

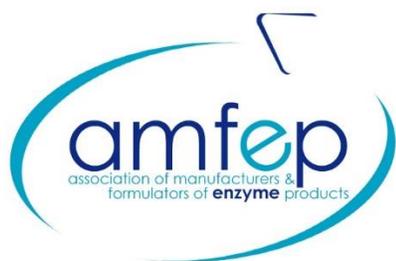


Industry Guidelines

On the Safe Handling of Enzymes in the Bakery Supply Chain



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

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

Fedima – Federation of European Union Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery and Patisserie Industries www.fedima.org

Any feedback on the content in this document is most welcome. Please contact the AMFEP or Fedima secretariats.

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List of Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
ACI	American Cleaning Institute
A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products / Association Internationale de la Savonnerie et les produits d'Entretien
AMFEP	Association of Manufacturers and Formulators of Enzyme Products
AVG	Average
BOS	Behavioural Observation System
BTPS	Body Temperature and Pressure, Saturated
CIP	Cleaning in place
CpK	Capability ratio
CV	Coefficient of variation
CVC	Central Vacuum Cleaning System
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
ELISA	Enzyme linked immuno-absorbent assay
Fedima	Federation of European Union Manufacturers and Suppliers of Ingredients to the Bakery, Confectionary and Patisserie Industries
FEV	Forced expiratory volume
FVC	Forced vital capacity
GLP	Good Laboratory Practice
GPIT	Guinea Pig Intratracheal Test
HACCP	Hazard analysis and critical control points
HEPA	High efficiency particle absorption which typically removes >99.995 % of particles
HSE	Health and Safety Executive (UK)

IBCs	Intermediate Bulk Containers
IgE	Immunoglobulin E
IUATLD	International Union Against Tuberculosis and Lung Disease
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
MCA	Multi-cause analysis
ng/m3	Nanogram per cubic metre
OEG	Occupational Exposure Guideline
OEL	Occupational Exposure Limit
PEFR	Peak expiratory flow rate
PIR	Problem investigation report
PPE	Personal Protective Equipment
PVC	Portable Vacuum Cleaner
RAST	Radioallergosorbent test
REACH	EU Regulation on Registration, Evaluation, Assessment and Restriction of Chemicals, 1907/2006/EC
RPE	Respiratory Protective Equipment
SDIA	Soap and Detergent Industry Association (UK)
SOPs	Standard Operating Procedures
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UCL	Upper Control Limit

Foreword

Flour has always been used within the baking industry, and for decades enzymes have also been widely used due to their valuable contributions to the quality of finished baked goods as well as fulfilling the need for sustainable ingredients.

Flour dust is known to cause allergy and “bakers asthma” when exposure is not well controlled. The allergy from flour dust is caused by one or more of the approx. 40 different protein allergens that are natural constituents of flour.

Enzymes are proteins and, similar to other proteins, may act as respiratory sensitizers if individuals are repeatedly exposed to airborne dust that contains them. Such sensitization may ultimately lead to respiratory allergy, but it is important to note that not all individuals who become sensitized to enzymes develop symptoms. Similar risks are posed by other ingredients used in the baking industry; e.g. wheat flour and other additives, which may also induce respiratory sensitization and allergy. Over the years several publications have described how flour and enzymes are capable of inducing respiratory allergy among the population that works in the baking industry.

However, it has also been demonstrated that the potential for this respiratory sensitization and allergy can be controlled by proper process controls, product formulation, and appropriate handling instructions to prevent airborne dust or aerosols.

AMFEP and Fedima have jointly developed this guidance document for the safe handling of raw materials and ingredients that contain enzymes; thereby providing the insight and tools to help safeguard the health of the workers in the bakery supply chain. These guidelines aim to cover the use of enzymes in all sectors of the baking industry but some sectors may be more fully described than others.

This document describes:

- Health hazards associated with enzymes
- Current regulatory framework concerning the use of flour and enzymes in the baking industry
- Management procedures required to ensure adequate controls and staff training
- Process and equipment design to minimise and maintain low exposure levels
- Air monitoring procedures to assess enzyme exposure levels
- Recommendations on health surveillance
- Enzyme allergy as a consumer issue.

These guidelines focus on how to reduce dust and how to avoid respiratory sensitization among the workforce. There are other hazards e.g. combustible dust which will need to be handled in the work place, however in these guidelines only the hazard of respiratory sensitization is addressed.

This document reflects the state of the technology and scientific understanding of dust control vis-a-vis flour and enzymes at the time of writing (2017). Therefore the approaches described will be subject to updates as technical advances and scientific understanding improves.

Furthermore, only the control of flour and enzyme exposure within the European baking industry has been addressed here. Although the general principles and recommendations are widely applicable, some of the guidance given may not be applicable to bakery production sites in other parts of the world.

The writing of this document has been very much inspired by the Guideline for the Safe handling of Enzymes in Detergent Manufacturing “Guidelines for the Safe Handling of Enzymes in Detergent Manufacturing” published by the International Association for Soaps and Maintenance Products (AISE, 2015). It is highly recommended that this guideline is consulted along with the additional enzyme safety tools represented on the AISE website for a more detailed understanding of the safe handling of enzymes in industrial settings.

Inspiration for this document has also been found in the initiatives from the Dutch “Arboconvenant” (sector agreement on working conditions) and “A Baker’s Dozen” from the Federation of Bakers in the United Kingdom. Reference to the following websites is recommended for further information:

<http://www.blijmetstofvrij.nl/handboek-stofbeheersing> (in Dutch) and
<http://www.bakersfederation.org.uk/> (in English)

The creation of this document is based on a joint initiative by the Association of Manufacturers & Formulators of Enzyme Products (AMFEP) and the Federation of European Union Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery, and Patisserie Industries (Fedima).

Useful links

- AISE: Safe Handling of Enzymes (Guideline, training materials, webinars)
<https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes.aspx>

- AISE: Guidelines for the safe handling of enzymes in detergent manufacturing (version 2.1, 2015). https://www.aise.eu/documents/document/20150603154418-aise-enzymes_safe_handling-v2-1-june_2015.pdf

1. Introduction

This document focuses on safe guidelines associated with dust from flour and enzymes in the baking industry. The consequences of uncontrolled exposure to flour and enzyme dust are generally well known. Health effects from uncontrolled enzyme dust exposures in the detergent industry were observed when they were first introduced into detergent products. As a result, several control measures were put in place to reduce exposures. The section below introduces enzymes and their benefits in baking as well as the potential hazards associated with the handling of enzyme products.

Enzymes are widely used in the baking industry due to their valuable and very specific activities; but what are they?

Enzymes form a special class of proteins being composed of the amino acid building blocks that are found in all other 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; 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 gastro-intestinal 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 technical (e.g. detergent, starch, textile, 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 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 and their contribution to finished product quality are mentioned in Table 1.

Table 1. Enzyme classes and corresponding functionalities in the bakery industry.

Enzyme class	Contribution
Fungal alpha-amylase	Flour correction: ensures desired end product characteristics such as volume, crust colour, and crumb structure
Lipase	Improves crumb structure and crumb colour
Phospholipase	Improves dough strength and stability, loaf volume and crumb softness
Xylanase	Improves dough stability, bread appearance and texture, superior volume of baked goods
Glucose oxidase	Improves gluten strengthening
Amyloglucosidase	Improves bread crust colour and bread volume
Maltogenic amylase	Improves moistness, softness and texture of baked goods
Protease	Reduces the strength of flour protein, thereby reducing mix time and elasticity and increasing the extensibility and softness of the dough.
Cellulase	Improves dough conditioning and nutritional profile in whole wheat or whole grain breads

Fungal alpha-amylase is the most commonly used enzyme in the baking industry and therefore most of the literature on bakery enzymes relates to this class; including knowledge related to the safe handling of enzymes in the baking industry.

Nevertheless, the same principles cover the safe handling of all other enzyme-containing materials used for baking.

Hazards associated with enzymes

Industrial enzymes have a low toxicity in humans; i.e. enzymes present no concern for endpoints like acute toxicity, genotoxicity, sub-acute and repeated dose toxicity, reproductive toxicity and carcinogenicity. (1)(2)(3) However, like many other proteins, enzymes may act as allergens via inhalation. A two-step process has to take place for the development of an inhalation allergy: initial **sensitization** followed by **elicitation**. (3)

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: Sensitized individuals may then develop an allergy, if they are repeatedly exposed to sufficiently high airborne concentrations of the allergen concerned. (4) 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.

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, and if such symptoms occur frequently at the workplace and only rarely at week-ends or during holidays, they may be the result of occupational enzyme exposure.

Allergy by inhalation caused by flour or 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 also similar. Some individuals are more prone to sensitization than others. Atopic individuals, i.e. persons already allergic to one or more of the common allergens, may develop a flour or enzyme allergy more easily than others. Not all atopic individuals will become allergic to enzymes or flour and non-atopic individuals may develop an enzyme or flour allergy if exposed to sufficiently high airborne concentrations on a regular basis.

Smokers have a markedly increased risk of becoming sensitized and developing allergy symptoms. (5) There is no scientific evidence that enzymes are associated with allergy caused by skin contact or ingestion. (6)(7)

In general, reducing flour and enzyme dust exposure in bakeries, flour mills and bakery ingredient manufacturers will reduce the likelihood of work related respiratory symptoms. Flour and enzyme handling activities that may generate 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 40 years of handling enzyme products in the detergent industry has proven that enzymes can be safely used in the workplace. This valuable experience and knowledge is now being applied to the baking industry to make it a safer place in which to work.

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Useful links

- General advice for bakers regarding COSHH (UK example)
<http://www.hse.gov.uk/coshh/industry/baking.htm>
- General advice regarding flour handling to avoid dust (UK example)
<http://www.hse.gov.uk/coshh/essentials/direct-advice/baking.htm>

2. Regulation OEL/OEG

At present, occupational exposure limits for only one enzyme class, Subtilisin, have been established by regulatory agencies. Subtilisin is a class of proteolytic enzymes that belong to EC 3.4.21.62 according to IUBMB Enzyme Nomenclature. A limit of 60 ng/m³, based on at least one-hour sampling, was set by the American Conference of Governmental Industrial Hygienists (ACGIH) and has been adopted by several countries, as shown in the table below.

Currently there are no regulatory requirements relating to particular exposure levels for other enzymes; with the exception of the EU legislation covering the technical applications of chemicals (REACH).

