produced products.

Enzymes are proteins and, like other proteins, may act as respiratory sensitisers if individuals are repeatedly exposed to airborne dust or aerosols that contain them. Such sensitisation may ultimately lead to respiratory allergy, but it is important to note that not all individuals who become sensitised to enzymes develop allergy symptoms.

The risk of becoming sensitised at the workplace can, however, be effectively minimized by implementing risk management measures that aim to prevent the generation of airborne dust or aerosol. Risk management measures such as comprehensive process controls, lower risk product formulations, and functional handling instructions have all been shown to effectively protect the health of workers.

The Association of Manufacturers & Formulators of Enzyme Products (AMFEP), and the European Apparel and Textile Confederation (EURATEX) have jointly developed this guidance document for the safe handling of enzymes in the textile and garment finishing industry ; thereby providing the insight and tools to help safeguard the health of the workers in this industry. It should be emphasized that this guidance document covers the occupational conditions of the workers. Proper aftertreatment leads to the wash out or denaturation of enzymes during the textile and garment finishing. Consumers are not exposed to any enzymes and are not in scope of this document.

This safe handling guidance document is aimed at all people that work towards the safe use of chemicals in the textile supply chain, such as site managers, health and safety specialists, industrial hygienists, occupational physicians, product stewards/managers, regulatory affairs managers, and (non-)governmental regulators. The chapters in this guidance document are focused on specific topics and can be read independently of each other. If relevant, there will be references made from one chapter to another.

To inform on which chapters are of relevance to the reader, a short summary of each chapter is given below:

- **Chapter 1 Introduction:** focuses on where and why enzymes are used in the textiles supply chain and why attention should be paid when handling enzymes.
- **Chapter 2 Regulatory Requirements:** provides insights on occupational exposure limits for enzymes and the appropriate supply chain communication, such as the information provided in the (extended) Safety Data Sheet and on the label.
- **Chapter 3 Management and Training:** describes how to establish a proper management structure to provide adequate controls and defines the responsibilities that apply to everyone.
- **Chapter 4 Exposure Controls:** Defines the necessary process and equipment design to minimize and maintain low exposure levels, including recommended work practices.

- **Chapter 5 Health Effects and Exposure Monitoring:** gives a comprehensive overview of the adverse health effects associated with high exposure to enzymes, how to measure occupational exposure and how to carry out health surveillance.

The reader should keep in mind that this guidance document solely focuses on how to reduce airborne exposure to enzymes and, thus, how to minimize respiratory sensitisation at the workplace. However, workers may be exposed to other hazards at the workplace, too, including other substances that are used as co-formulants in enzyme products. To protect the health and safety of workers, a thorough health risk assessment (HRA) is generally necessary for each workplace that addresses all hazards present at this workplace. Such an HRA may also need to include other hazards associated with (some) enzymes that are not addressed in detail in this guidance document, such as skin irritation.

For the creation of this guidance document, a specific questionnaire was developed by the AMFEP/EURATEX enzyme safety taskforce that was shared with members of the European textile and garment finishing industry. Additionally, three site visits were carried out by the taskforce. The feedback collected via this questionnaire and site visits was used to define typical processes involving enzymes in the textile and garment finishing industry and current best practices.

This guidance document reflects the state of technology and scientific understanding of controlling exposure to enzymes at the time of writing (2021). Therefore, the approaches described will be subject to changes as technical advances and scientific understanding improves.

Furthermore, the focus of this guidance document is on the control of enzyme exposure within the European textile and garment finishing industry. Although the general principles and recommendations are widely applicable, some of the guidance given may not be applicable to production sites in other parts of the world. Outside of Europe the best practices discussed in this guidance document shall be implemented in line with local regulations.

Similar guidance documents on the safe handling of enzyme products are also available for the textile chemical formulating industry[1], the detergent industry[2], the baking industry[3] and the pulp and paper industry[4].

[1] AMFEP & TEGEWA (2022) Industry Guidelines on the Safe Handling of Enzymes in the Textile Industry Supply Chain - Part I: Textile Chemical Formulating Industry:
https://amfep.org/publications/amfeptegewa-industry-guidelines-part-i-textile-chemical-formulators/
[2] AISE: Safe Handling of Enzymes (Guideline, training materials, webinars):
https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes
[3] AMFEP & FEDIMA (2018): Industry Guidelines On the Safe Handling of Enzymes in the Bakery Supply Chain:
https://amfep.org/_library/_files/Industry_Guidelines_on_the_Safe_Handling_of_Enzymes_in_the_Bakery_Supply_Chain_-_MARCH_2018.pdf
[4] AMFEP & CEPI (2019) Industry Guidelines on the Safe Handling of Enzymes in Pulp & Paper Manufacturing:
https://amfep.org/publications/amfep-cepi-industry-guidelines-on-the-safe-handling-of-enzymes-in-pulp-paper-manufacturing/

## 1. Introduction

The use of enzymes in the textile value chain (Figure 1) is gaining global recognition because of their eco-friendly characteristics. Therefore, enzyme usage in (chemical) processing is considered under the 12 principles of green chemistry (1).

The enzyme technology is attractive because enzymes are highly specific and efficient, and work under mild conditions. This means that the use of enzymes can result in reduced process times and chemical use, energy and water savings and improved product quality. More specifically, enzyme applications have the ability to avoid rinsing steps and/or processes can be carried out at lower temperatures. For some applications the use of conventional oxidizing and reducing agents can be avoided. For example, sulphur containing reducing agents can be substituted by peroxidases to remove residual hydrogen peroxide after bleaching.

While enzymes have many sustainability benefits, they may induce respiratory allergy if appropriate risk management practices are not in place. Therefore, a two-part guidance document series was developed on safe handling of enzymes in the textile value chain, *i.e.* how to avoid the formation of airborne dust and aerosols, which if inhaled in sufficiently high amounts can lead to respiratory allergy. This issue of the guidance document series focuses on the garment and textile finishing industry (Figure 1).

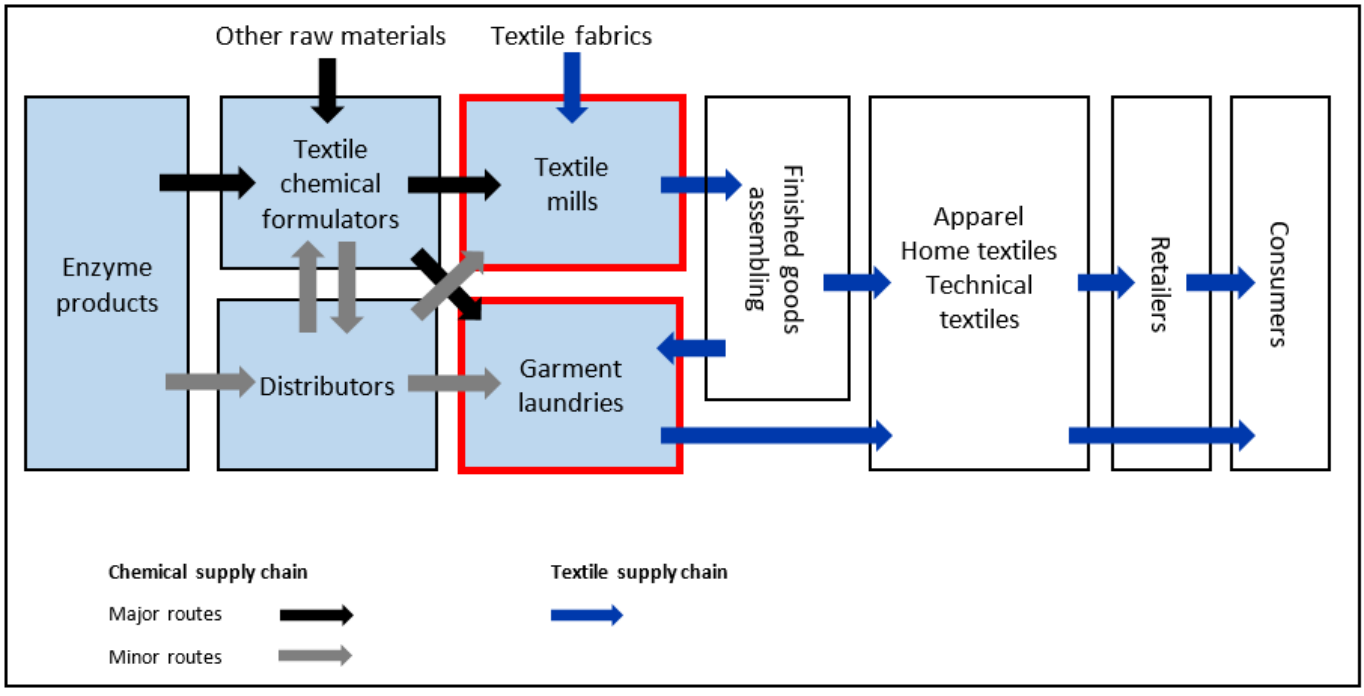


*Figure 1: General enzyme value chain in the textile market. The framed red boxes mark the sectors addressed in this guidance. Boxes coloured in blue represent sectors where enzymes are physically present.*

In general, liquid enzyme products or encapsulated low dust granulated enzyme products[5] are used in the textile and garment finishing industry. The use of solid enzyme products which are not encapsulated are not considered best practice and are thus not covered in this guidance document. Such products, *e.g.* powdered enzyme products, will even in low quantities generate high levels of dust, and during handling of such powdered products it will be extremely difficult to keep compliance to the occupational exposure limits (OELs) and/or the derived minimal effect level (DMEL).

The consequences of uncontrolled exposure to enzyme airborne dust or aerosols are well known, and the paragraphs below introduce enzymes and their benefits in the textile industry supply chain as well as the potential hazards associated with the handling of enzyme products. However, it is important to emphasize that when handled according to instructions and in well controlled industrial settings, enzyme products can be used safely.

Enzymes are used in the textile industry due to their valuable and very specific properties; but what are they?

Enzymes form a special class of proteins being composed of the amino acid building blocks that are found in all types of proteins. Proteins are naturally produced by all living cells, and all living organisms – whether human, animal, plant or microorganisms – need enzymes to conduct virtually all the physiological processes which are essential for growth and life.

Enzymes act as catalysts: substances which, in very small amounts, are able to significantly speed up the rate of specific chemical reactions by significantly reducing the activation energy of the reaction; for example, the building up or breaking down of organic matter such as carbohydrates, fats and other proteins. Enzymes are highly specialized in their functionality; with each enzyme acting only on a restricted number of substances, and only catalysing one specific reaction. For example, the starch degrading enzymes (amylases), present in human saliva break down starch into smaller molecules, which can then be degraded and absorbed when entering the gastrointestinal tract.

This specificity of enzymes makes them very useful in catalysing desired reactions in industrial processes. Consequently, enzymes are extensively used in several industries including in technical (*e.g.* detergent, starch, textile, pulp & paper and fuel alcohol), food (*e.g.* dairy, baking, brewing, wine and juice) and in animal feed arenas. Commercial enzyme preparations are produced by the carefully controlled fermentation (closed systems) of pure cultures of selected strains of non-pathogenic bacteria, yeasts or fungi.

Enzymes are grouped into several classes according to their activity: some of the most important classes to the textile supply chain and their contribution to manufacturing and finished product quality are mentioned in Table 1 (2)(3)(4).

[5] Exposure is controlled by encapsulation of active enzyme into granules. Granules used in technical application shall fulfil certain quality specifications so that during typically tasks, such as transfers, the encapsulation layer does not damage.

*Table 1: Examples of Enzyme classes and corresponding functionalities in the textile industry supply chain.*

| Application | Process | Enzyme Benefit | Enzyme classes |
|---|---|---|---|
| Pectin and protein removal (bio-scouring) | Textile pre-treatment / washing units | Saving energy, chemical use (*e.g.* caustic soda (NaOH) in cotton processes or chlorine in wool processes) water and time; less wastewater; gentle treatment of the woven fabrics and knit goods. | Pectinases & Lipases in some cases (vegetable fibres)<br>Proteases (wool, silk)<br>Xylanase (linen, jute, hemp) |
| Degradation of excess hydrogen peroxide | Textile pre-treatment and dyeing | Avoidance of hazardous chemicals like sulfur based reducing agents, saving of 1 or 2 wash cycles, saving of energy, water and time, reducing wastewater or loading. | Catalases |
| Starch removal | De-sizing | Avoidance of hazardous chemicals; gentle treatment of the woven fabrics. | Amylases |
| Carboxy methyl cellulose (CMC) size removal | De-sizing | Avoidance of hazardous chemicals like acids or persulfates; gentle treatment of the woven fabrics. | Amylases<br>Cellulases |
| Denim finishing | Garment finishing | Increasing reliability of the process, improving product quality, reducing the handling of stones and sludge generation, decreasing machine wear, sandblasting. | Cellulases |
| Bleaching of indigo dyed garment articles | Garment finishing | Avoidance of hazardous chemicals like various chlorinated compounds, gentle treatment of the woven fabrics, less polluting garment wash. | Laccases |
| Pilling reduction, surface cleaning and antifelting finishing | Textile & garment finishing | Avoidance of hazardous chemicals; additional quality treatment and softer handle effect. | Cellulases; Proteases |
| Post-textile treatment process: Decolorization of textile effluents and textile bleaching | Wastewater treatment plants | Avoidance of hazardous chemicals. | Laccases |

For all enzyme classes the same principles apply regarding the safe handling of enzyme-containing materials used in the textile and garment finishing industry.