In the case of enzymes, a DMEL of 60 ng/m³ for occupational exposure has been proposed. This is now being used in EU REACH dossiers which propose recommendations regarding the adequate management of risks to human health. This DMEL has been established following a thorough retrospective review of occupational experience, correlating validated employee medical surveillance data against exposure records generated over an extended period of time (1).

At the time of writing it is known that the Dutch authorities have received a proposal to establish an OEL (Occupational Exposure Limit) for fungal alpha-amylase. However, no conclusion has yet been drawn. In addition, investigations are ongoing within the scope of REACH to evaluate worker's health and safety with regards to enzyme exposure. The conclusions drawn from these evaluations may affect industries *outside* the scope of REACH, e.g. the baking industry.

In addition to the levels set for enzymes; guidelines and limits are also set in the EU for overall dust levels, including flour. The current guidelines and limits known by the authors at the time of writing can be seen Table 2 and Table 3.

The American Conference of Governmental Industrial Hygienists has recommended a Threshold Limit Value for inhalable (flour) dust of 0,5 mg/m³ (8 hour).

Overview of several countries via the Social and Economic Council of the Netherlands (SER) : <https://www.ser.nl/nl/grenswaarden/meelstof.aspx>

Table 2. Guidelines and limits for (flour) dust levels*

Country	Type of guideline or limit	Level and average	Legislation/Publication and date
Austria	MAK (= Maximale ArbeitsplatzKonzentration) for Cereal Flour dust (Getreidemehlstaub),	4 mg/m ³ TMW (=TWA), and 8 mg/m ³ KZW (=STEL, 30')	https://www.arbeitsinspektion.gv.at/inspektorat/Arbeitsstoffe/Grenzwerte/#5 and.... https://www.ris.bka.gv.at/Dokumente/Bundesnormen/NOR40135110/II_429_2011_Anhang_I_2011.pdf
Belgium	Total Limit Value for flour dust	0,5 mg/m ³ (8 hour average)	Royal Decree 11 March 2002 http://www.werk.belgie.be/defaultTab.aspx?id=616 Belgisch Staatsblad 19 mei 2009; N. 2009 - 2065
Denmark	Dust (organic matter)	3 mg/m ³	https://arbejdstilsynet.dk/da/regler/at-vejledninger/g/c-0-1-graensevaerdi-for-stoffer-og-mat
Finland	OEL for flour dust	2 mg/m ³ (8 hour average)	http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/79109/08_2016_HTP-arvot_suomi_22122016_nettilkansilla.pdf?sequence=1
France	VLEP Inhalable dust (valeurs limites d'exposition professionnelle)	10 mg/m ³	http://www.inrs.fr/media.html?reflNRS=ED%20984
Germany	Arbeitsplatzgrenzwerte	4 mg/m ³	https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Gefahrstoffe/Arbeiten-mit-Gefahrstoffen/Gefahrstoffverordnung/Gefahrstoffverordnung_node.html (TRGS900)
Netherlands	OEL	Currently investigating the possibilities for establishing a limit value of 1,2 mg/m ³ (8 hour).	The committee has advised the ministry of Social Affairs to establish a Occupational Exposure level of 1,2 mg/m ³ (8 hour). It is expected that this will be published in Q4 in the 'staatscourant'. After publishment,the OEL will be effective. http://www.ser.nl/nl/publicaties/adviezen/2010-2019/2016/grenswaarde-

			meelstof.aspx
Norway		3 mg/m ³ (8 hour average)	Administrative normer for forurensning i arbeidsatmosfaere; 13. utgave november 2009; Arbeidstilsynet
Spain		4 mg/m ³ (8 hour average)	Límites de Exposición Profesional para Agentes Químicos en España, Mayo 2010; Ministerio de Trabajo e Inmigración, INSHT
Sweden	Level Limit Value	3 mg/m ³ (8 hour average) Inhalable dust	Latest info from 2004
UK	Exposure limit Flour dust	10 mg/m ³ (8 hour average) 30 mg/m ³ (15 min. average)	Publication EH40/2005, reviewed in 2011 http://www.hse.gov.uk/pubns/books/eh40.htm http://www.hse.gov.uk/pubns/preced/eh40.pdf

*These levels may be subject to future revision.

Table 3. Subtilisin exposure regulatory limits (2).

Country	Value – ng/m ³	Time Limit
Argentina	60	Ceiling
Australia	60	“Peak Limitation”
Belgium	60	TWA
Canada ¹	60	Ceiling
China	15 30	TWA STEL Only applicable for the Detergent Industry
Colombia	60	Ceiling
Denmark	60	Ceiling
Finland	15 60	TWA (8hour) STEL
Iceland	60	STEL
Indonesia	60	Ceiling (High vol. Sampling)
Ireland	60	TWA (8 hour), STEL (15 min.)
Israel	60	Ceiling
Italy	60	Ceiling
Malaysia	60	Ceiling
Mexico	60	Ceiling
New Zealand	60	Ceiling
Nicaragua	60	Ceiling
Norway	60	Ceiling

Peru	60	Ceiling (High flow sampling)
Portugal	60	Ceiling
Singapore	60	STEL (15 min.)
South Africa	60	Ceiling
Spain	60	STEL (15 min.)
Sweden	90 (3 glycine units/m ³ *)	Occupational Ceiling Limit
Sweden	30 (1glycine unit/m ³ *)	Occupational Level Limit**
Switzerland	60	STEL (15 min.)
UK	40	TWA based on eight-hour sampling
U.S. - Workplace - ACGIH	60	Ceiling (STEL)
U.S. - Federal, Workplace - NIOSH	60	60 minute average (STEL)
U.S. State - California	60	≥ 60 minute average (STEL)
Uruguay	60	Ceiling
Venezuela	60	TWA

¹ Including all 10 provinces and 3 territories

* 1 glycine unit is approximately equivalent to 30ng of pure Subtilisin

** “Occupational Level Limit” not defined in regulation

TWA: Time weighted average

STEL: Short term exposure limit

These levels may be revised in the future.

The long established limit of 60 ng/m³ for **pure Subtilisin** (proteolytic enzyme) as originally set by ACGIH has been adopted by the majority of countries as illustrated in the table above.

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2. AISE: Guidelines for the safe handling of enzymes in detergent manufacturing (version 2.1, 2015). https://www.aise.eu/documents/document/20150603154418-aise-enzymes_safe_handling-v2-1-june_2015.pdf

3. Management and Training

3.1 Management

In every working environment employers are responsible for protecting the health of their employees. 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.

Most countries have regulatory requirements in place to protect the health and safety of employees. Within Europe these requirements are under continuous evaluation in order to protect the right of all employees to work in a safe environment; setting a strict legal duty for management to provide safe conditions of employment.

Even though management faces the majority 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.

Risk management measures should always be based on a **hierarchy of controls (Figure 1)**. This means that the exposure should primarily be prevented by eliminating or substituting the hazard. If this is not possible then exposure should be controlled by isolating the hazard or reducing it by means of engineering 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 **personal protective equipment (PPE)**.

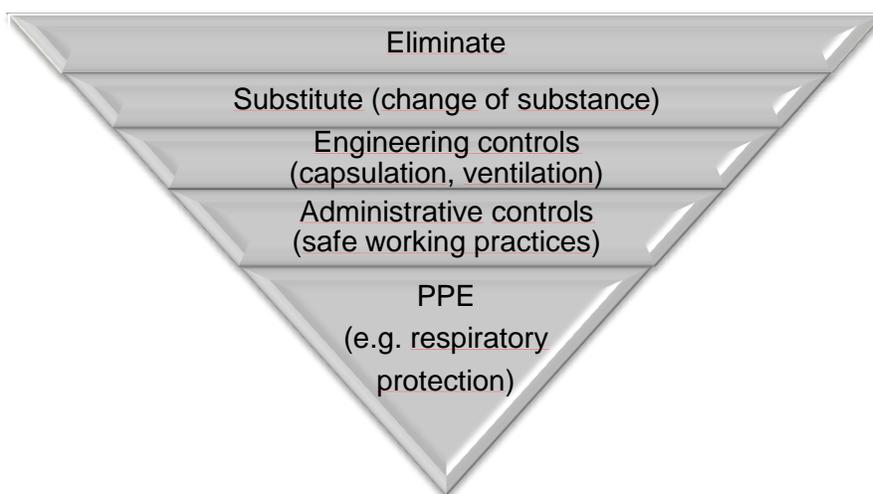


Figure 1. Risk measurement hierarchy.

Risk management processes should include the management of chemicals in the workplace. The **REACH regulation (1907/2006)** requires 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 to prevent similar incidents happening again.

3.2 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 professionalism. All workers handling powders should also have training in the potential hazards arising from flour dust and other bakery ingredients (such as enzymes) and the appropriate precautions to take when working with these materials. 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, standard instructions and emergency instructions. Everyone attending the site for the first time should be informed and/or trained about the basics of enzyme safety during their induction. Training should then be continued over time on a regular basis, and always when significant changes to processes or raw materials are made. Although basic elements of Health and Safety training are common to all, companies should augment this by planning their own training programs based on their specific needs.

Documenting the delivery of all training is as important as the monitoring of its comprehension. 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 about the content of training immediately after the event in addition to collecting it at a later date, once the new knowledge has been in use.

From the health perspective it is important to inform everyone who might be exposed about hazards, such as respiratory sensitizers. For example, standard operational procedures should be communicated to all staff so that they understand how, as well as why, they should avoid any unnecessary exposure. Even small things such as the correct way to handle empty raw material bags and packaging 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 personal protective equipment (PPE): for example

how to dress, undress and contain PPE's properly; and the key elements of how to maintain PPE's; including cleaning and checking their condition for wear and tear. Following the basic training for PPE it is essential for everyone to have the opportunity to test the effectiveness and the actual level of protection that the equipment gives. This can be done by fit testing of respiratory protective equipment and practice in a controlled environment

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 material for training when something new is observed or 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.

3.3 Bakery Schools

AMFEP and Fedima strongly encourage every bakery school throughout Europe to include training about flour and enzyme dust 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 flour milling or bakery industries.

Multimedia resources

There are many good resources available for flour and enzyme dust awareness on the internet. These include:

In English

<http://www.bakersfederation.org.uk/wp-content/uploads/BAKERS-DOZEN-April-2016.pdf>

In Dutch

<http://www.blijmetstofvrij.nl/>

Also: "*Blij met Stofvrij!*" YouTube channel

<https://www.youtube.com/channel/UC8o849iqLYBLnXg8NzDH8Xg>

In Finnish

https://ttk.fi/files/4648/Jauhopolyopas_LoRes.pdf

In Swedish

<http://www.prevent.se/bransch/industri/livsmedelsindustri/bageri/>

4. Control of exposure during the handling of enzymes in the bakery supply chain

4.1 Introduction: Key strategies for reducing enzyme dust

The bakery industry has been working for many years on effective strategies to minimise the exposure of employees to flour dust. Guidelines have been thoroughly investigated and restrictive flour dust limits have been set.