### Hazards associated with enzymes

Industrial enzymes have a low toxicity to humans, *i.e.* enzymes present no concern for endpoints like acute toxicity, genotoxicity, sub-acute and repeated dose toxicity, reproductive toxicity and carcinogenicity (5)(6)(7). However, like many other proteins, enzymes may act as allergens via inhalation. A two-step process must take place for the development of an inhalation allergy: initial sensitisation followed by elicitation (7).

**Sensitisation:** When allergens are inhaled in the form of dust or aerosols, they may give rise to the formation of antibodies that are specific only to them. At this stage, the sensitised individuals do not suffer from any allergic symptoms.

**Elicitation:** Sensitised individuals may then develop an allergy, if they are repeatedly exposed to sufficiently high airborne concentrations of the allergen concerned (8). At this stage, the individual will develop the symptoms typical for respiratory allergy such as hay fever. Some individuals may develop asthma upon continued exposure. When this condition is due to exposure in the working environment, it is called occupational allergy which may advance to occupational asthma.

The respiratory symptoms from allergen exposure may include itching of the nose and eyes, nasal and sinus congestion and sneezing. Coughing, hoarseness, tightness of the chest and shortness of breath are all indicators of asthma. These symptoms may occur during or after working hours and they disappear within hours or a few days after the exposure has ceased. Allergy symptoms may be similar to those of the common cold or seasonal allergies, and if such symptoms occur frequently at the workplace and only rarely at weekends or during holidays, they may be the result of occupational enzyme exposure.

Allergy by inhalation caused by enzymes is similar to the respiratory allergies that are caused by well-known allergens like grass-pollen, house dust mites or cat dander; and the symptoms are similar. Some individuals are more prone to sensitisation than others are. Atopic individuals, *i.e.* persons already allergic to one or more of the common allergens, may develop an enzyme allergy more easily than others may. Not all atopic individuals will become allergic to enzymes and non-atopic individuals may develop an enzyme allergy if exposed to sufficiently high airborne concentrations on a regular basis.

Smokers have a markedly increased risk of becoming sensitised and developing allergy symptoms (9). There is no scientific evidence that enzymes are associated with allergy caused by skin contact or ingestion (10)(11)(12). Some enzymes, specifically proteases, are classified skin irritants. At high concentrations, these may lead to localised irritation of the skin at point of contact to the enzymes. However, the condition is local, temporary and does not lead to the development of and allergy. Consequently, a contact irritant dermatitis should not be confused with skin sensitisation.

In general, controlling enzyme exposure in the textile and garment finishing industry will reduce the likelihood of work-related respiratory symptoms. Enzyme handling activities that may generate airborne dust or aerosols should be prevented to minimize the risk of exposures. This subject will be addressed in the following chapters of this document.

Experience from over 50 years of handling enzyme products in the enzymes manufacturing

industry as well as in the detergent industry has proven that enzymes can be safely used in the workplace (13)(14). This valuable experience and knowledge are now being applied to the textile and garment finishing industry to make it an even safer place in which to work.

## 2. Regulatory Requirements for Enzymes used by the Textile and Garment Finishing Industry in the EU

Ensuring workers' safety is a regulatory obligation for both enzyme suppliers and enzyme users in the textile and garment finishing industry. Safety information on the use of enzymes must be communicated by the enzyme suppliers and/or the textile chemical formulators (TCFs) and the appropriate risk management measures (RMMs) and operational conditions (OCs) must be implemented by the textile and garment finishing industry.

### Exposure limits

Due to the risk of respiratory allergy, exposure to airborne enzyme dust or aerosols needs to be in control in the working environment. Two types of exposure limits are applied for enzymes used by textile and garment finishers:

- Occupational exposure limits (OEL)

An occupational exposure limit of 60 ng active enzyme protein/$m^3$ has been established for those enzyme products which belong to the protease class of Subtilisin. This OEL has been adopted as a regulatory exposure limit in many countries.

For details, please see Appendix 2, D of this Chapter.

- Derived Minimal Effect Level (DMEL)

For all enzyme products a DMEL of 60 ng/$m^3$ is now being used within EU in REACH registration dossiers. This means that airborne exposure to all enzyme products should be kept below this limit in occupational settings of the textile and garment finishing industry.

For details, please see Appendix 1, A and C of this Chapter.

### Safety communication from enzyme suppliers and/or textile chemical formulators (TCFs) to the textile and garment finishing industry

- Safety Data Sheet (SDS) and Exposure Scenarios (ES)

Enzyme suppliers and/or TCFs must communicate safe use information via the SDS under REACH. All applicable exposure limits should be stated in the SDS (OELs and DMELs). Most enzymes used by the textile and garment finishers are to date registered under REACH. Thus, for substances that are marketed above 10 tons per year in the EU, the producer must make an extended SDS (eSDS) with ESs available.

ESs provide essential information on RMMs and OCs required to control enzyme exposure to humans and releases to the environment. For mixture SDS, ES information can be appended, integrated or attached on the SDS (check for an indication in the SDS Chapter 1.2, 8, 11 & 12 or for any attachments after Chapter 16). If the (complete) ESs are not appended or attached to the mixture SDS but integrated into the main body of the SDS, then the downstream user is

advised to request the missing ESs from the upstream supplier. According to the REACH Regulation the upstream supplier has to legal obligation to fulfil such a request.

For details, please see Appendix 1, A of this Chapter.

- Labels

Enzymes may possess respiratory sensitisation potential regardless of the type of catalytic activity. Therefore, in accordance with the CLP Regulation it is recommended classifying all enzymes as Respiratory Sensitiser Category 1 (H334): *May cause allergy or asthma symptoms or breathing difficulties if inhaled.* Enzyme containing mixtures must bear labels with hazard classification so that workers are aware of the warnings. If an enzyme protein is above a certain level (≥ 0,1%), a label should clearly indicate that the mixture contains enzymes as respiratory sensitiser(s). Additional pictogram and hazard/ precautionary statement is needed at higher concentration (≥ 1%).

For details, please see Appendix 1, B of this Chapter.

### Implementation of safety measures by the textile and garment finishing industry

- Basic requirements for employers

Textile and garment finishers have the obligation to implement RMMs and OCs aiming to protect the health of the workers. They must collect information, not only from SDS or labels discussed in the above paragraphs, but also from other resources, such as from this guidance document, and ensure that RMMs and OCs are in place for the safe use of enzymes. This requirement is set under the Council Directive 98/24/EC, commonly known as the Chemical Agent Directive (CAD).

For more details, please see Appendix 1, C of this Chapter.

- Exposure Scenarios (ES)

Once an ES in the eSDS is supplied to the textile and garment finishers by their enzyme suppliers and/or the TCFs, they have 12 months to implement necessary measures per downstream users' obligation under REACH. If it is not possible to do so, they have several options for compliance, such as carrying out a downstream user assessment. However, it is recommended as a first step to contact the upstream supplier to discuss possible solutions. The enzyme manufactures have a long history of working together with their customers to improve the safe use of their products along the complete supply chain and welcome any initiative that improves the safety of workers handling enzyme products.

The following appendices provide detailed information on the topics addressed earlier in this Chapter.

## Appendix 1: Main regulatory requirements in the EU

### A EU REACH

#### *Obligations of Registrants under REACH*

Enzyme substances included in products destined for technical applications such as detergents, textile processing, biofuels, pulp & paper processing *etc.*, need to be registered under the EU REACH Regulation[6] before they can be manufactured and/or imported into the EU in a volume above 1 ton per year. It lies with the manufacturers/importers to register the substance under REACH and provide evidence that the substance can be used safely in all registered uses and along the complete supply chain. The European Chemicals Agency (ECHA) is the implementing authority on an EU level and supervises the registration process.

Activities regarding REACH implementation for enzymes are discussed and facilitated within the Enzymes REACH Consortium (ERC) created by AMFEP. Since the third and final registration deadline of May 2018, most enzymes have been registered following the guidance documents developed by the ERC.[7]

As enzymes are in the scope of REACH registration and have been registered in tonnages > 10 tons per year, then their registration dossiers include a Chemical Safety Assessment (CSA). The CSA consists of:

- Generic Exposure Scenarios (GES)
- Exposure estimation for the different routes of exposure under the conditions of use described in the GESs
- Risk characterisation; comparison of exposure levels to no or minimum effect levels

GESs have been developed based on the knowledge available to the enzyme manufacturers/importers about the different market sectors in which their products are used. Each GES defines the RMMs and OCs required to control enzyme exposure to humans and releases to the environment for one market sector. As the available computational tools for occupational exposure are not functional for respiratory sensitisers with very low limit values, measurements of airborne enzyme (active enzyme protein) at the respective workplaces are required for the exposure assessment.

In the case of enzymes, a DMEL of 60 ng active enzyme protein/$m^3$ for occupational exposure has been proposed and is now being used in EU REACH dossiers for all enzymes. This DMEL has been established following a thorough retrospective review of occupational experience,

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[7] Enzymes REACH Consortium, http://www.enzymes-reach.org/content/welcome-enzymes-reach-consortium

correlating validated employee medical surveillance data against exposure records generated over an extended period (7). In case that several enzyme types are present at the workplace, it is typically not required to consider cumulative exposure. This means that for each enzyme type the DMEL of 60 ng/m$^3$ applies independently. Solely, for enzymes with the same immunochemically identity a cumulative assessment may be required, but the combined usage of such enzymes in the textile industry is unlikely.

### *Obligations of Downstream Users under REACH*[8]

The main obligation of downstream users under REACH is to comply with the information provided in the (e)SDS of the enzyme manufacturers and/or the textile chemical formulators (TCFs). This includes information provided in the main body of the SDS, and OCs and RMMs defined in the ES, which are typically listed in the SDS Annex. ES may be missing if 1) the single substance or all substances in a mixture are produced/ imported below 10 tons per year or 2) the formulator of a mixture decided to consolidate the safe use information of the different ingredients in the main body of the safety data sheet. If a downstream user does receive a consolidated SDS for mixtures, it is legally possible to request the specific ES of each ingredient from the formulator.

It shall be noted that the main body of the SDS is considered a guidance document. Downstream users of enzymes, such as the textile and garment finishing industry, are, however, legally required to comply with the OCs and RMMs listed in the respective ES. The OCs and RMMs have been defined by the enzyme manufacturer in their ES to ensure safe use of enzymes (*i.e.* to use adequate controls to keep exposure below the DMEL of 60 ng/m$^3$). If downstream users cannot comply or are unsure if they can comply with the OCs and RMMs laid out in the eSDS, then they are required to reach out to the enzyme manufacturers and/or the TCFs and jointly work on assessing the workplace in question and – if necessary – refine the respective ES. The enzyme manufacturers have a long history of working together with their customers to improve the safe use of their products along the complete supply chain and welcome any initiative that improves the safety of workers handling enzyme products.

Alternatively, downstream users can also carry out a “downstream user chemical safety assessment” and notify ECHA about this assessment.

Downstream users may be audited by National Inspectorates that have been identified by the national Member States (MS)[9]. These authorities have the authority to check if users of enzyme containing products comply with their obligations under REACH.

It is important to note that downstream users are not directly required to assess compliance with the DMEL under REACH. They are solely required to comply with the OCs and RMMs that have been defined in the eSDS and to support manufacturers to define functional exposure scenarios that allow the safe use of the enzyme products. Legally binding exposure limits are solely national OELs, which are discussed further down below.

[8] European Chemicals Agency (ECHA), “Downstream users”, https://echa.europa.eu/regulations/reach/downstream-users

[9] European Chemicals Agency (ECHA), “National Inspectorates”, https://echa.europa.eu/regulations/enforcement/national-inspectorates

## B CLP classification of enzymes and enzyme mixtures

The EU Regulation for "Classification, Labelling and Packaging" (commonly known as CLP Regulation)[10] adopts the United Nations' Globally Harmonised System on the classification and labelling of chemicals (GHS) across all European Union countries. The regulation requires companies to appropriately classify, label and package their substances and mixtures before placing them on the market. Since 1 June 2015, it is the only legislation in force in the EU for classification and labelling of substances and mixtures.

Enzymes may possess respiratory sensitisation potential regardless of the type of catalytic activity. Therefore, it is recommended to classify all enzymes as Respiratory Sensitiser Category 1 (H334) in accordance with the CLP Regulation, unless there is scientific evidence from *e.g.* immunochemical/ immunological testing that they do not induce a specific response. CLP Annex VI currently includes harmonised classifications for 17 enzymes.

All these 17 enzymes are classified and labelled as Respiratory Sensitiser Category 1 (H334): *May cause allergy or asthma symptoms or breathing difficulties if inhaled*. In addition to the Respiratory Sensitiser Category 1 classification, proteases in Annex VI have additional harmonised classifications, namely STOT Single Exposure Category 3 (H335), Skin Irritation Category 2 (H315) and Eye Irritation Category 2 (H319) (except subtilisin, which is classified as Eye Damaging Category 1 (H318)). The REACH registration dossier for subtilisin includes additional self-classification as Acute Toxicity Category 4 (H302), Aquatic Acute 1 (H400) and Aquatic Chronic 2 (H411). These additional classifications are due to the proteolytic activity of proteases.

A mixture containing several enzymes must be classified as a respiratory sensitiser when at least one ingredient has been classified as such and is present at or above the appropriate generic concentration limits, unless enough data on the mixture itself indicating otherwise is available and bridging is not possible. Substances that are classified as sensitisers may elicit a response, when present in a mixture in quantities below the generic concentrations or specific concentration limits for classification and must thus be indicated on the label at the lower concentrations established in Table 3.4.6 of Annex I to CLP.

Thus, for an enzyme (solid or liquid) that is a Respiratory Sensitiser Category 1 in a mixture, the general threshold concentration is 1% for the classification of the mixture (Table 3.4.5 of Annex I to CLP), and 0.1% for the inclusion on the label of the supplementary statement EUH208 — *'Contains (name of sensitising substance). May produce an allergic reaction'* (Table 3.4.6 of Annex I to CLP). The threshold is considered based on active enzyme protein (aep).[11]

[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[11] European Chemicals Agency (ECHA), Hazard classification of industrial enzymes, June 2016 https://amfep.org/_library/_files/hazard-classification-of-industrial-enzymes.pdf

C Worker's safety and obligations along the supply chain

The Chemical Agents Directive (CAD)[12] lays out provisions aimed at the protection of workers whose work brings them into contact with hazardous chemical agents. Under CAD, a substance is regarded as hazardous if it meets the criteria for classification as hazardous within any physical and/ or health hazard classes laid down in CLP Regulation. Since enzymes are classified as Respiratory Sensitiser Category 1, they are in the scope of CAD. There are no specific provisions for enzymes as a generic class of substances in CAD therefore enzymes are subject to the general provisions of this directive.

Where hazardous chemical agents are present in the workplace, employers must determine whether any risks to safety and health arise from their presence. The employer must be in possession of an assessment of the risk and this risk assessment must be kept up-to-date. The employer must take the necessary preventive measures to eliminate or reduce to a minimum the risks identified in the risk assessment following a hierarchy of prevention measures (described in Article 6 of CAD). Where this is not possible, the following shall be considered in order of priority:

I. design of appropriate work processes and engineering controls and use of adequate equipment and materials;

II. application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures;

III. where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Directives are not implemented directly into national Member States (MS) legislation but set minimum standards which MS are required to reflect in corresponding national provisions. On this basis, employers operating within the EU that are fully complying with national workplace legislation should be managing the risks from enzyme and enzymes containing products according to these principles.

In addition, REACH Regulation[13] requires demonstration of adequate control of risks for identified uses and exposure scenarios. This should be communicated to ensure implementation of risk managements throughout the supply chain. Enzyme manufacturers have developed GESs, containing information on the safe handling of enzyme products, which are communicated downstream via the eSDS. In addition, TCFs may consolidate this information in the main body of their mixture SDSs or create consolidated ESs for textile chemicals containing enzymes which are also communicated downstream via their respective SDSs. When downstream users such as textile and garment finishers receive an eSDS from their enzyme supplier and/or their TCF

[12] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
[13] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

they must check that the ESs annexed to them cover their own use of the substance and their conditions of use or take alternative actions. If the ESs have been consolidated in the main body of the mixture SDS, then this information must be considered in the local health risk assessments as defined in CAD.

### D Occupational Exposure Limits

Several exposure limit values for enzymes have been derived by various groups and institutions. To understand their area of application, it is necessary to briefly explain two basic principles around exposure limit values:

First, the legal obligation: Generally, two types of exposure limit values exist. On the one hand, governmental (*e.g.* NIOSH, ECHA) and non-governmental (*e.g.* ACGIH) institutes and groups may derive exposure limit values for chemicals that aim to protect workers, but which are not legally binding and predominantly act as guidance for risk assessors[14]. On the other hand, regulatory agencies (*e.g.* MAK Commission, HSE) may set exposure limit values that are legally binding and must not be exceeded. This type of exposure limit values is typically referred to as OELs, although no proper definition does exist. The European Standard EN689:2018 may be used as a basis to determine compliance with OELs.

Second, the exposure duration: Limit values are typically defined for an exposure duration of 15-minutes (often referred to as short-term exposure limit (STEL)) and/or 8-hour, but occasionally also other durations are used as benchmark (*e.g.* for enzymes sometimes 60-minute limit values exist). This means that the time-weighted average (TWA) exposure over the defined period may not exceed the limit value. Additionally, for some few chemicals, including enzymes, a so-called ceiling limit value has been determined by some countries. Such ceiling limit values are set where it is necessary to avoid transient excursions above the identified limit. If a ceiling limit value has been defined, then the exposure duration is irrelevant, and the exposure may not exceed the ceiling limit value at any time.

Currently, OELs have been derived for the protease subtilisin and for fungal alpha-amylase (only in the Netherlands). In the early 1970's, the American Conference of Governmental Industrial Hygienists (ACGIH) established a ceiling threshold limit value (TLV) of 60 ng/m$^3$ for the protease subtilisin. The ACGIH recommended limit has been adopted into national workplace legislation in several countries, in many cases as a ceiling limit (see Appendix 2). Some countries have also derived full shift exposure and/or short-term exposure limits, which are partly lower than 60 ng/m$^3$.

Although limits for other enzymes have not been established in national or EU-wide workplace legislation, the 60 ng/m$^3$ level is used by companies manufacturing enzymes and formulating enzyme-containing products as a benchmark applicable to all enzymes for their health risk assessments and to identify tasks where workers may need to wear respiratory protective equipment (RPE) to supplement the engineering controls that are in place.

[14] It shall be noted that several countries frequently use the recommended ACGIH values as basis to set their legally binding national OELs, such as Spain and Belgium. Additionally, the OELs recommended by ECHA (previously SCOEL) have often been included in the Annex of the Chemical Agents Directive or Carcinogens at Work Directive.

## Appendix 2: Examples of Subtilisin (Protease) regulatory exposure limits.[15]

| Country | 8-hr TWA limit (ng/m3) | Short-term limit (ng/m3) | Ceiling limit value (ng/m3) |
|---|---|---|---|
| Australia | | | 60 |
| Belgium | 60 | | |
| Canada (Alberta, British Columbia, Manitoba, Ontario, Quebec) | | | 60 |
| China | 15 | 30 | |
| Colombia | | | 60 |
| Croatia | 40 | | |
| Denmark | 60 | | 60 |
| Finland[16] | 15 | | 60 |
| Iceland | | 60 | |
| Indonesia | | | 60 |
| Ireland | 60 | 60 | |
| Israel | | | 60 |
| Italy | | | 60 |
| Malaysia | | | 60 |
| Mexico | | | 60 |
| New Zealand | | | 60 |
| Nicaragua | | | 60 |
| Norway | | | 60 |
| Peru | | | 60 |
| Portugal | | | 60 |
| Singapore | | 60 | |
| South Africa | | | 60 |
| Spain | | 60 | |
| Sweden | 1 glycine unit/$m^3$ | | 3 glycine unit/$m^3$ |
| Switzerland | | 60 | |
| USA-OSHA | | 60 | |
| U.S. States (California, Tennessee) | | 60 | |
| Uruguay | | | 60 |
| United Kingdom | 40 | | |
| Venezuela | 60 | | |

[15] Information obtained from the GESTIS International Limits Values database (accessed on 11 December 2020) https://limitvalue.ifa.dguv.de/ . Some of the limits may be sector specific.
[16] In Finland the limit values apply to all proteases.

## Appendix 3: Definitions and explanations

**aep (active enzyme protein):** enzyme protein which has a catalytic activity.

**Annex VI of the CLP Regulation[17]:** A list of substances with mandatory classifications – all other end points than those listed in the Annex are liable to self-classification.

**Classification:** The process of evaluating available test or other data on a substance or mixture to determine if the substance or mixture meets any of the criteria for assigning a class (type) and category (severity) of hazard to the substance or mixture. Description of relevant classifications:

Applicable to all enzyme classes:

- Resp. Sens. Cat 1: Respiratory sensitiser in category 1. CLP also includes additionally the possibility to subcategorise into 1A and 1B, however this is not possible for enzymes.

Applicable only to proteases due to their proteolytic activity:

- Acute Tox. Cat 4: Acute toxicity in category 4 (harmful). For Subtilisin the route of exposure is oral intake. The oral toxicity data behind subtilisin (1800 mg/kg) is used for classification of mixtures.
- Skin Irrit Cat 2: Skin irritation in category 2 (moderate skin irritation)
- Eye Dam. Cat 1: Eye damage in category 1 (severe and irreversible eye damage, Subtilisin only)
- Eye irrit Cat 2: Eye irritation in category 2 (serious, but reversible eye irritation)
- STOT SE 3: Specific target organ toxicity – single exposure in category 3. For proteases the relevant effect in this category is respiratory irritation.
- Aquatic Acute 1: Acute toxicity towards aquatic organisms in category 1 (short term environmental hazard). For classification of mixture it is also important to know that the "M-factor" is 1.
- Aquatic Chronic 2: Chronic toxicity towards aquatic organisms in category 2 (long term environmental hazard).

**Enzyme:** Enzyme concentrate as defined as "substance" by REACH including constituents from manufacturing processes but excluding solvent *e.g.* water. In this guidance, "enzyme" refers to this definition. enzyme mixture: A formulated product with an enzyme and other formulation ingredients.

**Index No.:** Number assigned to substances in CLP Regulation Annex VI.

**Immunochemically identity:** If two enzyme proteins cross-react with the same antibody, they are immunochemically identical.

**IUBMB name and number:** Enzyme nomenclature defined by Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (NC-IUBMB) http://www.chem.qmul.ac.uk/iubmb/enzyme/

[17] REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
EUR-Lex - 32008R1272 - EN - EUR-Lex (europa.eu)

# 3. Management and Training

## 3.1. Management

In general, employers are always responsible for health and safety in workplaces. The health and safety laws apply to all businesses and those determine the basic precautions and responsibilities that apply to everyone. A significant part of this responsibility is **risk management** beginning with **hazard identification**. Every type of hazard which may be potentially harmful to employees must be identified, and suitable controls must be in place to mitigate those risks. The responsibility for providing a safe place to work is not only limited to employees but also includes other stakeholders such as contractors, cleaners, visitors and others who may be affected by their activities.
Even though management faces most of the responsibility for safe workplace provision, the participation of others should not be ignored. Full participation of all employees is the most effective way to create a safe working environment – whether with enzymes or any other potentially hazardous substances. Employees should be consulted in any decision-making process regarding risk management practices and solutions. In many countries it is even a legal requirement for employees to participate in such processes, report unsafe situations, and follow the implemented risk management practices and solutions.
Risk management measures (RMMs) should always be based on a **hierarchy of controls** (Figure 2), also known as STOP principle: Substitution, Technical, Organizational solution, use of Personal protective equipment (PPE). According to this STOP principle, the first choice to manage the risk to a specific hazard should be to eliminate or substitute the hazard. Substitution can also be the choice of the right product form, *e.g.* replacing powdered enzymes by encapsulated low dust granules or liquid formulations. If further risk management measures are necessary, then the next risk management level shall focus on controlling the risk by isolating the hazard or reducing it by means of engineering controls and/or design. In addition, administrative controls may be used such as the imposition of safe working practices & procedures. The final measure for reducing the exposure is the use of appropriate PPE.

Risk management processes should include the management of chemicals in the workplace. In Europe, the OSH Directives (89/391/EEC and individual directives, such as CAD) and the REACH Regulation (EC No 1907/2006) require that adequate control of risks be demonstrated for identified uses of substances and gives a clear framework of precautions that must be in place before any kind of hazardous substances are used.

**Safety management** in the workplace should cover near miss and accident investigations, and reporting procedures for these events. Learning from such incidents is a key element for the development of a safer workplace for everyone and this can be achieved by reviewing every significant near miss or accident. The outcomes of investigations inform future risk assessments and corrective actions to prevent similar incidents happening again.

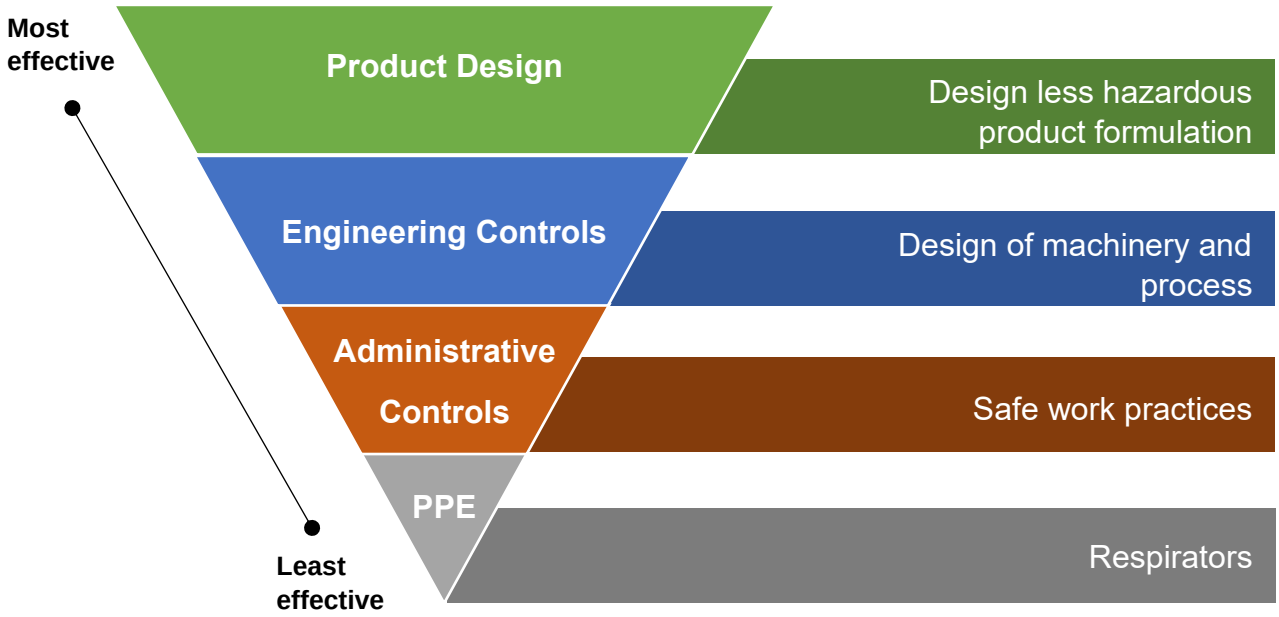


*Figure 2: Controlling exposure to hazards through the hierarchy of controls (© IFF)*

### 3.2. Continuous training

**Training is a key element for raising the awareness, competence and knowledge about safety matters.** All employees must have basic training in general health and safety in addition to their task specific training to gain knowledge on the risk control measures that may be needed for the specific tasks. All workers handling chemicals and especially enzymes should also have training in the potential hazards and risks arising from different chemicals used (such as products containing enzymes) and the appropriate precautions to take when working with these substances. Chemical safety related training should include information about the right working methods with chemicals, specific hazards and how to protect against those, for example with personal protective equipment (PPE) or the use of technical protection solutions. Also, training should include chemical product label warnings and potential cross reactions of chemicals present in workplace. Emergency response instructions should be trained in case of an accident such as a spill. All necessary information for workplace specific chemical safety training can be found from the safety data sheet (SDS) of each product used.