However, with the ever increasing use of microbial enzymes in the bakery production chain and with the increasing awareness of the potential health effects of enzyme dust inhalation, the methods to prevent dust formation and the guidelines on dust levels will need to be continuously reviewed and amended accordingly.

A series of well-established engineering controls and operational procedures have been developed over many years by other industries, such as the detergent industry, to prevent the exposure of employees to enzymes. These are now considered to be best practice and applicable over different industries; for example during the manufacture of flour, bakery ingredients/improvers; and in the artisan and industrial bakery chain. These are complementary elements, and each should be in place if proper control is to be achieved. These key elements are:

- The prevention of dust formation by plant design.
- The prevention of aerosol formation (or dried-in deposits) by plant design.
- Containment at the source of dust/aerosol formation, principally via the use of completely closed systems within the bakery chain.
- Avoidance of routine and uncontrolled spillage throughout the complete process.
- Appropriate design of equipment used in the bakery production chain.
- Proper training and education of production staff using clearly described procedures, guidelines and standard operating procedures (SOPs).

Based on the hierarchy of controls, the following control measures can be considered in order to prevent exposure

- Elimination or substitution of risk-prone materials and ingredients: the most effective step to prevent flour and enzyme dust formation. Due to the fact that flour and enzymes are vital ingredients in any baking process that will be considered in this document, this measure will not be considered further.
- Use of enzymes in low/no dusting formats such as granulated and/or liquid products rather than (spray dried) powder products
- Isolation, enclosure and ventilation: all these measures are reflected in the use of closed systems for transporting & storage (supply chain), and the blending and mixing of wheat flour and additional ingredients, including enzymes.
NB: this measure may only be applicable in larger manufacturing units and large volume production operations.
- Mechanical control measures including local exhaust ventilation, vacuum cleaning and protective equipment.

- Respiratory Protective Equipment (RPE) or Personal Protective Equipment (PPE) should be considered as a last resort of control; for example, in specific situations with high risk of exposure or in case of emergencies. Face masks that are in common use to protect against dust inhalation offer limited protection against enzymes. A risk analysis should be conducted to define in which production areas and in which circumstances RPE and PPE should be used.

This document reflects the state of the art on enzyme dust and aerosol prevention within the bakery chain at the time of writing (2017), taking into account production plant schemes and any relevant information received from the milling industry, bakery ingredient blenders, improver producers, industrial and artisan bakeries across Europe. Whilst the general advice is widely applicable, some of the guidance given may not be applicable to specific production sites in other parts of the world.

4.2 Enzyme quality and format

Historically, the baking industry has used enzymes produced in **powdered** form. These have gradually evolved towards the manufacture and use of **granulated** or **liquid** formulations in order to reduce the risk of dust creation and inhalation.

Powdered enzyme products have the smallest particle size and pose the greatest risk of dust creation during handling. Typically, the particle size in a powdered enzyme formulation is between 10 and 50 µm; consequently powdered enzyme products may easily become airborne resulting in a high risk of exposure. This exposure may be 10 – 200 times higher than that from granulated enzyme products. (1)

It is for this reason that enzyme products for the baking industry are becoming more frequently supplied as **granulates** of various forms as, from a safety point of view, this is a preferred option to powdered formulations. Enzyme granulates can be agglomerated enzyme particles, single enzyme particles with a relatively large particle size, or enzyme particles that have been coated with another material so that the enzyme core is not exposed. Granulated enzyme products are now available in sizes ranging from the smallest granulates between 50 and 250 µm, to the larger granulates between 300 and 500 µm. The perception within the baking industry is that the smaller granulates are more easily dispersed in flour giving better homogeneity in mixing. The airborne exposure from granulated enzyme products during handling will depend on the chosen size of granulation, and can vary by up to a factor of 10. It is very important that granulated enzyme products are handled, transported and mixed in such a way that protects the integrity of the granules. If they are crushed during one of the processes, smaller enzyme particles will be released and airborne enzyme dust may be generated.

Liquid enzyme products are also used within the baking industry, but their use is not currently widespread.

When handling a liquid enzyme formulation it is important to ensure that wet aerosols (mists) are not generated. This can occur during dosing, mixing or transport if open equipment or

vigorous actions are being used. It is generally considered that airborne exposures from liquid products are more easily controlled than that of dry enzyme products. Furthermore, the handling processes for liquid enzyme formulations may give rise to dried liquid deposits. When this occurs, enzyme-containing dust may be formed at these sites.

4.3 Supply Chain of enzymes and enzyme- containing bakery powders

4.3.1 From enzyme delivery to finished bakery products

The choice of supply unit is often very strongly influenced by cost, size, availability, transport, the options for handling and discharge, and the disposal of the empty packaging. The entire supply chain process could be considered as a highly relevant step within the framework of potential enzyme exposure and enzyme dust control through the bakery chain.

Firstly, wherever they are available, raw materials and bakery ingredients should be ordered according to low dust specifications made for all these products. These specifications must be set by the buyers and based on critical evaluations of potential dust levels using well established and accepted methods.(2)

Secondly, the choice of supply units (packaging) can have a major impact on potential dust or aerosol formation during transport, storage, loading and discharge or re-loading of the materials under consideration. For example, and paper bags can be damaged during transport or storage, which could lead to spillages and consequent dust formation. However, there are advantages with big bag discharge systems that are equipped with ventilation to control exposures during unloading.

The selection of supply unit type also impacts on a production environment. Specifically, it will determine the method of transport inside the production unit; and the method of filling, refilling and emptying of silos. Therefore, the choice for a specific supply chain-unit needs to be considered in the context of strict procedures in terms of transport, stacking and general use (load – unload) in order to prevent unwanted damage to the different packaging materials used. Recommendations below can apply to any stakeholder within the entire bakery production chain, from enzyme supplier to artisan/industrial bakery. Sections below will focus specifically on different supply chain packaging, storage considerations and disposal of empty supply packaging.

4.3.2. Supply Units

4.3.2.1 Powdered and encapsulated enzymes may be supplied in:

- Returnable Heavy Duty Rubber/PVC Big-bags
- Disposable Big-bags with a fixed / removable polythene liner

- Intermediate Bulk Containers (Rigid IBCs)
- Polythene Lined Cardboard Kegs
- Metal or plastic drums

4.3.2.2 Liquid Enzymes - or slurries - may be supplied in:

- Intermediate Bulk Containers (Rigid IBCs)
- Metal drums
- Plastic drums
- Batch size unit dose containers (5 – 25 litre)

4.3.2.3 Flour & Powdered bakery improvers – may be supplied in:

- Silo-to-silo by road tankers
- Paper bags with PE or COEX in-liner
- Multilayer (COEX) plastic bags
- Disposable/Returnable Big-bags with a removable / fixed multilayer plastic liner

4.3.2.4 Liquid bakery improvers – may be supplied in:

- Road Tankers
- Intermediate Bulk Containers (Rigid IBCs)
- Plastic drums, Jerry Cans or batch size unit dose containers (5 – 25 litre)

4.3.3 Storage of supply units

As a first recommendation, the storage of enzymes or enzyme- containing raw materials in a warehouse should be organized in such a way that surrounding traffic is minimized in order to prevent damage caused by passing vehicles. The storage locations should be signposted with proper hazard signs. It is imperative that damaged packaging materials are removed from the supply chain immediately. If the damaged packaging results in a spillage, only trained operators or emergency response teams should be called upon to contain the spill and remove the damaged supply units. Proper personal protective equipment (PPE) must be available in any storage facility where potential dust generating products are stored. Cf. sections 4.4.4 and 4.6.5 of this document.

In terms of storage organization; palletization of multilayer bags, buckets, drums, jerry cans, etc. should be evaluated and controlled in order to avoid packaging damage. Large supply units (industrial containers and pallets) of some bulk raw materials, semi-finished goods or finished goods may be “double stacked” to save space during storage and/or transport; i.e. where one supply unit is stacked directly on top of another one.

However, the principle of “double stacking” should only be adopted provided that no physical damage to the packaging and to the material itself (e.g. granulated enzymes) occurs. Stacking height studies, pallet weight control, and stretch foil studies should be used to determine whether the supply units are strong enough to endure double stacking without damage, and also whether the granulation/encapsulation of the enzyme material within the unit can maintain its integrity under such weight loading. Both the containment provided by the supply unit and the encapsulation/granulation of the raw material are fundamental exposure control measures for enzymes and these must be preserved at all cost. Therefore the double stacking of enzyme supply units must only be carried out if there is no risk to the integrity of the supply unit; nor any risk to the format of the contents.

The above recommendations should be applied to all types of storage processes and packaging materials considered for the storage of enzymes and of enzyme containing products. Partly used packs should be carefully closed, resealed and stored in such a way that their contents are disturbed as little as possible. They should be stored in an area where any accidental spillage may be cleaned up rapidly and safely.

4.3.4 Disposal of empty supply units

There are a few options for dealing with empty supply units:

- Return to the packaging supplier for disposal or re-use
- Disposal as waste
- Recycling at a local facility where these exist

Whichever option is adopted, contaminated packaging waste should be safely enclosed within another container to ensure safe handling at all downstream stages of the disposal operation. For example; empty paper bags used for flour, pre-mixes and improvers should be put in a clean polythene bag (Figure 2) or cardboard box; or should be palletized and stretch wrapped in a closed plastic container.

Any preparation of packaging waste for disposal, for example compaction, should be carried out under controlled conditions, preferably in an isolated discharge area, by operators wearing suitable respiratory and personal protection. Guidance on respiratory and personal protection may be found in Chapters 5 and 8.



Figure 2. Automatic disposal unit for empty (used) product bags in a PE-liner.

In artisan/craft bakeries, empty bags that previously contained flour or powder bakery mixes/ingredients are often re-used for the storage of powdery residues from bakery processes. These bags may also contain residues from the original contents of the bag, and these could easily create airborne dust. If the re-use of these bags is unavoidable, then all precautions necessary should be taken to minimize any dust formation, and the bags should be closed using a clip-on seal to prevent any escape of dust as far as possible. It is preferable that raw material bags be removed from the bakery environment as soon as possible after emptying, and disposed of in an appropriate manner.