Training must also be organized for others who may be exposed on site (such as maintenance personnel, external contractors etc.), and should include background information on hazards, RMMs in place, standard instructions and emergency instructions. Everyone attending the site for the first time should be informed and/or trained about the basics of chemical safety during their induction. Training should then be continued over time on a regular basis, and always when significant changes to processes or chemicals used are made.

From the health perspective, it is important to inform everyone who might be exposed about hazards, such as respiratory sensitisers. For example, standard operational procedures (SOPs) should be communicated to all staff so that they understand how, as well as why, they should avoid any unnecessary exposure. Even small tasks such as the correct way to handle empty chemical containers can make a big difference. Other important training subjects include possible symptoms of respiratory allergy, correct handling of spillages and cleaning situations as well as emergency situation procedures.
After basic training has been covered, more task specific training should be given. This should also cover the usage and maintenance of PPE: for example, donning and doffing procedures, cleaning and storing PPE's properly, and the key elements of maintaining PPE's, including cleaning and checking their condition for wear and tear. Following the basic training for PPE, fit testing is required to make sure the equipment has an appropriate seal for adequate protection.

The company's training program should be reviewed regularly and always when significant changes are made to its processes. Risk assessments should also provide new training material when something has changed in the process. Investigations of accidents and near miss situations should contribute to the content of training to ensure that lessons are learned.
The company's safety committee is a useful group to coordinate the results of both risk assessments and near miss reports to ensure that they are taken into account in the planning of the training program.
Documenting training and monitoring for comprehension is very important. Verifying the effectiveness of every step of risk management controls is always important, but it is vital for discerning the best ways to develop them further. For example, it is good practice to collect feedback on training immediately after the event in addition to collecting it at a later date, once the new knowledge has been in use.

Documentation shall be extended to SOPs, which are clear and easy to be understood. SOPs are meant to describe the right way of working in each task to ensure safety and effectiveness. The risk assessments in workplace shall also develop these SOPs to cover the risks present. As systems and methods of working continually evolve, it is vital that SOPs are periodically reviewed to ensure that they are still relevant and fit for purpose. It is also important to ensure and monitor that workforce continually adhere to those.

AMFEP and EURATEX strongly encourage every vocational **school and university** providing training in textile industry practices to include training about chemical safety, including enzyme related hazards in the curriculum. Knowledge about the hazards present in the industry and the control measures used to manage risks should be introduced as early as possible for every person starting in the textile industry supply chain.

In Table 2, the key learning objectives of an enzyme safety training programme are briefly summarised.

*Table 2: Summary of "Enzyme Safety Training" Programme Elements*

| | Learning Objective | Knowledge Gained |
|---|---|---|
| **Chapter 1** | Understand the **health effects of enzymes** and how they are classified | ✓ Enzymes are classified as respiratory sensitisers<br>✓ Enzymes can elicit an immune response in susceptible individuals that can cause respiratory allergy and may result in occupational asthma from repeat exposures over time |
| **Chapter 2** | Understand the **regulatory requirements** for the safe handling of enzymes | ✓ The safe use information for enzymes must be communicated in the SDS, either via ES or in the main body of the SDS.<br>✓ A local health risk assessment must be carried out for each hazardous chemical and the conclusions must be made available to every employee, e.g. via SOPs.<br>✓ Employees shall support such health risk assessments and report unsafe situations |
| **Chapter 3** | Understand the **management responsibility** and the importance of **continuous training** | ✓ Employers are responsible for health and safety in workplaces<br>✓ Participation of all employees is the most effective way of creating a safe working environment<br>✓ Regular and targeted training is a key element for raising the awareness, competence and knowledge about safety matters |
| **Chapter 4** | Understand the **hierarchy of controls** for risk management strategies to minimize enzyme exposures | ✓ The hierarchy of controls from most effective to least effective are: product design, engineering and process design, administrative controls and finally PPE. |
| | Learn about the **various product forms** of enzymes and their risk profiles | ✓ The enzyme product forms from highest enzyme to lowest enzyme exposure potential are powders, liquids and low dust granulated enzyme products.<br>✓ The risk profile is based on the product form most likely to become aerosolized and leading to the highest enzyme exposure potential |
| | Identify the specific types of **engineering controls** that are used to minimize enzyme exposures | ✓ The engineering controls from most effective to least effective are e.g.: containment, ventilation enclosures, and local exhaust ventilation. |
| | Understand the **administrative controls** that are used to work safely with enzymes | ✓ Administrative controls include: work practice controls, training and awareness, housekeeping, and regular maintenance |
| | Identify **the types of PPE** to consider for appropriate selection | ✓ PPE selection is based on work activities and exposure potential. Respirators with a P3 air filter shall be used to prevent inhalation of enzyme aerosols. Protective clothing shall also be considered based on the work performed. |
| **Chapter 5** | Understand the purpose of **enzyme monitoring** | ✓ Quantify airborne enzyme exposures against established limits during worker operations<br>✓ Understand areas of high exposure potential and consequently to reduce the risk of sensitisation that can lead to adverse health effects.<br>✓ Verify that control measures are adequately protecting against exposures |
| | To understand the purpose and main objectives of a **medical surveillance program,** including the **importance of early reporting** and intervention | ✓ To Identify as early as possible, any adverse health effects which may be caused by the exposure to enzymes and provide more specific guidance on safe enzyme work practices and controls based on the results of the medical assessment<br>✓ Early reporting to the respective occupational health professional of enzyme related symptoms is important to prevent the progression of adverse health effects. |

# 4. Control of Exposure during the Handling of Enzymes in the Textile and Garment Finishing Industry

## 4.1. Introduction

The intent of this chapter is to prevent operator exposure to enzymes, via inhalation, during the manufacturing process of textiles and garments. Ensuring workers' safety is a **regulatory obligation** for all actors along the supply chain, including enzyme suppliers, formulators and enzyme end-users.

In Europe, the OSH Directives (such as Chemical Agents Directive (CAD)[18]) and the REACH Regulation[19] lay out provisions aimed at the protection of workers whose work brings them into contact with hazardous chemical agents. In short, for all work activities carried out at a site, the employer is responsible to evaluate all risks to the safety and health of their workers. These assessments need to determine if any chemical agent that is present at the workplace constitute a health risk for the workforce, including chemical agents released by any work activity, whether or not produced intentionally. The employer must implement risk management measures (RMMs) that are necessary to eliminate or reduce the health risk to a minimum following the hierarchy of controls (see Figure 2 in Chapter 3). These implemented RMMs may be the result of a local risk assessment and/or may be communicated in the SDS Annex by enzyme manufacturer or by textile chemical formulators (TCFs).

Since most enzymes are classified as Respiratory Sensitisers Category 1, they in principle need to be included in any chemical risk assessment. Due to their low exposure limit value, enzymes may under some circumstances constitute a health risk below the classification cut-off defined in the CLP Regulation[20]. This should be kept in mind in any risk assessment involving enzymes.

To prevent exposure of employees to enzymes during the manufacture of textiles and garments, there is a series of well-established engineering controls and operational procedures that have been developed and successfully applied over many years by different industry sectors and which are now considered best practice when handling enzymes. They are complementary elements, and each element should be in place if proper control is to be achieved.

[18] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). Directive is not implemented directly into national legislation but set minimum standards which member states are required to reflect in corresponding national provisions. National OSH laws can, thus, vary.
[19] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[20] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

**The key strategies are**:

- Selection of a safe enzyme product form (liquids, encapsulated low dust granules, or enzymes encapsulated in (soluble) polymer bags). Powdered forms shall not be used in the textile supply chain.
- Prevention or minimisation of any relevant aerosol formation from liquids containing enzyme by proper plant design (closed systems, engineering controls, etc.)
- Containment at source of any liquid aerosols that may be produced during handling by using closed process equipment, or enclosed equipment
- Avoidance of any routine or uncontrolled spillages of enzyme-containing materials, including from waste and packaging, and immediate clean-up of any spills
- Clean / hygienic design of plant and equipment

The employer must take the necessary preventive measures to eliminate or reduce to a minimum the risks identified in the risk assessment following a **hierarchy of controls**.

**Substitution** shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which is not hazardous or **less hazardous** to workers' safety and health. Substitution can also be the choice of the right product form, *e.g.* replacing powdered enzymes by encapsulated low dust granules or liquid formulations.

Adversely to liquids or encapsulated low dust granules, powdered enzymes have more of a potential of becoming airborne, hence creating a significant higher potential for occupational exposures and shall not be used.

Referring to the 'hierarchy of controls' pyramid as can be seen in Chapter 3 (Figure 2), for the textile supply chain, reasonable elimination is only an option regarding the selection of the enzyme product form but not for the use of enzymes themselves, as the use of enzymes has many sustainability benefits for textile processing. Instead, product design is the appropriate measure to reduce the hazard. Engineering controls, such as automation, containment and ventilation will isolate people from the hazard. Under administrative controls, much attention should be paid to safe work practices and therefore it is of key importance to adequately train the workforce in 'enzyme safety'.

#### 4.1.1. Enzyme Exposure Scenarios

As referred to in Chapter 2, if an enzyme is in the scope of REACH registration and has been registered in tonnages > 10 tons per year, then its registration dossier shall include a Chemical Safety Assessment (CSA). The CSA consists of:

- Exposure Scenario (ES), including use description.
- Exposure estimation for the different routes of exposure under the conditions of use as described in the ESs.

- Risk characterisation: comparison of exposure levels to no or minimum derived effect levels.

These ES are attached to the extended safety datasheets (eSDSs) that may be received from the enzyme suppliers or the TCF. Depending on the process categories, *e.g.* open versus closed process, dedicated versus non-dedicated facilities, *etc.*, different risk management measures (RMMs) are communicated to control workers exposure. These RMMs are legally binding.

TCFs may consolidate ES into the main body of their mixture SDS. If requested, the TCFs is legally required to supply the ES of each ingredient of the mixture, assuming that a CSA has been conducted by the manufacturer/importer of the ingredient.

### 4.1.2. Enzymes Product Forms / Supply units

Both liquid and encapsulated low dust granulated enzyme formulations are used in the textile and garment finishing industry. However, typically liquid enzyme formulations are used. Low dust granulated enzyme formulations are less common but are still addressed in this document. The typical active enzyme protein (aep) content of enzyme formulation used by textile and garment finishers is between 0.1 and 10%, with textile finisher typically using formulations with higher aep.

Powdered enzyme products are extremely difficult to handle and shall not be used. Therefore, they are not further discussed below.

In **Error! Reference source not found.**, the difference between encapsulated low dust g ranulated enzyme formulations and powder formulations is depicted. The former is coated with a protective layer and in the size range of several hundred micrometres, which makes them too large to be inhaled. The latter shall not be used, as these products become easily airborne.