4.3.4.1 Direct Disposal

The majority of empty supply units throughout the bakery chain are directly disposed of through the waste chain. The chosen disposal route may depend upon local or national legislation, or availability of suitable incineration and recycling facilities, landfill areas and costs.

Commonly used packaging materials with direct disposal throughout the bakery chain are:

- Paper bags with PE or COEX in-liner / Multilayer (COEX) plastic bags
- Plastic bag (PE / COEX) in carton board box
- Plastic, hard cardboard or metal drums
- In-liner materials for industrial solutions

When contaminated packaging is being disposed of as “special waste” off site, it is imperative that only licensed contractors and licensed disposal facilities are used in order to prevent any environmental contamination.

4.3.4.2 Return to the supplier

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

Return for re-use is practical for:

- Returnable Bag-in-Plastic Containers
- Intermediate Bulk Containers (IBCs)
- Metal drums

- Plastic drums

For supply units that contain removable polythene or COEX-liners, carefully remove the inner liner as it may need to be treated as contaminated waste (cf. Chapter 4.6 and 4.9.2), providing that the outer supply unit remains uncontaminated throughout its use. A clear communication with the packaging supplier regarding dust/aerosol formation and enzyme exposure can help to avoid unnecessary exposure risks.

Before returning rigid IBCs [plastic or metal] to a supplier it is preferable to denature the residues left inside the containers by placing them outside the production facility and washing them inside and out with hot water at 80°C. The rinse water inside the IBC should be maintained at 80°C for 30 minutes to ensure the enzyme is denatured prior to draining according to local environmental regulations. A full risk assessment and documented procedure is required, and respiratory protection must be used as a safeguard during this activity. Cleaning IBCs with high pressure equipment must be avoided to prevent any formation of concentrated aerosols that may contain enzyme residues.

Recycling at a local facility:

The disposal of smaller packaging containers; e.g. paper bags that have contained bread improvers, should be done in an environmentally friendly manner. After ascertaining that local recycling facilities exist, the empty bags should have the inner liner carefully removed and placed in a separate container for disposal. The paper may then be recycled. It is recommended that this operation is performed:

- In an area that is separate from the main working area of the factory, preferably with suitable ventilation/extraction
- By personnel who are well aware of the hazards
- By personnel that are wearing the appropriate PPE

Where special disposal facilities do not exist, then packaging should be disposed of in such a manner that it does not expose the waste management worker to enzyme dust or liquids.

4.4 Use of enzymes and enzyme containing products in bakery manufacturing

4.4.1 General Considerations

Buildings and factories throughout the bakery chain should be designed so as to provide an environment that is easy to maintain in terms of hygiene; and which minimizes the risks of dust formation and spillages where bakery powders are used; or minimize the generation of aerosols where liquid enzyme preparations are used by avoiding spraying, splashing, or spillage.

Any area of the environment where it is difficult to remove spillage or settled dust, due to restricted access or location, will act as a “reservoir” for spilled enzymes or enzyme residues and therefore provide a constant background of airborne dust and enzymes. During

maintenance operations/ refurbishment, etc. this “reservoir” may also give rise to significant peak exposures and/or personal contamination when the dust is disturbed, or when periodic cleaning is attempted.

It is therefore essential that clean design principles are always used for a bakery working environment. The blueprints for a new bakery or plant should always be designed taking into account following rules:

- 1) The environment should be easily accessible for engineering maintenance, cleaning, and hygiene.
- 2) The environment should minimize the risk of dust formation, granulate damaging, and spillage in powder handling plants or bakeries.
- 3) The environment should minimize the generation of aerosols in liquid handling plants or bakeries by avoiding spraying, splashing, or spillage.

In order to examine the potential of each of the possible dust-forming or possible aerosol-forming operations throughout the different processes used; this section will focus on a wide overview of recommendations that should be taken into account by each of the stakeholders present in the bakery production chain. These recommendations are not exhaustive.

This section will cover 4 main areas:

- Flour Millers
- Bakery Ingredient and Improver Suppliers
- Industrial Bakers
- Smaller Bakeries / Artisans

There are some common considerations and steps that are applicable to all of the above sectors. These are:

- Building design
- Plant and equipment
- Powder and liquid handling equipment (transferring and discharging) methods

4.4.2 Building design considerations

- **Walls** should be smooth, and sealed (e.g. painted), or clad in a smooth material that is easy to keep clean.
- **Skirting** (or baseboards) should be rounded.
- **Fittings** such as shelves, cupboards, etc., should be kept to a minimum and be positioned in such a way that they can be easily cleaned. Old fittings and fixtures that are no longer necessary should be removed.
- **Ceilings** should be smooth, and consideration given to access for periodic cleaning.
- **Floors and stairs** should be non-slip, but smooth and easy to clean. They should be painted a dark colour to make any spillage of powder or encapsulates easy to see. Open metal gridding should not be used as this is difficult to clean and allows spillage to percolate through to other levels.

- **Windows:** complex window frames should be avoided, as these act as dust traps if they are awkward or difficult to keep clean.
- **Beams / girders / equipment supports / ductwork** should be tubular shapes instead of boxed or I-Beams, with clean design [curved] column feet. Consideration must be given to access for periodic cleaning, and/or provision of specialist cleaning tools.

4.4.3 Plant and Equipment considerations

Process equipment in bakeries and powder plants should be designed to minimize dust and / or aerosol formation and ‘wear and tear’ of raw materials. Enzyme liquids or slurries pose a risk of dust generation if they dry out, and a greater potential risk for aerosol creation. Therefore, process and packing equipment should be designed to control this risk by effectively containing liquids without leaks, and minimizing the chance of spraying and/or splashing of liquids.

The interaction between employees and the manufacturing plant is critical. These interactions, or at least the frequency at which they need to occur, should be eliminated or reduced as far as possible; for example:

- Using “gentle” tangential transfer points. Soft and/or angled surfaces and restricted drop heights all help to avoid splashing of liquids onto surfaces [including liquid surfaces].
- Design efficient enclosures to fully contain any spillage and liquid splashes within the equipment.
- Use internal spill pans/trays to collect and fully maintain spillage within the equipment with suitable spillage removal designed in.
- Design access doors that can be opened without causing spillage to the floor. Sliding doors are best: hinged doors tend to pull air and airborne material out of an enclosure when the door is opened.
- Incorporate product reject positions within the enclosure.
- Incorporate proper sampling points into plant and equipment.
- Schedule machine/production in such a way as to avoid frequent stoppages and manual interventions. This measure will improve overall plant efficiencies too.
- Use CIP Technologies [Cleaning in Place] wherever possible

4.4.4 Powder and liquid handling equipment considerations

Belt Conveyors (Powder Plants & Industrial Bakeries)

- Belt conveyors should be fully enclosed under ventilation control with a recommended inward velocity of 1m/s at all openings.
- Safe collection of spillage should be built into the design to reduce the need for routine entry for cleaning.
- Transfer points should also be fully enclosed and ventilated as above. Any provision for access should be lockable if not intended for use by unauthorized employees.

- Any doors or openings that are necessary for routine access should be taken into consideration when specifying the level of ventilation control. Adequate ventilation should be applied to ensure that no dust turbulence occurs

Storage Tanks, Silos, Hoppers (Industrial Bakeries, Powder Plants)

- The vent pipes on any tanks, vessels or hoppers into which enzymes / enzyme products are discharged or collected must be controlled to prevent the release of enzyme dust into the workplace. This may be achieved by use of passive HEPA filtration on the displaced air if it is vented into the building, or by directing the vent pipe into the local exhaust ventilation system.
- In the event of the latter option, the vent pipe can be de-coupled from the ventilation system to prevent excess negative pressure from developing within the vessel. Depending on local legislation, the vent may alternatively be exhausted externally, without filtration, at a suitable location to prevent re-entry of the exhaust back into the building.
- All dust control filters should be fitted with an automatic cleaning device for the filter medium.

Pipes (Artisans, Industrial Bakeries, Powder Plants)

- Rigid pipes should be leak free. Welded joints are preferred.
- Other options are compression joints and flanges. If flanges are used, these should be covered with a flange protector to prevent the development of sprays if the flange/seal fails.
- Flexible pipes for unloading should be robust enough to withstand abrasion and bending.
- Couplings for flexible discharge lines should be dry-break or cam-lock type to prevent spillage from pipe work that is disconnected.

Pumps (Industrial Bakeries, Powder Plants)

- Preferred pumps for transfer and dosing are based on a leak free mechanical seal design i.e. magnet drive or sealed motor and pump combination.
- Pneumatic pumps may be used but exhaust air must be vented outside the building away from any air intakes, or filtered through a HEPA filter prior to discharge.
- Isolation valves should be fitted to the feed and delivery side of the pump for spill free removal during maintenance.
- Single diaphragm pumps used for liquid enzymes (or intermediate enzyme products) should only be used if the exhaust air is vented to the outside (away from any air intake) as minor faults in this type of equipment can generate significant aerosol concentrations in the exhaust air. Some types of air driven multiple diaphragm pumps may be acceptable due to the very low risk of the simultaneous failure of multiple diaphragms. Their use should be backed up with regular maintenance to ensure reliability, and the use of a detection system to detect a faulty membrane.

- HEPA filters may be used as a secondary protection on the air exhaust. For specifications, please refer to section 4.11.1 of this document.

Tank Vents (Artisans, Industrial Bakers, Powder Plants),

- Depending on the local legislation, displaced air from tanks/vessels that is vented back into the workplace must be controlled by HEPA filtration.
- Air vented outside should be vented well away from any air intake, and can be done so without filtration.
- It is not recommended to vent back into the workplace, even with HEPA filtration, as there may still be an exposure risk. This should be avoided when dealing with CMR's and respiratory sensitizers.

4.5 Flour Millers

The process steps in a flour mill are schematically outlined in Figure 3. This scheme shows the various steps in the process that produces a finished product. In blue colour are the various process steps where flour dust and enzyme dust can possibly be formed.

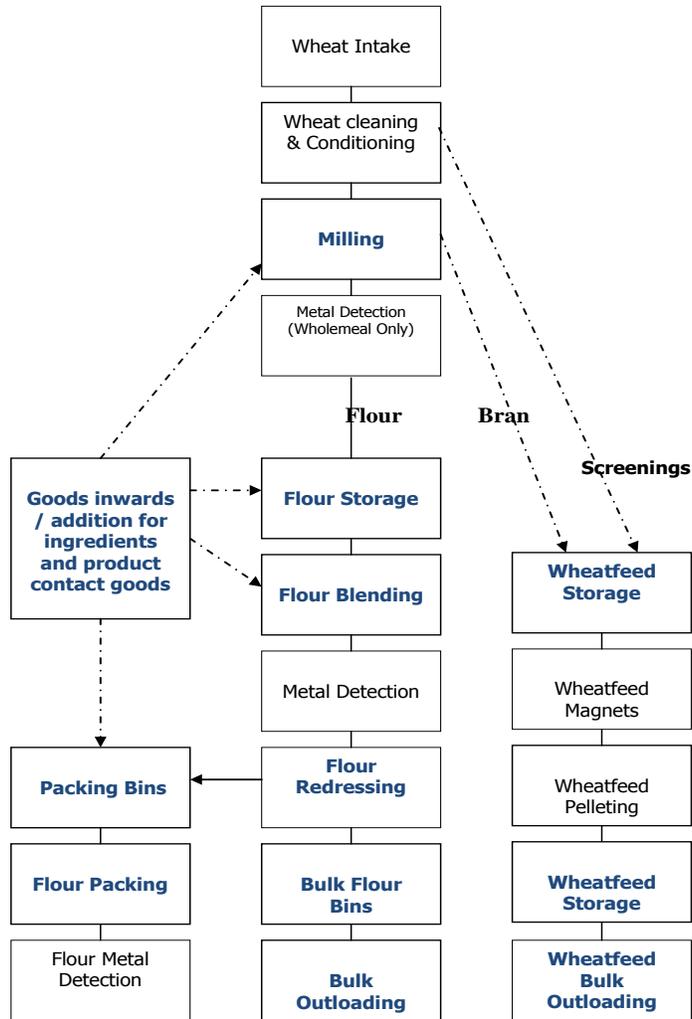


Figure 3. Flow chart of different operations at a flour milling production unit.

In flour mills the main raw material is wheat; but enzymes, improvers and gluten are often added in order to condition the flour for specific purposes, or to make multipurpose flours.

The cleaning of wheat is an automated process. Pre-treatment and conditioning is also automated, but these are process in which limited or no dust is released. Enzyme addition to the flour normally takes place after or at the end of the milling process. This addition is usually from storage bunkers, which are filled and refilled from bags.

Cleaning the mill: Rollers, sieves, sieve frames and other equipment needs to be exchanged, replaced and cleaned very regularly; and the floors also need to be cleaned frequently. These cleaning procedures can lead to significant dust formation, especially the replacement of sieves, rollers and sieve frames. These procedures should take place under local exhaust ventilation.

4.6 Bakery Ingredient and Improver Suppliers

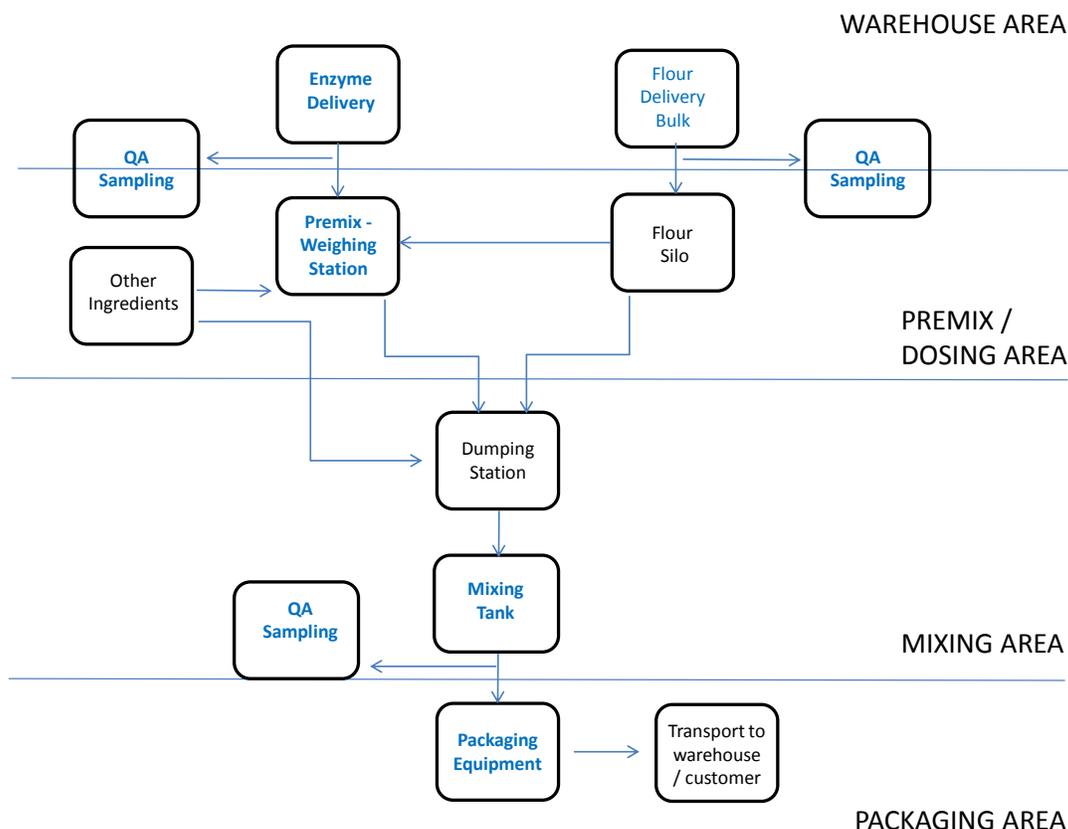


Figure 4. Flow chart of different operations at a bakery improver production unit.

Ingredient blends, improvers, concentrates, mixes, etc. often contain enzymes and are usually manufactured using standard blending operations. Figure 4 shows the various steps in the process that produces a finished blended product. In blue colour are the various process steps where enzyme dust is likely to be formed.

Transport and storage are not coloured blue, but it must be kept in mind that packs or bags may be damaged during transport and storage, leading to spillages and potential dust formation.

4.6.1 Weighing

In large blending operations, ingredients are weighed automatically from silos and closed dosing systems before being added to the blender. However, in smaller blending and mixing operations this is usually not possible so that manual weighing is necessary.

Due to the nature of powdered and granulated ingredients, the transfer of enzyme-containing products from a bag or box to a weighing bowl via a hand-scoop can generate high levels of dust. This work should be done in a weighing cell (Figure 5), where air is constantly being removed by local exhaust ventilation. This can either be a 'down flow' booth, or a 'back flow' booth (as in the picture). However, even when using flow booths, it is highly recommended that the operators use respiratory protection equipment (RPE) to minimise dust inhalation and to comply with the use instructions given by the supplier of the flow booth.



Figure 5. Examples of (pre-) weighing units for enzymes.

4.6.2 Blending

Industrial blenders exist in a wide variety of forms (ribbon, conical, rotating, horizontal, etc.) and sizes (1000 – 5.000 litre). A few different types are shown in Figure 6.



Figure 6. Examples of industrial blending stations for bakery improvers & mixes.

Most blending operations are closed systems, although this is highly dependent on scale. In a closed system there will be no dust problems during the actual blending step, but they can occur during the filling and emptying of the blenders.

Filling a blender (Figure 7) can also be done using closed systems, but this is purely dependent on the size of the blender. A blender which is smaller than 500 kg in size will generally be filled using bags and boxes which are emptied manually:



Figure 7. Examples of dumping stations.

This is the process step where dust formation is virtually unavoidable. In spite of clearly described working procedures (as described in [Blijmetstofvrij](#) and in [Bakers Federation: Bakers Dozen](#)) there will always be some dust formation during this operation and therefore it is strongly recommended that operators use respiratory protection equipment (RPE) and/or have strong local exhaust ventilation above and around the entrance of the blender.

The blending operation itself occurs in a closed system. In the case of blending dry non-fat based ingredients some oil, or a comparable de-dusting system, is usually added to the mix.

When fat based ingredients are used in combination with dust generating products such as flour and enzymes, the resulting mix will be much less likely to create dust.

4.6.3 Packing

After blending the product is delivered into a bag (in box), a paper bag, a big bag or into even larger packing units. The emptying of the blend into paper bags, or plastic bags in a box, is another step where high levels of dust can be generated and where LEV in combination with RPE is strongly recommended.

Again this delivery can be done using a fully closed system, but more often occurs through an open outlet of the blender. When a closed system is used, the most critical step with regard to dust formation is the removal of air from the bags or sacks before they are sealed. This must be done very gently using well defined procedures. When an open outlet is used, it is highly recommended for operators to use RPE (Figure 8), and process ventilation is also highly recommended. Cleaning of the packing area after filling the boxes should be done after each batch using vacuum cleaners that have been equipped with the appropriate HEPA filters.



Figure 8. Type of respiratory mask only suitable for low-risk operations based on the results of the risk analysis.

4.6.4 Waste management

Regarding waste the most critical issues are the complete emptying of bags (big bags and paper bags) and the compression of the waste in waste presses or garbage containers.

- Emptying of paper bags should be carried out with utmost care according to well established and precisely described procedures in order to prevent any dust formation as far as possible (Figure 9).
- Emptying of big bags and containers into silos should happen only through carefully controlled and properly closed connections.
- Liquid IBC containers: regardless of whether these will be disposed of or sold on; washing with high pressure hoses must be avoided as large concentration of aerosols containing enzyme residues could easily be formed by this operation.



Figure 9. Ventilation principles for paper bag emptying operation (preferably through the back of the unit).

4.6.5 Storage of finished goods

If they are handled carelessly, big bags and paper bags can be damaged during transport and storage and this could lead to spillages and unnecessary dust formation. The type of supply units used in a production environment also determines the way that storage bins and silos are filled and refilled.

With regards to stacking, the storage of big bags and regular paper bags needs to be controlled by strict procedures in order to prevent damage to the packaging unless they are specifically designed to be stacked. Where bulk containers, drums, jerry cans and other solid packaging materials are used this problem is less prevalent.

Storage in a warehouse needs to be organised in such a way that surrounding traffic is minimized in order to prevent damage caused by passing vehicles. The storage locations must be signposted by proper hazard signs. Emergency procedures must be in place in case of spillage and proper personal protective equipment (PPE) must be available in any storage facility where potential dust generating products are stored.

4.7 Industrial Bakeries

In industrial bakeries the whole process of dough preparation, pre-proofing, moulding, proofing, baking and packing closely resembles that of artisanal bakeries, as can be seen Figure 10.