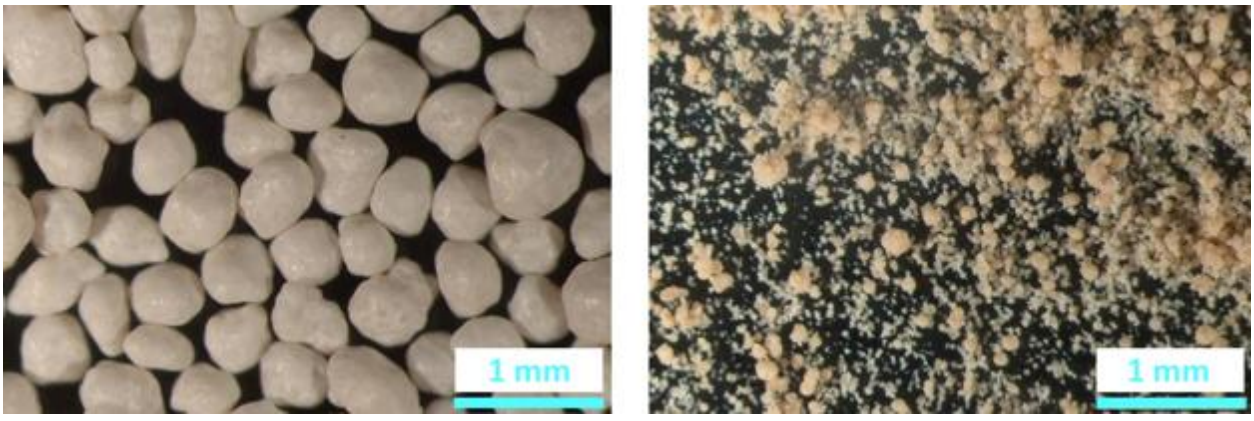


*Figure 3: Comparison of encapsulated low dust granulated enzyme formulations (left) and powder formulations (right)*

**Liquid enzyme formulations** for the textile and garment finishing industry are available in 3 main supply units:

- Jerrycan or canister: 20 to 30 Litre

- Drums: 100 to 250 Litre

- IBC: 1000 Litre

**Encapsulated low dust granulated enzyme formulations** for the textile and garment finishing industry are typically supplied in small plastic or cardboard drums, boxes or bags (<30 kg):

- Cardboard drums

## 4.2. Textile Finishers

This sub-chapter discusses the specific tasks that are typically performed in textile finishing industry, which are:

- Delivery and storage of supply units (Section 4.2.2)
- Repacking of supply units (Section 4.2.3)
- Dosing of enzyme products (Section 4.2.4)
- Application of enzyme products (Section 4.2.5)
- Cleaning and maintenance (see Sub-chapter 4.4)
- Waste disposal (see Sub-chapter 4.5)

Following this sub-chapter, there are additional considerations on how to minimise enzyme exposure due to plant design (Sub-chapter 4.6), and appropriate use of personal protective equipment (Sub-chapters 4.7 and 4.8). These additional considerations apply to both, textile and garment finishers.

### 4.2.1. Introduction: Describing the Process

Enzyme formulations are used in continuous, semi-continuous and discontinuous (batch) processes.

- The typical machines for continuous processes are continuous washing machines.

- In semi-continuous processes (mostly cold pad-batch technique), enzymes are applied in so-called padding devices (foulard), the treated textile is stored for a few hours to allow the enzyme reaction and afterwards washed out in a continuous washing machine.
- Dyeing machines are used for discontinuous (batch) processes.

The enzyme formulations are used for all kind of processes in highly dilute form.

In continuous processes or semi-continuous chemical mixtures are dosed automatically to the application devices (*e.g.* foulard or box).

The mixing of the chemicals used for batch processes is executed separately (in the so-called dye- or finishing kitchen). Dosing of the chemicals to the batch process happens preferably in a closed setting but can be done also manually.

At the end of the process no enzymes are present. They either degrade during the washing step (pH change and/or temperature change) and/or are flushed during the rinsing step into the sewage system.

The main purpose for the use of enzymes are:

- De-sizing (most significant use)
- Bioscouring
- Biofinishing
- Biobleaching
- Degradation of excess hydrogen peroxide (post conventional bleaching)

The typical enzyme concentration in textile auxiliaries used at textile finishing sites is 0.1% to 10% aep.

#### 4.2.2. Delivery and storage of Supply Units

In the textile finishing industry typically IBCs or drums are used for textile auxiliaries containing enzymes.

All supply units should be delivered on pallets for ease of handling. Four drums can be put on one ISO pallet (dimensions: 1000 × 1200 mm). Smaller pallets exist where for example only two drums fit on. Plastic film is wrapped around the smaller supply units for transportation. The European law for road transport dictates it as such (ADR/Directive 2008/68/EC).

After deliver, the supply units should immediately be transported to a dedicated warehouse. For IBCs, it is good practice to put maximum 3 IBCs on top of each other, depending on the allowed bearing load of the IBC themselves and/or storage rack. Please consult your IBC supplier for further guidance.

A containment bund shall be present to prevent liquid chemical spills from spreading uncontrollably.

See Figure 4 for good practice examples below.

*Figure 4: Storage of supply units of textile auxiliaries containing enzymes*

During delivery and storage, the enzyme supply units are unopened. Since enzymes are essentially non-volatile, there is no risk of getting exposed to enzymes while handling unopened supply units. In case of a spill or leakage appropriate precautionay measures must be taken. The reader is referred to Sub-chapter 4.4 for more information on how to handle spills and leakages.

### 4.2.3. Repacking of Supply Units

Due to the large volumes of textiles handled by a textile finisher, relatively large volumes of enzyme products are consumed. To safely repack such large volumes of textile auxiliaries containing enzymes, dedicated risk management measures (RMMs), such as ventilation with a high-efficiency particulate absorbing filter (HEPA) filters, are required. As such RMMs are typically not available at textile finishing sites, it is not recommended to carry out any repacking activities on site.

If a specific supply unit dimension is needed, then it is recommended to directly request such a supply unit from your enzyme supplier or TCF.

Sometimes with liquid enzyme formulations in IBCs intertank transfer is used *e.g.,* to IBCs connected to automated dosage systems. This happens in a closed system with pumps and tubes. Care must be taken, that especially at the end of the transfer the suction tube stays below the surface to avoid formulation of aerosols by suction of air (see Section 4.2.4).

#### 4.2.4. Dosing of Enzyme Products

For liquid products, **best practice** when designing a safe system for dosing enzymes into textile finishing equipment is to isolate the operator from the open textile auxiliary supply unit that contains the enzymes. There shall be no direct interface between the operator and the textile auxiliary during normal operations. The supply units (*incl.* intertank solutions) should be coupled directly to an automated dosing and mixing system to ensure this (see *e.g*. Figure 5). The process should be undertaken in an area that can provide a high level of containment and control, in case a spillage, or release, should occur. The discharge area shall be provided with suitable secondary containment to contain spillage of enzymes in the event of a failure of the supply unit or associated pipework. The open supply units, such as IBCs and drums, should be connected to the automated dosing and mixing equipment using a dry-break or cam-lock type coupling to avoid any spillages during the coupling / de-coupling operation.

Before empty supply units are removed from the automated dosing system, it shall be confirmed that they are contained and externally clean. Any hoses or lancets used for the coupling of the supply unit to the automated dosing and mixing equipment shall be cleaned when the empty supply unit is removed. Any spillage during the coupling / de-coupling operation shall be immediately cleaned (see Sub-chapter 4.4).

*Figure 5: Example of a closed automated dosing (left) and mixing system (right) of a continuous washing machine*

In some situations, it may not be possible to use an automated dosing and/or mixing system, and manual dosing may be required (*e.g.*, dosing small amounts). Due to the relatively large volumes and partly highly concentrated enzyme products handled by textile finishers, **good**

**practices** to minimise exposure to enzyme aerosols must be in place to ensure the safety of the worker during manual activities.

Good practices for the different activities associated with manual dosing are discussed below and include transfer from the supply unit and mixing. The distance between these activities shall be minimised to the degree possible.

For all these activities it is recommended to provide a good standard of ventilation (*i.e.* at least 3 air exchanges per hour) and to clean immediately any spills (consider the use of spill trays) and the dosing equipment after use. Otherwise wet residue can dry out and form a fine dust containing enzymes. In particular, for highly concentrated enzyme products, this may lead to exposure of the worker.

*Transfer from the supply unit*

Liquid enzyme formulations from an IBC and drum may be transferred into *e.g.* a measurement cup, which is then dosed into the mixer. To avoid the creation of aerosols, the transfer and flow rate height shall be minimised. The latter may be minimised by reducing the diameter of the hose. When dosing small amounts (< 250 mL), it is recommended to let the enzyme formulation run slowly down the wall of the cup. When dosing larger amounts (< 10 L), a lid and dip-pipe shall be used that allows submerged transfer into the measurement cup (see Figure 6). Quantities above 10 L should not be transferred manually.

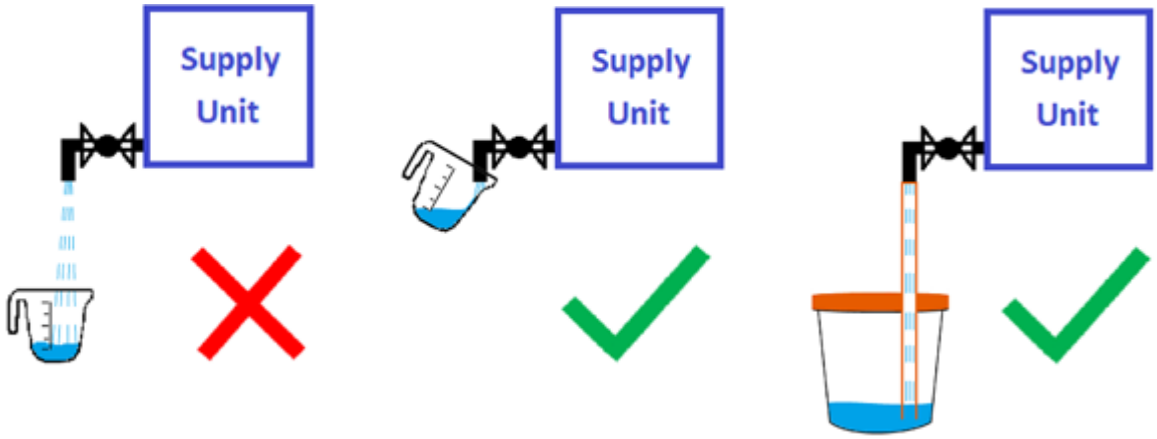


*Figure 6: Do's and don'ts when transferring liquid enzyme formulations*

*Mixing*

Mixing creates an agitated surface, which is a major generator of aerosols. To ensure the safety of the worker during the mixing activity several RMMs need to be in place:

- The mixer shall be in a dedicated area that can provide a high level of containment and control
- The mixer must be closed with a lid

- The mixing process shall not start until the impeller blades are completely submerged
- The worker shall not be in the proximity of the mixer during the mixing activity
- The lid shall be kept closed for approximately five minutes after the mixing activity ends to allow the aerosols to settle

Due to the large volume, it can be assumed that the solution from the mixer is dosed automatically into the textile treatment equipment. Due to the high dilution of the enzyme, no specific RMMs are required during the transfer. Any spills or leakages shall be immediately cleaned (see Sub-chapter 4.4).

#### 4.2.5. Application of Enzyme Products

In the textile finishing industry, enzymes may be used in continuous washing machines (Figure 7), in the cold pad-batch treatment of textiles (Figure 8) or in batch processes (Figure 9). All application types will be addressed separately below. Enzymes are commonly used in highly diluted forms during all types of textile applications[21].

*Figure 7: Example of a continuous washing machine*

[21] A typical dilution factor for an enzyme containing textile auxiliary in the washing machine is > 1000. The fraction of active enzyme protein (aep) in a continuous washing machine is <0.01%.

*Figure 8: Example of a cold pad-batch treatment*

*Figure 9: Example of a dyeing machine that is used for batch processes*

*Continuous process: Washing machine*

Enzymes are typically used for de-sizing, which is the first step in the treatment of textiles in a continuous washing machine. This first process step happens typically in an open setting (see *e.g.* Figure 10).

For processes with such a high dilution factor typically no specific RMMs need to be in place.

When high concentrations of enzymes are used in the de-sizing bath (>0.005% aep) it may be required to control exposure to enzymes with a low-level containment around the de-sizing bath.

At the end of the washing process, the enzymes have degraded or have been flushed into the sewage system during the rinsing step. This means that also no specific RMMs need to be in place when handling the treated textiles.

Any other enzyme applications happen at later stages of the continuous washing machine, which are closed processes. For such closed processes, no additional RMMs need to be in place.

*Figure 10: First processing step (typically de-sizing) of a continuous washing machine*

*Semi-continuous process: Cold pad-batch treatment*

During the cold pad-batch treatment the textile rolls are soaked in the treatment solution and wrapped in plastic film. The textile rolls are continuously turned at a slow speed. The whole treatment may take several hours and is typically done overnight.

The soaking of the textile rolls is an automated process, happens at low speed and with highly diluted enzyme concentrations. Thus, no specific RMMs need to be in place.

During the (overnight) treatment no specific RMMs are required. The process is semi-closed, and the enzymes are highly diluted. It happens occasionally, however, that the soaking solution leaks out of the plastic film wrapping or that the plastic film wrapping rips. Such leaks and spillages shall be cleaned in a timely manner as described in Sub-chapter 4.4.

After the (overnight) treatment the soaked textile rolls are cleaned in a washing machine. For this task no specific RMMs need to be in place.

*Discontinuous process: Dyeing machines*

Dyeing machines are closed systems (see example in Figure 11). Dosing of the chemicals to the batch process happens preferably in a closed setting but can be done also manually. In the dyeing machine, enzymes are only used at highly diluted concentrations. Thus, no specific RMMs need to be in place during the operation. In case of manual dosing, the reader is referred to Section 4.3.4 for more information on the safe handling of enzymes.

At the end of the discontinuous textile finishing process, the enzymes have degraded or have been flushed into the sewage system during the rinsing step. This means that also no specific RMMs need to be in place when handling the treated textiles.

*Figure 11: Example of a dyeing machine used to treat textiles. In the lower right corner, the automated dosing and mixing system can be seen.*

## 4.3. Garment Finishers

This sub-chapter discusses the specific tasks that are typically performed in garment finishing industry, which are:

- Delivery and storage of supply units (Section 4.3.2)
- Repacking of supply units (Section 4.3.3)
- Dosing of enzyme products (Section 4.3.4)
- Application of enzyme products (Section 4.3.5)
- Cleaning and maintenance (see Sub-chapter 4.4)

- Waste disposal (see Sub-chapter 4.5)

Following this sub-chapter, there are additional considerations on how to minimise enzyme exposure due to plant design (Sub-chapter 4.6), and appropriate use of personal protective equipment (Sub-chapters 4.7 and 4.8). These additional considerations apply to both, textile and garment finishers.

### 4.3.1. Introduction: Describing the Process

Liquid or encapsulated low dust granulated enzyme formulations are mixed and then dosed into garment finishing washing machines. The mixing and dosing should be preferably done automatically but also happen by hand. Alternatively, enzymes encapsulated in (soluble) polymer bags may be directly placed into the washing machine, which is however uncommon. Manual handling may be done in particular at sites where the enzyme usage is so low that an automated dosage system cannot be used efficiently. State of the art washing machines are closed, with minimal release. At the end of the process no enzymes are present. They either degrade during the washing step (pH change and/or temperature change) and/or are flushed during the rinsing step into the sewage system.

The main purpose for the use of enzymes are:

- De-sizing
- Garment washing (*e.g.* biofinishing, biopolishing, biostoning)
- Colour modification (*e.g.* denim bleaching)

The typical enzyme concentration in textile auxiliaries used at garment finishing sites is 0.1% to 5% aep.

### 4.3.2. Delivery and storage of Supply Units

All supply units should be delivered on pallets for ease of handling. 32 Jerrycans or four drums can be put on one ISO pallet (dimensions: 1000 × 1200 mm). Smaller pallets exist where for example only two drums fit on. Plastic film is wrapped around the smaller supply units for transportation. The European law for road transport dictates it as such (ADR/Directive 2008/68/EC). After deliver, the supply units should immediately be transported to a dedicated warehouse. For IBCs, it is good practice to put maximum three IBCs on top of each other, depending on the allowed bearing load of the IBC themselves and/or storage rack. Please consult your IBC supplier for further guidance. A containment bund shall be present to prevent liquid chemical spills from spreading uncontrollably.

See Figure 12 for good practice examples below.

*Figure 12: Storage of supply units of textile auxiliaries containing enzymes*

During delivery and storage, the enzyme supply units are unopened. Since enzymes are essentially non-volatile, there is no risk of getting exposed to enzymes while handling unopened supply units. In case of a spill or leakage appropriate precautionay measures must be taken. The reader is referred to Sub-chapter 4.4 for more information on how to handle spills and leakages.

### 4.3.3. Repacking of Supply Units

Due to the high efficiency of enzymes, it is common that only a small quantity of enzyme product (<250 mL) is needed for the garment finishing process. Consequently, some garment finishers manually repack enzyme products from drums or IBCs into jerrycans. These jerrycans are placed next to the washing machine from which the enzyme product is dosed by hand into the washing machine.

**Best practice** in such an instance is to directly source jerrycans in the preferred dimension and avoid any repacking on site. This is in particular true if such repackaging activities occur regularly.

**Good practice** in such an instance is to train workers on the safe handling of enzyme products, use proper equipment and clean any contaminated equipment immediately after repackaging. Proper equipment includes:

- a right sized funnel with a dip-pipe that allows submerged transfers,
- a dripping pan that collects any (minor) spills,

- limitation of the transfer height to <0.5 meters, and
- an appropriate respirator (see Sub-chapter 4.7) in case that the mixture is classified as respiratory sensitizer (indicated by the “Health Hazard” pictogram - GHS08)

#### 4.3.4. Dosing of Enzyme Products

For liquid products, **best practice** when designing a safe system for dosing enzymes into garment finishing equipment is to isolate the operator from the open textile auxiliary supply unit that contains the enzymes. There shall be no direct interface between the operator and the textile auxiliary during normal operations. In particular large supply units, such as IBCs and drums, should be coupled directly to an automated dosing system to ensure this (see *e.g.* Figure 13). The process should be undertaken in an area that can provide a high level of containment and control, in case a spillage, or release, should occur. The discharge area shall be provided with suitable secondary containment to contain gross spillage of enzymes in the event of a failure of the supply unit or associated pipework.

Ideally, large open supply units, such as IBCs and drums, should be segregated from the workplace by placing them in a dedicated area and they should be connected to the automated dosing equipment using a dry-break or cam-lock type coupling to avoid any spillages during the coupling / de-coupling operation.

Before empty supply units are removed from the automated dosing system, it shall be ensured that they are contained and externally clean. Any hoses or lancets used for the coupling of the open supply unit to the washing machine shall be cleaned when the empty supply unit is removed. Any spillage during the coupling / de-coupling operation shall be immediately cleaned (see Sub-chapter 4.4).

*Figure 13: Example of a closed automated dosing system for garment finishing washing machines*

As discussed above, often the amount of enzyme material needed in the garment finishing industry is so low that an automated dosing system cannot be applied efficiently. In such cases, it is still common to dose the textile auxiliaries containing enzymes manually into the washing machine.

In such an instance **best practice** is to use unit doses, *i.e.* enzymes encapsulated in (soluble) polymer bags. In industrial settings such unit doses are not that frequently found but can in principal be used for liquid and encapsulated low dust granulated enzyme formulations.

**Good practice** to minimise exposure to enzyme dust and aerosols for the different activities associated with manual dosing are discussed below, and include transfer from the supply unit, weighing, mixing and transfer into the washing machine. The distance between these activities shall be minimised to the degree possible.

For all these activities it is recommended to provide a good standard of ventilation (*i.e.* at least 3 air exchanges per hour) and to clean immediately any spills (consider the use of spill trays) and the dosing equipment after use. Otherwise wet residue can dry out and form a fine dust containing enzymes. In particular for highly concentrated enzyme products, this may lead to exposure of the worker.

*Transfer from the supply unit*

Liquid enzyme formulations from a jerrycan may be directly transferred into *e.g.* a measurement cup. To avoid the creation of aerosols, the transfer height shall be minimised. When dosing small amounts (< 250 mL), it is recommended to let the enzyme formulation run slowly down the wall of the cup. When dosing larger amounts (< 10 L), a lid and dip-pipe shall be used that allows submerged transfer into the measurement cup (see Figure 6). For large supply units, such as IBCs and drums, the same principle applies. Due to their large volume, the flow rate shall additionally be limited, *e.g.* by reducing the diameter of the hose. This should prevent any aerosol formation and spillages at the workplace. Quantities above 10 L should not be transferred manually.

Encapsulated low dust granulated enzyme formulations may be carefully scooped out of the supply unit using *e.g.* a measurement cup. No specific RMMs are required.

*Weighing*

Liquid or encapsulated low dust granulated enzyme formulations may be weighed. Liquids may be transferred into *e.g.* a measurement cup as described above (see also Figure 6 for reference).

Granules are specifically designed to release practically no dust. Small amounts (<250 gram) may be transferred into *e.g.* a measurement cup on a balance without any specific RMMs in place. A surplus of granules may be simply returned to the supply unit. It is generally recommended to minimise the transfer height to the degree possible to avoid the breakage of granules.

After use, any cups or containers shall be cleaned to avoid built up of dried enzymes and/or enzyme dust.

*Mixing*

In most instances the mixing of the enzyme formulation will happen within the washing machine, which is a closed system. However, if any liquid or encapsulated low dust granulated enzyme formulation is mixed prior to its dosing into the washing machine, then this should happen in a closed system. Any mixing process creates aerosols that can effectively be contained with a lid on the mixing tank (see *e.g.* Figure 14). After mixing the lid shall be kept closed for approximately five minutes to allow any aerosols to settle. From experience it is known that open mixing could result in enzyme airborne levels significantly above the DMEL of 60 ng/m³.

*Figure 14: Mixing tank on the back of a washing machine used in the garment finishing industry*

*Transfer into the washing machine*

Manual transfer of liquid or encapsulated low dust granulated enzyme formulations from a measurement cup into a washing machine, which is comparable to dosing a detergent into household washing machines, may be done without any specific RMMs.

Some washing machines may have the possibility to flush the measurement cup with a water jet from the opening used for the dosing. In other instance it may be required that a water jet is used to flush the residual material that gets stuck at the surface of the opening used for the dosing into the washing machine. In both instances this flushing shall be done with cool low-pressure water whenever possible. The use of hot or high-pressure water shall be minimized because they produce high levels of aerosol.

### 4.3.5. Application of Enzyme Products

In the garment finishing industry, enzymes are used in semi-closed and closed washing machines (see Figure 15) to *e.g.* de-size, stonewash or colour modify garments. The enzymes

are used in highly diluted form in these washing machines[22]. For processes with such a high dilution factor no specific RMMs need to be in place. At the end of the washing process, the enzymes have degraded or have been flushed into the sewage system during one of the rinsing steps. This means that also no specific RMMs need to be in place when unloading the washing machines or handling the garments in a further processing step.

*Figure 15: Small (left) and large (right) garment finishing washing machine*

Next to classical washing machines, enzymes may also be used in spray applications for the use in creating a stonewashing effect using enzymes. Such activities should be avoided and if performed, must only be performed in fully closed and automated systems and according to the provisions laid out by the textile auxiliary supplier in the technical data sheet and SDS. To ensure the safe use of enzymes in such spray applications, two approaches are possible:

1) The enzyme manufacturer may test upfront certain enzyme product - stonewashing spray machine combinations. They then communicate the safe use conditions down to the garment finishers. In such instances, it is imperative that one does not deviate from these safe use conditions, including the type of stonewashing spray machine. Regular air monitoring by trained professionals is required.

2) Garment finishers may determine locally the safe use conditions. In such cases, air monitoring by trained professionals will be a pivotal element of risk assessment. An initial risk assessment before staring operations is required and may only be done by qualified personnel.

In both scenarios, it is assumed that the stonewashing spray machines are regularly maintained, and regular air measurements are carried out. For more information on how to do air monitoring

[22] A typical dilution factor for an enzyme containing textile auxiliary in the washing machine is *ca.* 500. The fraction of active enzyme protein (aep) in the washing machine is in the order of 0.001% to <0.01%.

the reader is referred to Sub-chapter 5.2.

In case of trouble shooting, respiratory protection may be needed if it involves the pure textile auxiliary containing enzymes (see Sub-chapter 4.7). Whether a respirator is needed depends on the exact type of situation and common trouble shooting scenarios shall be assessed regularly to define appropriate RMMs for such situations. The worker shall determine in a Last-Minute Risk Analysis (LMRA) what type of protective equipment is needed.

### 4.4. Dealing with Spillages, and Cleaning of Plant and Equipment

This sub-chapter focuses preliminary on spills of textile auxiliaries containing enzymes. Once these textile auxiliaries have been diluted in the textile or garment finishing equipment, there is typically no specific risk associated with enzyme exposure, if the spills are cleaned up immediately. A LMRA before any spill removal or equipment maintenance shall clarify if enzyme exposure needs to be controlled by a specific RMM, such as a respirator.

The use of improper or improvised clean-up methods can result in generation of airborne enzymes. This can result in the exposure of operators in the immediate area of any cleaning operation and in adjacent areas via general ventilation. Clean-up operations are a significant potential source of peak enzyme exposures, which need to be managed by a combination of equipment and proper procedure.

Cleaning up spilled enzyme granulates shall be done with the use of a (portable) vacuum cleaning system fitted with HEPA filtration. The air inflow at the vacuum tool provides some containment of dusts or aerosols at the pickup point. Normal industrial vacuum cleaning systems without HEPA filtration shall not be used, as the filtration systems will not adequately remove enzyme dust and/or aerosol before it is returned to the working environment.

Liquid enzyme spillages may be washed to a drain by a soft/low pressure water hose. Spill pans may be drained down to an internal sump, from where it goes to the wastewater.

Depending on the size of a liquid spillage, the use of a sorbent material can be considered. The contaminated sorbent must be shovelled up and placed into a sealed plastic bag / plastic container and disposed of by incineration, or through the wastewater treatment plant. However, this will require additional handling controls and disposal of the contaminated packaging.

Brushes, brooms, compressed air, and high-pressure water **must never** be used for cleaning spillages of products with significant enzyme concentrations (*i.e.* enzyme products bearing the classification EUH208 or H334), as these can either generate significant airborne dust and / or aerosol, or leave behind a wet residue, which can dry out to form a fine dust. Vacuuming with a HEPA filter followed by wet mopping is preferred.

Respiratory protection shall be used for all large cleaning / spillage operations because the risk of exposure is always high (see 4.7).

#### 4.4.1. Cleaning of Spare Parts

In general, the parts cleaning station is an enclosed area where change parts and other equipment are cleaned. It is an isolated room with sufficient ventilation. Change parts shall be transported to the cleaning bay/area in a rigid solid sided container to minimize spills. The area should be under negative pressure with respect to the remainder of the plant.

PPE in accordance with your plant matrix shall be worn when inside the room to protect against product splashing back from the wash down. As this is an operation with a high potential for exposure to dust and/or aerosol therefore respiratory protection must be worn as a safeguard (see Sub-chapter 4.7 below).

Cool low-pressure water is used for cleaning whenever possible. The use of hot or high-pressure water shall be minimized because they produce high levels of aerosol. Water from parts cleaning runs down the sloped floor of the room and drains to the plant effluent system.