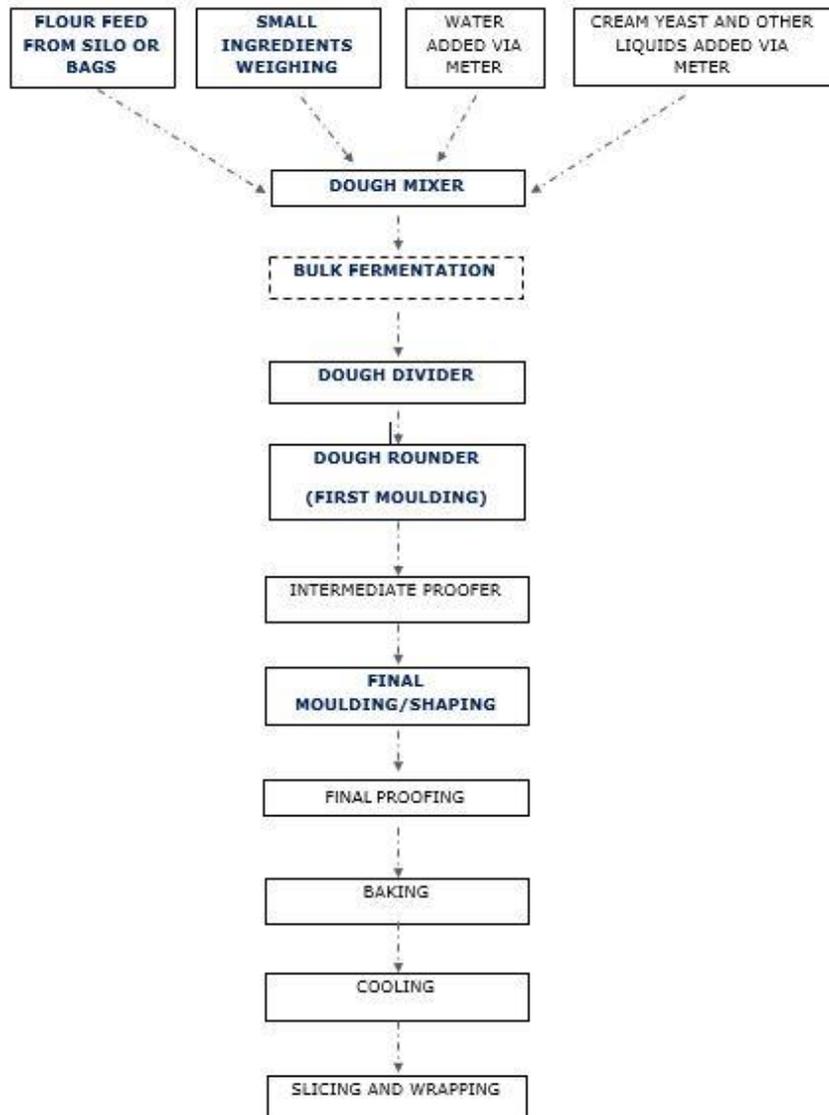


Figure 10. Flowchart of different operations in an industrial bakery unit.

Once more, the green colour below denotes the process steps at which limited or no risk exists for dust formation, whereas the blue areas indicate where dust formation is likely or very likely; depending on the equipment being used.

Compared with artisanal bakeries, the industrial bakery process is more highly automated, including the considerably more frequent use of silos and closed dosing systems (Figure 11). Very often only one or two people are responsible for each process step. This strongly reduces the exposure risk of the rest of the staff to possible dust formation.



Figure 11. Silos at an industrial bakery facility.

Filling and refilling of small silos can still be done from big bags containing dust forming raw materials. In this case, specialized equipment should be used (Figure 12), which moves material from the big bag through an almost closed system into the silos. Nevertheless, since this is not a completely closed system, dust formation can still occur.



Figure 12. Safe discharging of big bags containing enzyme products.

Figure 13 shows a system in which the inner big bag liner seals to the discharge equipment before the bag is opened. Since the inner liner is sealed before automated removal there is no spillage: the ultimate in safe handling.



Figure 13. Sealing system for big bag discharging purpose.

Figure 14 shows a possible connection of the silos towards the mixing equipment with limited dust formation.



Figure 14. Connection system for silos.

The use of closed, automated dosing systems tends to be limited to large throughput and high volume processes due to the cost. Some special bread types are still being made with the use of bagged powdered ingredients and additives. Occasionally additives, ingredients and processing aids are used in liquid form, which makes automated dosing much easier and which greatly reduces dust levels. However, the formation of aerosols is a serious risk to consider in such cases. Water and yeast are added through dosing pipes to the mixing bowl.

There is no further risk of enzyme dust formation once the dough has been mixed. Any further handling processes of the dough (dividing, rounding, moulding, proofing, baking, slicing, packing, etc.) is not expected to generate enzyme dust at all.

As can be seen in Figure 15, flour could be scattered over dough pieces in order to prevent them from sticking to the belt or to rollers and other moulding equipment.



Figure 15. Open dough preparation line at an industrial bakery.

However, this scattering is done from minimal height and with minimal force so that dust formation is negligible. At this stage there is low potential for enzyme dust formation.

All further steps (baking, cooling, transporting and slicing) do not generate flour or enzyme dust in any way (Figure 16).



Figure 16. Conveying final product in industrial bakeries.

4.8 Smaller bakeries / Artisans / Craft bakeries

Artisanal bakeries can be broadly categorised according to their product ranges as follows:

- bread bakeries,
- confectionery/pastry bakeries;
- Mixed bread and confectionery bakeries.

In practice, most bakeries belong to the latter class, where the bread bakery is separated from the confectionery bakery. This separation is mainly established in order to prevent

contamination of wet pastry products with wheat flour, but also because pastry production needs cooler conditions. However, in many confectioners, whether stand-alone or just separated from a bread bakery, par-baked goods are often sourced externally and only finished on-site. In such bakeries, the exposure to flour or enzyme dust is quite limited.

Several processing steps can be identified in the craft bakers' production process. Flour is poured or dumped into the mixing bowl from a silo or from bags. Water, yeast, additives and processing aids are then added. The powdered raw materials, ingredients/processing aids/additives are usually poured or scooped from a bag or an ingredients bin. Then the dough is prepared by automatic mixing, after which the dough is divided into pieces and further processed. In between batches of production in an artisanal bakery, the tables and floor are usually cleaned, using brooms, vacuum cleaners, and washing machines; From time to time, there might be wet cleaning of tables and equipment.

Above described process clearly shows that dust formation can occur in the early stages of the artisanal bread & pastry making processes; mainly:

- During pouring or scooping of the raw materials into scales or mixing bowls.
- During the mixing of flour and dry ingredients into a dough.
- During the further processing of the dough (flour is used to prevent dough from sticking to tables and equipment).
- During cleaning (incl. removal of empty packaging) or after the process has been completed (if not cleaned).

It is the exception rather than the rule if small bakeries are using fully closed systems and silos: the size of their operations does not usually justify the expense of this investment. However, in case of larger production sites they may be more widely used.

A more detailed description of the various processing steps is shown in the sections below, including recommendations and stewardship with the objective of reducing dust formation by flour & improvers as far as possible.

4.8.1 Storage

Bags may occasionally be torn or opened during delivery, transport or use; causing unwanted dust in storage areas. It is therefore important to store all raw materials properly and in a well-organized manner in the storage area. Open bags should be carefully closed. It is recommended to remove torn, ripped, burst or broken bags from the storage space and/or to use them immediately in the process. Part-used bags should be carefully closed, sealed and stored in such a way as to minimize dust formation and avoid spillage. It is recommended that part-used bags are stored in an area where any accidental spillage may be rapidly and safely dealt with (Figure 17).



Figure 17. Storage of powder bags.

4.8.2 Weighing of flour and ingredients

The weighing and addition of flour and other dry ingredients, especially in large volumes, can lead to formation of dust. Flour and other dry powders should not be thrown directly from the bag into the mixing bowl. It is recommended to ensure the provision of sufficient scoops so that the ingredients may be carefully and gently transferred from the bags into the weighing pan or mixing bowl.

The use of an air local exhaust ventilation system in this area could help to reduce the exposure to flour and improve dust. In order to get the optimum effect of such a system, the inlet to the local exhaust is best placed directly above or just behind the mixing bowl.

Some good manufacturing practices in comparison to the inappropriate ones are shown in Figure 18.





Figure 18. Manufacturing practices on dosing and ventilation principles at artisan bakeries.

4.8.3 Unloading flour from a silo (semi-industrial craft bakery)

High levels of dust can be formed when the flour falls down from a silo into the mixer. This can be reduced by placing the silo outlet deep into the mixing bowl. A silo outlet consisting of a smooth, flexible material may even reduce the dust formation; and little or no flour dust will remain on its surface.

A silo outlet which is placed too high, or firm shaking of the outlet upon unloading, can lead to high levels of dust in the environment. It should be made clear to operators that this should be avoided as far as possible (Figure 19).



Figure 19. Unloading flour and improvers in mixing bowls: dos and don'ts.

4.8.4 Unloading flour and improvers from bags

Opening and unloading flour and improver bags (Figure 20) might be considered as one of the most critical steps in the craft bakery process during which dust may be released into the environment. Therefore, it is recommended to open the bags at the height of the stitching (if applicable) and empty the content slowly into the mixing bowl. Furthermore, it is advised to slowly lift the bag in order to allow the contents to slide gently into the bowl. Making a slit in the bag at the opposite end allows a small influx of air into the bag which helps the flour to slide out

easily without the need to shake the bag. It is recommended that a RPE be used during this operation to minimize enzyme exposures.



1. Open the bag at the stitched end



2. Place the open bag end in the mixing bowl



3. Make a slit in the opposite end of the bag with a knife



4. Tip the bag gently into the bowl



5. Lift the bag so that the flour slides out cleanly into the bowl

Figure 20. Guidelines for emptying paper bags containing bakery ingredients safely.

The height from which the bags are emptied should be as low as possible. Any knocking or shaking of the bag in order to remove the last remnants should be done as gently as possible. When removing the empty bag from the weighing device or mixer (Figure 21), it should be gently rolled or folded carefully to prevent unnecessary dust formation that may be caused by abrupt movements. It is recommended that the opening of the bags is directed towards the local exhaust ventilation point. Any additional dry ingredients should not be thrown abruptly into the weighing equipment or mixing bowl, but should be added gently.



Figure 21. Safe vs. unsafe removal of empty paper bags from the baking environment.

Once all the dry ingredients are added into the mixing bowl, water and other liquid ingredients should be added slowly to the dry blend, preferably along the edge of the bowl and preferably by using a guiding hose (Figure 22).



Figure 22. Safe addition of water into mixing bowls without creating dust.

4.8.5 Dough preparation

When all of the ingredients are added to the mixing bowl, the mixing can start. The greatest concentration of dust is generated at the start of the mixing process. **Therefore, mixing bowls with a lid (Figure 23) should be used to safeguard workers' health & safety.**



Figure 23. Mixing bowls with covering lids.

Dust formation is further prevented by starting the mixing process on a slow speed. As soon as all the dry and wet ingredients are properly blended, the mixing speed can be increased. If an air ventilation system is present, the local exhaust ventilation point should be placed right above or just behind the mixing bowl.

Moreover, it is recommended to limit the use of dusting flour in the mixing bowl. Dusting flour is used to reduce the sticking of the dough during mixing and during further processing of the dough. Alternatively, a small amount of oil added at the end of the mixing process may help to release the dough properly from the bowl. This oil could be streamed or sprayed in (Figure 24).



Figure 24. Safe vs. unsafe release of the dough from the mixing bowl.

4.8.6 Dough handling

Once the dough is removed from the mixing bowl, it is a common habit for craft bakers to scatter dusting flour over the work bench and the dough to prevent it from sticking to the equipment and benches used. This is an obvious source of dust exposure for the operative and so the amount of dusting flour used (and the method of scattering) should be limited/controlled as far as possible. High levels of dusting flour not only increase the chance of inhaling flour dust, but also have a detrimental effect on the dough structure.

Low-dust flour or dust-free flour should be used for dusting purposes. This type of flour is commercially available, but can also be made by the craft baker himself by mixing conventional flour with a small amount of oil; e.g . 2 Kg flour + 15 ml sunflower oil. Potentially, these alternatives could reduce the dust level caused by dusting flour by more than 50%.

Benches made from materials such as inox, stainless steel or polyethylene are recommended for dough handling. The incidence of dough sticking appears to be significantly less with these when compared with the use of other bench materials. In this way the need to use dusting flour, and the subsequent risk of dust exposure are greatly reduced (Figure 25).



Figure 25. Dough handling principles related to dust formation: do's and don'ts.

4.8.7 Protection in craft bakeries

The use of a respirator, which covers mouth, nose and chin is strongly recommended in areas where there is a high risk of exposure to dust; and the installation of an air ventilation system should be considered. A local exhaust ventilation system immediately removes dust particles from the air and is preferably placed close to the points where most of the dust is generated i.e. weighing and blending locations (Figure 26).

More information on the appropriate technical specification for this type of protective equipment can be found in Chapter 5 of this document.



Figure 26. Protection principles in craft bakeries (P3 respirator used when exposed to enzymes)

4.9 Product Reclaim, rework and trade returns

Reclaim and rework of a product (flour, enzymes and other ingredients, bakery improvers and bakery mixes) occurs when a quality specification has not been met, or the product may have been incorrectly packed (over or under weight). The product may also need to be reworked if it is packed in a faulty container, or is returned from the trade as surplus material. These circumstances occur most often at the sites of industrial flour millers and bakery ingredient and improver suppliers. Consequently, recommendations provided in this section will mainly focus on their activities.

Reclaim of a packed product is often a manual operation, unit by unit. This means that there is a close interface between the operator, the product, and the packaging. It is essential that exposure to dust and aerosol is properly controlled during this type of operation. As rework-operations in general are potentially high exposure spots, this area should be properly isolated from other operational areas. Operators in this specific area need to wear RPE for complete protection.

At the time of writing, there were no examples of automated reclamation processes within the bakery chain (flour millers and bakery ingredient and improver producers). Therefore, only the manual reclaim processes will be considered further.

4.9.1 Manual Reclaim of bakery powders and bakery liquids containing enzymes

The whole reclaim process of **bakery powders** (including pure enzymes) should be carried out within the containment of a booth fitted with effective ventilation. This includes operations to open paper bags or cartons, to tip out product, to collect reclaimed product, and to dispose of *contaminated* packaging.

- Disposal of empty packaging materials is often neglected; and in many instances empty packs, containing powder and/or dust, are removed from the booth prior to compaction and collation. This results in exposure of operators to airborne dust, personal contamination (clothing, shoes, etc.) and powder spillage. It is therefore necessary that the rework booth design should facilitate the safe collation and disposal of contaminated packaging.
- Big-bags are often used for the accumulation of reclaimed bakery powders, and their eventual reintroduction into the process. The re-use of big-bags in this way has to be carefully managed as the process can lead to significant dust exposure if the bags become externally contaminated, worn and/or damaged, or if they are deflated and folded in a careless manner.
- To minimise the risk of dust exposure from rework, reclaimed powders should preferably be collected in a fixed hopper, from which they can be directly re-introduced into the process via a closed system, or they may be conveyed to a hopper or directly back to the process by an enclosed conveyor or dense phase vacuum transfer.

- Operators undertaking manual reclaim of powders should always use suitable respiratory protection. Whilst full control during the actual **reclaim** process is achievable, there is always a risk of exposure outside the environment of the reclaim booth from handling packs that may be faulty, damaged, partially open, or externally contaminated. The use of respiratory protection is therefore essential for this type of task and is discussed in detail in Chapter 5.

Essentially, the same basic exposure control requirements that are used for powders are also necessary for the manual tipping and reclaim of **bakery liquids containing enzymes**. However, the dust exposure risk from handling full bottles, cartons and empty liquids packaging is somewhat less than for powders; although dried out residues from spillages or overfilled containers may present a risk from dust inhalation.

- Bottles or cartons should only be opened and poured out within an enclosed and ventilated reclaim booth.
- For heavy-duty liquids that are slow to pour, the packs may be mounted upside-down in a frame, or on spikes, and left to drain completely.
- Liquids are best drained into a hopper, and then pumped directly back into the process or into a storage vessel; taking care that any microbiological spoilage risks are addressed.

4.9.2 Disposal of Waste Packaging from Reclaim Operations

Waste packaging materials delivered from the reclaim operations of bakery ingredients that contain enzymes should be handled carefully to avoid exposure to dust or aerosol. The best practice is to collect packaging for disposal as soon as the material has been emptied, thus avoiding any secondary handling of packaging.

For **bakery powders**, empty paper bags or cartons should be placed into a large polythene sack; the neck of which can be tied closed when it is full. Alternatively, they can be placed into a ventilated compaction unit which then “extrudes” the compacted packs into a closed polythene liner. Operators undertaking these manual operations should always use the appropriate respiratory protection.

For **liquids**, “empty” bottles pose little exposure risk unless they contain sufficient traces of the product to generate spillage; or if they are compacted or shredded in which case the forces involved are normally sufficient to generate aerosols. Care should be taken to avoid the spillage of liquid from empty bottles by ensuring that they are completely drained.

Third-party waste recycling companies should be informed of the hazards and risks associated with the handling of these empty packaging materials.

4.10 Dealing with spillages, and cleaning of plant and equipment

Clean-up operations are a significant source of peak enzyme exposures within the entire bakery chain, which need to be managed by a combination of equipment and proper procedures. The use of improper or improvised clean-up methods may lead to the generation of airborne enzyme dust or aerosols, which can result in the exposure of operators and bakers in the immediate area, and in adjacent areas via general ventilation.

- The cleaning up of spilled **bakery powder products** should be done with the use of a **vacuum cleaning system** fitted with appropriate **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 should not be used, as standard filtration systems will not adequately remove enzyme dust and/or aerosol before the air is returned to the working environment. The contents of the vacuum cleaner must be disposed of in a way that does not generate dust clouds.
- **The use of brushes, brooms, compressed air, and high pressure water must be avoided as far as possible for cleaning spillages and contaminated equipment**, as these will either generate significant airborne dust and / or aerosol; or leave behind a wet residue which can then dry out to form a fine dust. Vacuuming followed by wet mopping is preferred. Smaller spillages may be washed to a drain by a soft / low pressure water hoses (Figure 27).



Figure 27. Cleaning principles: do's and don'ts.

An alternative to manual vacuum cleaner systems is a central vacuum system with centralized waste collection and treatment. Regular filter control (HEPA) and a well-considered design are key to prevent any dust formation at the collection bin within this system (Figure 28).



Figure 28. Centralised ventilation system.

- Depending on the size of a **liquid spillage** the use of a sorbent material may be considered. The contaminated sorbent must be collected and placed into a sealed plastic bag / plastic container and disposed of by incineration, or through the waste water treatment plant [though this will require additional handling controls and disposal of the contaminated packaging].
- **Respiratory protection** should be used for all cleaning / spillage operations because the risk of exposure is always high.
- Whilst the area is being cleaned, it should be **cordoned off** to prevent the risk of exposure to passers-by (Figure 29).



Figure 29. Safety warnings during cleaning or if enzyme spills occur.

4.10.1 Cleaning of Size Change Parts in Semi-Industrial Production Units

It is recommended that an isolated and ventilated area is specifically designated for the purpose of cleaning change parts (i.e. machine parts removed for product changeover – (cold-) sealing vs. stitching of paper bags, different sieve sizes, hopper equipment, etc.). Change parts should be transported to the cleaning area in a rigid solid-sided container to minimize spills. The area should fulfil requirements similar to an isolated discharge area (see Section 5) in that it should

be under negative pressure with respect to the remainder of the plant. An example of such an isolated room is shown in Figure 30.

The parts cleaning station is an enclosed area where change parts and other equipment is cleaned. It is an isolated room with sufficient exhaust ventilation to maintain a recommended 1m/s face velocity across the door as shown. Vacuum cleaning followed by low pressure water is the recommended method for cleaning parts. Vacuum cleaners must meet the specifications detailed above with regards to HEPA filtration. Low pressure water should be used for cleaning whenever possible. The use of hot or high pressure water systems should 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.

As this is an operation with a high potential for exposure to dust and / or aerosol, **respiratory protection must be worn** as a safeguard (see Chapter 5).