### 4.5. Disposal of Empty Supply Units

There are two options for dealing with empty supply units:

- Return to the supplier for disposal or re-use
- Disposal as waste

In either case, contaminated packaging waste must be prepared to ensure safe handling at all downstream stages of the disposal operation.

Cardboard boxes for encapsulated low dust granulated enzyme formulations may be safely contained within another closure (*e.g.* a clean polythene bag).

IBCs have a special recall policy, so-called “reverse logistics”. With every IBC delivered, documents are attached for the end-user with instructions what to do in order that a disposal company come to pick them up. Drums may or may not fall under a similar recall policy. Jerrycans are normally disposed at the end-user’s site.

Before returning or disposing any supply unit, it may be required to clean any residual product from inside the IBC or drum. Such cleaning activities shall be carried out under controlled conditions, *e.g.* in an isolated cleaning area, by operators wearing suitable respiratory and personal protection (see Sub-chapter 4.7). The isolated cleaning area shall have an enhanced air change rate to effect rapid dilution and removal of any airborne dust or aerosol in a direction away from the operator’s breathing zone, and without allowing the dust or aerosol to settle. Alternatively, the isolated discharge area may be located outdoors.

Any cleaning activity shall be done with cool low-pressure water whenever possible. The use of hot or high-pressure water shall be minimized because they produce high levels of aerosol.

#### 4.5.1. Return to the supplier

In some instances, it may be possible to return some, or all, of the packaging to the supplier for either disposal, recycling, or re-use. Packaging returned to the supplier shall be in a safe condition, with no external contamination, and no risk of loss of integrity during the return trip.

Return to the supplier for disposal essentially applies to any type of supply unit, but this will need to be checked and agreed with the supplier in advance.

#### 4.5.2. Direct Disposal

The chosen disposal route may depend upon local or national legislation, or availability of suitable incineration facilities or landfill areas. It should be taken care of that all supply units are carefully closed (lids, caps, taps etc.).

When disposing of contaminated packaging as “special waste” off site, it shall be ensured that only licensed contractors and licensed disposal facilities are used. The factory shall adhere to “Duty of Care” to ensure that contaminated waste is disposed of correctly, and according to contract (*i.e.* transferred using approved transport, to an agreed waste disposal facility, where it is handled accordingly). The contracted waste recycling company shall be informed of the hazards and risks associated when handling supply units that are potentially contaminated with enzyme material.

### 4.6. Building and Plant Design Considerations

#### 4.6.1. General Principles

Buildings and plants should be designed to the extent possible to provide an environment that is easy to maintain in terms of hygiene and which minimizes the generation of aerosols by avoiding spraying, splashing, or spillage. Therefore, it is essential that clean design principles are used for buildings.

#### 4.6.2. Buildings

**Walls** should be smooth, and sealed (*e.g.* painted), or clad in a smooth material that is easy to keep clean. Fittings such as shelves, cupboards, *etc.*, should be kept to a minimum and be positioned such that they can be easily cleaned. Old fittings and fixtures that are no longer in use should be removed.

**Ceilings** should be smooth and give easy access for periodic cleaning.

**Floors and stairs** shall be easy to clean.

**Windows:** complex window frames should be avoided, as these are difficult to keep clean.

**Ductwork** should be tubular shapes.

#### 4.6.3. Equipment

Liquid textile auxiliaries containing enzyme have a significant potential for aerosol formation during handling and a risk of dust generation if spillages are left to dry out. The process shall be designed to control this additional risk by effective containment of liquids, *i.e.*, no leaks, and by minimizing the chance of spraying and/or splashing of liquid.

One of the largest potential source of personal exposure to enzyme aerosols is the storage and refilling equipment for the enzyme dispersion. Interface and frequency of exposure shall be eliminated or reduced as follows:

The design shall prevent external spillage and spattering of fluid by:

- Limited drop heights and avoidance of splashes of liquids on surfaces (including liquid surfaces).
- Design of efficient enclosures to completely recirculate spilled liquid splashes
- Spill trays to completely collect and return the spilled material.
- Suitable sampling points
- Efficient machine setup to avoid frequent interruptions and manual intervention
- Using CIP technologies (Cleaning in Place)

In places where spills are evident or routine and have not yet been disposed of, drip pans shall be provided for product removal.

The design shall avoid or reduce spills, thus reducing the need for frequent cleaning of spilled material.

Leak free pipes (*e.g.* flexible pipes shall be robust enough to withstand abrasion and bending), pumps (*i.e.*, magnet drive or sealed motor and pump combination) and valves should be used. Any flanges should be covered with a flange protector to prevent the development of sprays if the flange/seal fails.

### 4.7. Respiratory Protective Equipment (RPE)

#### 4.7.1. Use of Respiratory Protective Equipment (RPE)

In **standard** operational conditions, the use of RPE shall be considered as **secondary** protection

where a risk assessment has shown that there is a potential for exposure despite the presence of engineering controls, *e.g.*

- Dealing with small spillages of textile auxiliaries containing enzymes
- Cleaning and “on-line” maintenance of equipment in contact with high concentrated enzyme products, such as automated transfer, dosing and mixing stations
- Quality sampling of enzyme products

In some **standard operational** conditions, the use of RPE shall be considered, *e.g.*

- Open transfer and dosing of textile auxiliaries with significant enzyme concentrations (*i.e.* textile auxiliaries bearing the classification EUH208 or H334)
- Cleaning of supply units prior to waste disposal

RPE shall also be used where, due to a failure of a critical engineering control, there is a very significant risk of a peak exposure, *e.g.* during discharge of enzymes.

During **trouble shooting**, RPE may be required as **primary** protection. In this instance, the standard of RPE shall be identified by a risk assessment for the task, including the likely level of exposure. Abnormal situations include:

- Major spillage of textile auxiliaries with significant enzyme concentrations (*i.e.* textile auxiliaries bearing the classification EUH208 or H334)
- Dealing with, and repair of, damaged supply units for textile auxiliaries containing enzymes
- Maintenance, decontamination or repair of contaminated plant and equipment, of equipment in contact with high concentrated enzyme products, such as automated transfer, dosing and mixing stations

#### 4.7.2. Standards of Respiratory Protection

All employees required to use RPE must be adequately trained in its selection, use and maintenance. In some countries, it is regulated that the site doctor shall assess them as medically fit to wear and use respiratory protection.

The selection of suitable RPE will depend upon the task, the potential level of exposure, and whether the RPE is required for primary or secondary protection. The time for which RPE needs to be worn shall also be taken into consideration as should comfort, fit, and compatibility with other PPE, to ensure that there are no issues that could result in incorrect use, or misuse.

The respirator selected must have an assigned protection factor (APF) adequate for the particular workplace exposure. The required APF to provide the necessary protection shall be

determined by undertaking a risk assessment for the particular task. The minimum standard when handling enzyme containing products shall be P3 for airborne enzyme dust only and P3SL is effective for both dust (S) and aerosol (L). It is recommended to comply with the relevant EN standards for RPE (see *e.g.* EN 529:2005[23] for APF of different respirator types and according to different countries) and to conduct a fit testing prior to the use.

In Figure 16 to Figure 18, examples of the type of RPE available are depicted that cover a range of contingencies. Disposable respirators (FFP3) may be used for open transfer and dosing of textile auxiliaries containing enzyme or as a secondary protection. Half-face reusable respirator or Powered Air Purifying Respirator (PAPR) may be used during trouble shooting as defined above. The half-face respiratory and PAPRs offer a higher level of protection than disposable respirators and are thus more suitable if there is greater potential for enzyme exposures.

*Figure 16: Disposable respirators (FFP3) (courtesy: IFF)*

*Figure 17: Half-face reusable respirator (courtesy: IFF)*

*Figure 18: Powered Air Purifying Respirator (PAPR), (courtesy: IFF)*

In the event that normal orinasal face masks cannot be used because the employee has significant facial hair, *e.g.* a beard, large moustache, *etc.*, and a good face seal cannot be achieved against the skin, then positive pressure respiratory protection shall be used, such as a PAPR. RPE shall be compatible with any other protective equipment provided, such as safety glasses, safety goggles, hearing protection, *etc.*

### 4.8. Other Personal Protective Equipment (PPE)

In general, skin and eye contact with textile auxiliaries containing enzymes shall be avoided

[23] EN 529-005 – Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document

through the use of suitable RMMs like PPE. Proteases, which are not commonly used in textile and garment finishing, may irritate skin and eyes if in contact and require gloves and safety glasses during handling. Please follow the product safety data sheets.

#### 4.8.1. Protective Clothing

Under **standard** operational conditions, all employees, contractors and visitors shall use the relevant PPE and work clothing appropriate for the areas they visit or for the tasks they undertake. Often this will be mandated by site policy. For handling liquid products, gloves shall be impermeable.

Safety shoes, whilst not related to enzyme safety, and eye protection shall also be used by all persons on site as is appropriate; rubber boots (with safety caps) may be required for major wet cleaning operations.

Decontamination facilities (showers) and a change of protective clothing / work clothing shall be available for employees in the event that personal contamination occurs.

Under **emergency** conditions, such as a major spillage, the required PPE shall be identified by risk assessment for each specific activity.

Normal work clothing shall be changed / laundered as per site policy, and contaminated work clothing shall be changed as soon as is possible depending upon the degree of contamination, and in accordance with the following guidance for personal decontamination. In addition, contaminated work clothing must not be worn in areas such as in offices, meeting rooms, control rooms, canteen, *etc.* as this presents a risk of exposure outside of the manufacturing / process area. For maintenance or high-risk tasks, where personal contamination is likely, a disposable work wear is an option.

#### 4.8.2. Personal Decontamination

Ideally, the plant layout should allow the most convenient and shortest distance from potential exposure areas to personal decontamination areas. Emergency showers are required to be located in the vicinity of the workplace.

There shall be standard operational procedures (SOPs) available for undertaking personal decontamination after emergency events or after undertaking abnormal tasks where the potential for personal contamination is high. The SOPs should be aligned with the information provided in the SDS of the enzyme containing products.

Following high-risk tasks, contaminated clothing shall be removed whilst still wearing respiratory protection. Clothing shall be placed into a plastic bag for disposal or laundering.

Following decontamination clean work clothing shall be available for use.

## 5. Health Effects of Enzymes and Occupational exposure assessment

### 5.1. Health Effects of Enzymes

As described previously in this guideline, enzymes are proteins and, like other proteins, may act as respiratory sensitisers if individuals are repeatedly exposed to airborne aerosols that contains them. **Respiratory allergy**, which is also called Type 1 allergy is caused by enzyme airborne exposures. Enzymes do not cause allergy via skin contact and have not been associated with food allergy.

It is essential to understand that developing a respiratory allergy is a **two-stage process**.

***The induction (sensitisation) stage:*** It begins with the individual being exposed to airborne allergens in the form of dust or wet aerosols. If this exposure is sufficiently high, and lasts for a sufficiently long period of time, the individual may become sensitised. Sensitisation is the early warning that an allergy may develop. However, prompt and correct intervention may prevent the development of a fully blown allergy.

***The elicitation stage:*** A sensitised person does not show any allergy symptoms, but the immune system has been activated and specific IgE antibodies have been generated. The presence of specific IgE antibodies can be detected by a skin test or a RAST analysis of the blood. If a sensitised person is repeatedly exposed at sufficiently high level and for sufficiently long periods of time, allergy symptoms may develop.

In the case of enzyme allergy, recent literature suggests that the exposure level required for ***elicitation*** of an allergy is higher than the exposure level required for ***inducing*** sensitisation. Therefore, it is of key importance to prevent peak exposures (8).

If a person develops an enzyme allergy, it will be a workplace related allergy, and symptoms may develop during or after working hours. In most cases the symptoms will disappear when the exposure ceases, for example at weekends or during vacations. Symptoms are identical to those presented by allergies towards common allergens. In order of appearance and increasing severity these are:

- itching and redness of the mucous membranes
- watery eyes/nose
- sneezing
- hay fever
- hoarseness or shortness of breath
- coughing
- tightness of the chest
- asthma

The first symptoms to appear will usually be less severe, such as watery eyes or sneezing. If the individual is continually exposed to the allergen for a long period of time, more severe symptoms may appear, and in some cases, these may become chronic.

It is, therefore, vital that swift and appropriate intervention shall take place as soon as possible; preferably before any further symptoms appear.

Some people are defined as being ***"atopic",*** which means that they are allergic to one or more of the common allergens like pollen and house dust mites. It has been long discussed whether atopic individuals are at a higher risk of developing allergy, but there is no clarity on this point. Smoking has been identified as a factor which can increase the risk of becoming sensitised and of developing symptoms.

Some enzymes may cause **skin irritation**. These enzymes all belong to the class of proteases, which degrade protein. No other class of enzymes possesses this characteristic. The irritation will appear as redness of the skin, and only after intensive contact. The irritation will be localised and disappears after the skin contact with the protease enzyme has ceased. Skin irritation should not be mistaken for a skin allergy, as enzymes do not cause skin allergies (12).

An enzyme allergy is exclusively an occupational health hazard for people working in the enzyme manufacturing industry; or for downstream users such as workers handling textile auxiliaries containing enzymes in the textile and garment finishing industry. Proper aftertreatment leads to the wash out or denaturation of enzymes during the textile and garment finishing. Consumers are, thus, not exposed to any enzymes and are not at risk. Therefore, an enzyme allergy is the result of an occupational exposure and its cause will always be found in the working environment.

## 5.2. Air monitoring

For this sub-chapter, we refer to the Operational conditions (OCs) and Risk management measures (RMMs) as highlighted in the SDS.

Air monitoring techniques are available to measure the level of enzyme dust or mist in the air to assess the effectiveness of engineering controls and the potential for employee exposure. The enzyme supplier can provide information on the enzyme air monitoring and analytical methods that are recommended for their products. All exposure should be below the derived minimal effect level (DMEL) based on measured data from the manufacturing site. If more than one enzyme product is used the exposure of each of them should be below the DMEL. The manufacturing site shall maintain a robust occupational health and industrial hygiene program, which includes sampling for airborne enzymes as determined by the health risk assessment (HRA). Additional risk management measures are implemented when exposure levels are measured or estimated above the DMEL. Additional respiratory protection is required if new air monitoring data reveals elevated enzyme concentrations and the source cannot be traced to a process or equipment malfunction (*e.g.*, a leaking gasket).

In addition, HRA for every workplace where enzymes or enzyme containing products are handled, which must be carried out under Chemical Agents Directive (CAD) and shall incorporate occupational exposure measurements. Due to the extremely low exposure limit values that have been derived for enzymes (see Chapter 2, Appendix 2), other exposure estimation approaches, such as computational models or read-across, are largely not applicable

to enzymes. Various sampling protocols, which will be discussed further, provide advice on how to develop an air monitoring strategy for chemical agents.

The objectives for monitoring of airborne dust and enzyme dust/aerosol are:

- It enables the quantification of employee exposures to enzymes
- It enables the overall evaluation of the effectiveness of control measures.
- The results can be used to identify where control measures are found to be insufficient so that respiratory protective equipment shall be worn.
- The results may also be used to identify where working practices may need to be reviewed in order to reduce exposure; *i.e.* less prone to create airborne exposure.

Monitoring should be prioritized based on the risk of exposure to workers. The basis for the workplace air monitoring strategy is for example located in the **EN689:2018 standard**. A qualitative assessment of the risks should be initially conducted as this will define the ultimate air monitoring strategy for the site. The air monitoring strategy may also depend on the outcome of medical surveillance: for example, if immunological testing reveals that there is an increasing trend in the incidence of sensitisation. Moreover, the strategy will also depend on the outcomes of performance assessments of the equipment, work practices and behaviours of the workforce.

Once the qualitative assessment is complete, an air monitoring plan can be created that takes into consideration routine exposures and peak exposures. Routine air monitoring is a quantitative tool to measure levels of background exposure to enzymes and dust; whereas peak sampling is used to measure high risk exposures; *e.g.*, due to equipment defects and/or unsafe behaviour, such as using pressurized air to clean equipment or work clothes. Air monitoring includes area and personal sampling and can be undertaken with either high or low volume samplers depending on the analytical restrictions of the type of monitoring to be undertaken.

Both **high** (up to 600 l/min) and **low flow** (2-30 l/min) **samplers** can be used.

Your enzyme supplier should be able to give advice on how to measure inhalable enzyme dust or aerosol. In most of the cases, only the producer or manufacturer of the enzyme is able to carry out the analytics on the collected dust/aerosol sample. So, it is typically required to get support from the producer or manufacturer of the enzyme, either directly or via the TCF.

Different sampling approaches may be used; although it may be necessary to follow local authority regulations or the guidance of EN standards (15)(16)(17)(18).

EN689 (15) and EN482 (16) are the basic standards for workplace exposure measurements and all measurements carried out to compare with limit values should be done within the workers breathing zone.

Prior to any air monitoring event, all sampling equipment must be calibrated using a typical set-up shown in Figure 19. The calibration is needed to ensure that the pumps flow rates are accurate as this will impact the final air monitoring result.

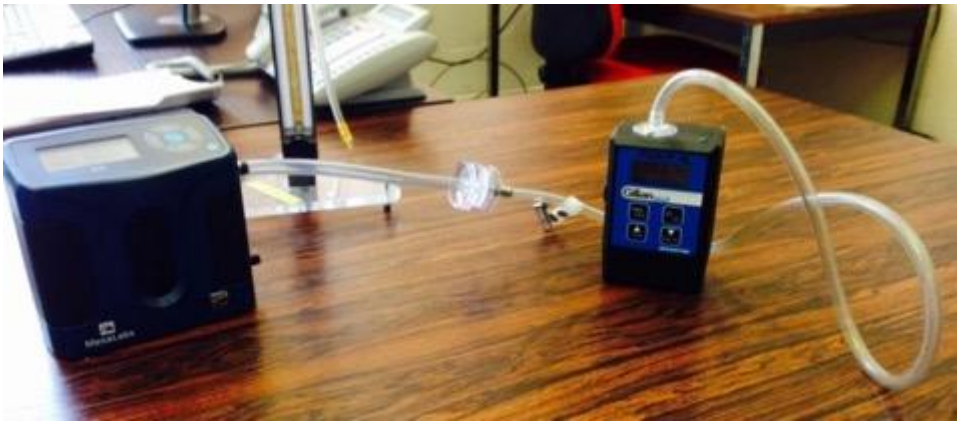

*Figure 19: Calibration set-up for air sampling equipment. (Courtesy: IFF)*

### 5.2.1 Areas to Consider for Air Monitoring

Areas with the highest potential for exposure shall be chosen as area sampling locations.

Appropriate monitoring locations can be selected in each facility by an appropriately qualified team, including industrial hygiene and manufacturing personnel. This may be done by a qualified external occupational hygiene consultant if internal resources are lacking.

As a general guideline, air monitoring should be conducted during the tasks most commonly associated with aerosol generation, including:

- Transfer of enzyme containing substance/mixture into containers
- Transfer of enzyme containing substance/mixture from/to containers at non-dedicated facilities (direct interface between operator and textile auxiliary)
- Sampling and quality control
- Weighing
- Mixing
- Handling of empty enzyme supply containers/bags
- Cleaning of plant and machinery
- Technical maintenance
- Any other activities of concern that are indicated by historical results of medical surveillance or air monitoring

As referred to in the introduction, monitoring shall be conducted to measure employee's exposure to potential airborne enzymes during the textile manufacturing processes, **including material transfer.**

### 5.2.2 Data Analysis and Interpretation

If there is a national limit value for workers exposure, data interpretation should be done according to EN689 (15).

Data interpretation is perhaps the most difficult part of the whole exposure assessment and depends on the eventual use of the data, *e.g.*:

- Is this data going to be used to verify the effectiveness of engineering controls and the potential capital investment for the improvement of engineering controls?
- Is this data going to be used to assess the necessary respiratory protective equipment requirements?

Remedial steps shall be taken immediately to resolve any exposure conditions leading to an air sampling result above the limit value (OEL and/or DMEL). When re-sampling confirms the high level, then the use of RPE or stopping production shall be considered until appropriate controls can be implemented. The follow-up procedure is defined in EN689 (15).

If the exposure in an area is above the DMEL, employees shall be informed immediately and wear RPE until the measurements return to the acceptable limits.

Analytical methods are used to measure the enzyme levels from samples collected during the air monitoring event. There are two common methods, of which the **activity-based assay** is still the most practical one. The other method is an immunoassay, known as the enzyme-linked immunosorbent assay (ELISA)**.** Please contact your enzyme supplier for further guidance on the analytical methods, which are typically performed by a qualified laboratory.

Air sampling results, together with the outcomes of the medical surveillance programme, provide valuable information regarding the effectiveness of control measures

In cases where there may be a lack of available qualified internal resources, a certified consultant (industrial hygienist) shall be contracted to conduct the air monitoring; and a certified laboratory employed to carry out the air monitoring analysis.

For the components of an air monitoring program, please consult the AISE “Guidelines for the safe handling of enzymes in detergent manufacturing”.[24]

## 5.3. Health surveillance

This sub-chapter is intended to guide occupational health professionals in implementing the current best practice for the health surveillance of workers at risk of exposure to **enzymes.** Health surveillance will be to identify those workers who become sensitised and to prevent these workers from developing allergy symptoms. The protocols recommended in this document may be refined by occupational health specialists based on historical results obtained from their

[24] AISE (2018), Guidelines for the safe handling of enzymes in detergent manufacturing, https://www.aise.eu/documents/document/20180405111438-aise-enzymes_safe_handling-v2-2-march_2018.pdf

specific area of textile and garment finishers.

The content of this sub-chapter is based on the “Current Best Practice for the Health Surveillance of Enzyme Workers in the Soap and Detergent Industry”, issued in March 2001 by the Medical Sub-Committee of the UK Soap and Detergent Industry Association (SDIA) (19). It also includes, with the exception of some modifications, recommendations given in that publication.

Health surveillance is the periodic medical examination of workers potentially exposed to enzymes.

Health surveillance is recommended for employees that are exposed to enzymes in the textile and garment finishing industry. In some countries, employers may be obliged to provide occupational health service if there is a known risk of identifiable disease.

The objectives of health surveillance related to enzyme exposure include:

- Protecting the health of individual employees by the earliest possible detection of any adverse effect which may be attributed to enzyme exposure.
- Assisting in the evaluation of measures taken to control enzyme exposure.
- Collecting and maintaining objective data to detect and evaluate hazards to health.
- Giving guidance on how to continue working in an environment where enzyme exposure cannot be avoided, based on the outcome of medical assessments.

Elements of a health surveillance programme could be:

- **A pre-employment testing**
- **Medical history** could be assessed with particular reference to, for example, asthma, allergic rhinitis, eczema, urticaria, allergies, chronic lung disease and any medication. Reference to work history with previous contact to industrial enzymes should also be included.
- **A respiratory questionnaire** could be completed including details of smoking habits. Examples of such pre-employment and periodical questionnaires are given in the AISE “Guidelines for the Safe Handling of Enzymes in Detergent Manufacturing” (see Chapter 5A)
- **Assessment of lung function** could be made using a suitable spirometer and following an accepted standardized procedure and protocol conducted by a medical professional in order to minimise measurement errors. The parameters that could be measured are FEV1, FVC, PEFR.
- **Immunological Tests,** *e.g.* **skin prick** or **serological tests** could be performed by a medical professional (Figure 20). The purpose of immunological monitoring is to monitor the appearance of sensitisation among the workforce, revealed by the development of specific IgE antibodies. It is important to remember that sensitisation is not a disease: it is an indication that a person has been exposed and may develop an allergy if exposures are not controlled.

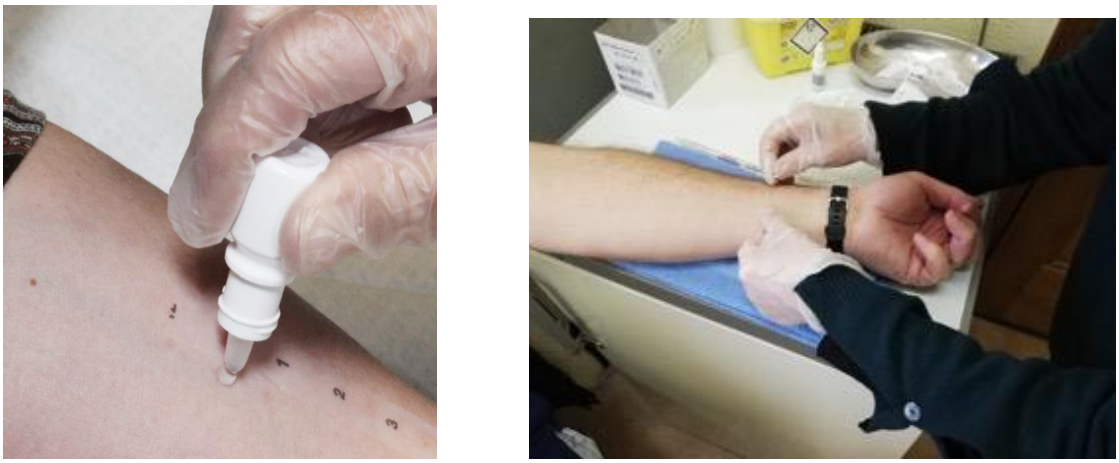

*Figure 20: Skin prick testing*

Those with **normal findings** may continue to work until the next examination.

Those who have developed a **positive immunological test** result to enzyme and have no other adverse findings may continue to work with enzymes, although an increased frequency of medical surveillance of such workers may be appropriate.

In this case, we also suggest a workplace (root cause) investigation should be conducted to ensure that exposures are in control. If possible, it is important to understand if a positive immunological test is related to a specific incident (higher exposure than normal work) or if it cannot be ruled out that normal work operations might result in sensitisations. In that case risk management measures must be improved to prevent reoccurrences.

Those with **abnormal findings** to the respiratory questionnaire which (in the opinion of an occupational health professional) could be due to enzymes; and those with impaired lung function according to spirometry readings; shall have immediate further assessment and may need to be removed from further work with enzymes.

## 6. Concluding Remarks & Acknowledgements

In this document, the authors have demonstrated the importance of controlling aerosol exposure throughout the supply chain of the textile and garment finishing industry. This control is achieved based on a holistic approach: including the use of closed equipment and processes, operator safe work practices, personal protective equipment, and overall effective management. The advice and best practices provided in this document shall be read in conjunction with local guidelines and current regulations where applicable.

Should you require further guidance on enzyme safety, it is are recommended to contact your enzyme supplier or TCF.

This document will be updated as new and significant insights become available.

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