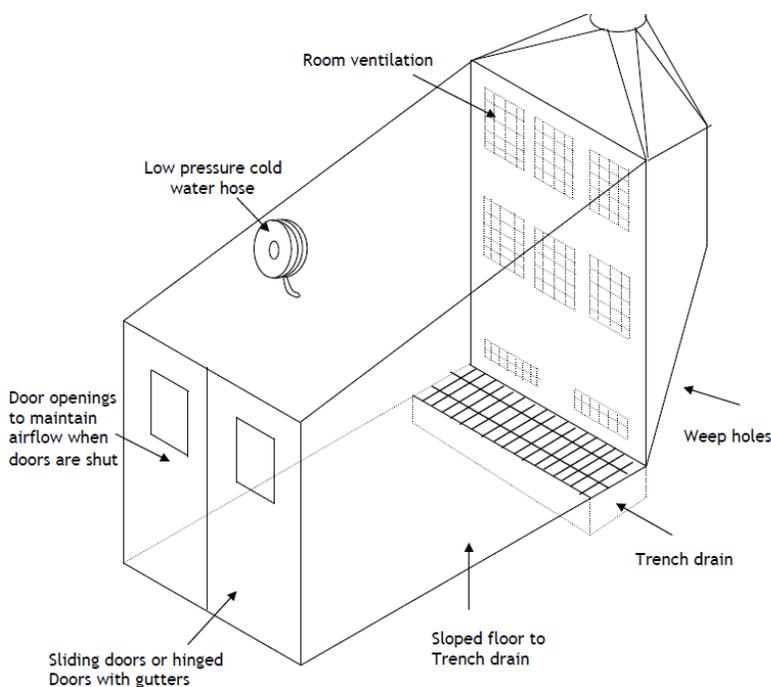


Figure 30. Example of isolated room for cleaning of change parts.

4.11 Ventilation Efficiency and Recommendations

Ventilation and filtration of air extracted from the production environment may be seen as a critical step in airborne enzyme dust and aerosol control throughout the bakery chain. There are many different ventilation systems currently in existence and these vary widely in terms of size, efficiency, filtration capacity and extraction performance. The appropriate selection largely depends on different types of production and bakery environment. Therefore this section will be divided between semi- or industrial environments and “artisan” working environments. However, the general and basic principles will equally apply:

- Air ventilation systems should be placed in spots wherever there is a possible risk of dust or aerosol formation; e.g. dumping stations, mixers (incl. Hobarts), and bakers' working tables.
- Fine-tuning and positioning of air ventilation systems should be carefully investigated before installation. It is a wise precaution to consult with certified ventilation installation professionals in order to design the installation in the most efficient and effective way.
- To avoid unwanted emission/escape of enzyme/dust from ventilation duct; systems should be kept constantly under negative pressure and well-closed at any spot (in case the air ventilation stops).
- Keep ventilation duct systems as short and as simple as possible.
- Ventilation ducts should be designed (slope, dimension, air speed etc) to avoid settling of material in the pipes/ducts. This principle applies to both ventilation efficiency (avoiding blockage), enzyme & flour exposure risk during maintenance and repair work and minimizing the combustible dust risk (ATEX)
- Replacement / cleaning of (HEPA-) filters should be as easy and as safe as possible and should be taken into account during the design stage of bakery planning.
- Regular maintenance of ventilation systems by professionals is required. Maintenance contracts on ventilation systems could be a benefit for year-on-year control of the ventilation system.
- Keep a logbook of inspection reports and HEPA filter replacements in ventilation units. Refer to on site policy for the frequency of replacement.
- Examples of ventilation / vacuum systems / filters are: cyclones, drop-out boxes, wet scrubbers, bag filters or electrostatic precipitators.
- **Important notice:** exhaust air that contains allergens, must not be re-circulated into another area where those substances are not present. When circulating back into the same area, the allergen concentration should not exceed 10% of the OEL for that substance.

4.11.1 (Semi-) Industrial Production Environments

The treatment method for extracted air contaminated with enzyme dust and/or aerosol will depend upon:

- The type of plant and/or equipment that is under control
- The degree of contamination
- The location into which the extract air is discharged.

In some countries reference should be made to guidance issued by enforcement authority of industry best practice for example UK companies should comply with HSG 258 - Controlling airborne contaminants at work: A guide to local exhaust ventilation (LEV) when designing and installing LEV systems.

Most countries already have legislation concerning the concentration of particulates that can be discharged to the external atmosphere. Legislative requirements regarding the venting of exhaust air should always be adhered to first, followed by the guidance in this document.

- Most local exhaust ventilation systems throughout the (industrial) bakery chain are directly discharged outside in accordance with local environment emission regulations and in a location which prevents intake back into the building. However, if the local exhaust ventilation discharge is purposely re-circulated back into the workplace, then extra filtration is needed to prevent the discharge of enzyme dust and/or aerosol back into the working environment. In this case the minimum standard of filtration is considered to be HEPA filtration, to at least H14 (EN1822). Measurement of the quality of the discharged air (emission) is necessary to prevent the spread of enzyme containing material into the workplace.
- HEPA filters are normally preceded by one or two pre-filters to remove the bigger particle sizes. This prevents the HEPA filter from blocking up, thus prolonging its operating life. This is typical of the filtration necessary for a laminar down flow booth which re-circulates air to the working environment (Appendix 1).
Equipment suppliers can recommend suitable pre-filters according to the expected dust loading, but a typical three-stage system would be comprised of the elements in Table 4.

The International Standard EN 1822 has revised filter classifications; the recommended finishing filter class for enzymes is now H14. Previously this document referred to HEPA filters in class EU13 and you may still see this on some older stock or products.

Table 4. Dust Filters

Filter Type	Classification	Efficiency
Pre Filter	G4	95% @ 10 µm
Fine Dust Filter	F8	90 – 95% @ 5 µm
HEPA Filter	H14	99.995 – 99.9995% @ 0.3 µm

The minimum standard of filtration required is to F8 (see above) and after filtration the extracted air should be discharged externally to the building. This standard of filtration is typically provided by bag, sock, or cartridge type filtration systems. Finished powder handling normally generates a significant dust load for the associated filtration systems, therefore some form of automated filter cleaning systems are required. Reverse jet cleaning is the most efficient self-cleaning system and is recommended. Mechanical cleaning systems that shake the internal filters are generally far less efficient.

As stated before, it is not recommended that air extracted from production units throughout the bakery chain is re-circulated to the working environment.

4.12 Artisan Bakeries – Demonstration Bakeries – Bakery Schools

In general, filtration systems in artisanal bakeries and demonstration bakeries are less sophisticated compared with their (semi-)industrial equivalents. Nevertheless, the minimum standard of filtration required is also F8 (formerly EU8) and after filtration extracted air should be discharged externally from the building. Bag, sock or cartridge type filtration systems are recommended. Older artisan bakeries without ventilation units, or modern artisan bakeries where no attention was paid to the implementation of the minimum ventilation requirements, should consider the feasibility of designing and retro-fitting a simplified ventilation unit that meets the minimum requirements.

Where retro-fitting is not possible, the presence of a constant air flow/circulation and air refreshment in the bakery with a maximum airflow of 1 m/s at ventilation openings is recommended. It is also important that the turbulence intensity is as low as possible, preferably below 30%. Turbulence zones are responsible for higher exposures of particles in the breathing zone, even if the worker is not performing dust generating tasks. Opening doors or windows can help to prevent high peak exposures of airborne enzyme dust and aerosols, but the latter recommendation should be considered as a last resort when no other measures are possible but when area ventilation and LEV is in place, opening doors and windows should be avoided.

The use of electrical fans (generally used to create a sense of refreshment for workers) to generate airflow in the bakery is not recommended, as it could be considered as air re-circulation within the bakery and as a consequence a source for increased airborne enzyme dust. For this reason, and because fans spread dust around rather than removing it, electrical fans should be avoided as far as possible.

References

1. SDA, US. (2005). Risk assessment guidance for enzyme-containing products. *Soap and Detergent Association, Washington*.
2. AMFEP & Fedima (November 2003). Measuring of Dust Levels in Bakery Ingredients Using the Heubach Method.
3. AISE: Guidelines for the safe handling of enzymes in detergent manufacturing (version 2.1, 2015). https://www.aise.eu/documents/document/20150603154418-aise-enzymes_safe_handling-v2-1-june_2015.pdf

Useful links

- Example of technical information on ventilation from the UK
<http://www.coshh-essentials.org.uk/>

5. Respiratory Protective Equipment (RPE)

Respiratory Protective Equipment (RPE) is now well integrated into (semi-)industrial production environments and the application of RPE is usually well defined in risk assessment plans and procedures. Often, artisan bakeries and demonstration bakeries lack knowledge on the correct use of RPE in their production sites. The recommendations and standards of RPE, described in sections below, are therefore of common interest for artisan and demonstration bakeries.

5.1 Use of Respiratory Protective Equipment

In normal operational situations, the use of RPE should always be considered as secondary protection where a risk assessment has shown that there is a potential for airborne enzyme dust exposure, despite the presence of engineering controls. Some examples of these situations are:

- Filling station
- “On-line” maintenance
- Access into filling machine enclosures
- Product reclaim and rework
- Dealing with small spillages
- Cleaning of equipment
- Quality control sampling

RPE should 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 recalled bakery powders, In special circumstances RPE may be required as primary protection. In this instance the type and degree of RPE should be identified by a risk assessment for the task, including the likely level of exposure. Abnormal situations include:

- Major spillage of enzyme raw material
- Dealing with, and repair of, damaged supply units e.g. hoppers, sieves, packaging equipment
- Major spillage of bakery powders and/or their raw materials
- Gross failure of containment or control
- Maintenance or repair of contaminated plant and equipment
- Decontamination of plant and equipment

5.2 Types of 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 should 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 following are examples of the type of RPE available that is often used [or available] in (semi-) industrial plants, including flour mills, bakery powder and improver houses and (semi-) industrial bakeries, to cover a range of contingencies (Figure 31).

It is always recommended that P3 respirators are used when handling enzymes and enzyme containing products.

- Disposable orinasal masks (which must be close-fitting); these masks are generally not protective enough for enzyme exposures
- Re-usable orinasal masks and cartridge filters
- Full face masks and cartridge filters
- Positive pressure respiratory protection

The specification required to provide the necessary protection should be determined by undertaking a risk assessment for the particular task. All employees that are required to use respiratory protective equipment must be adequately trained in its selection, use and maintenance. In addition, employees should be adequately assessed by a trained professional to ensure that they are fit to wear and use the appropriate respiratory protection. A respirator fit test is also required to assign designated respirators to employees and this equipment should not be shared.

If an employee has facial hair, e.g. beard, moustache, etc. that prevents a good facial seal against the skin: then positive pressure respiratory protection should be used instead of an orinasal face mask. RPE should be compatible with any other protective equipment provided, such as safety glasses, safety goggles, hearing protection, etc. Consideration should also be given where any personal aids are in use such as corrective spectacles and hearing aids.



Figure 31. Personal Respiratory Protection.

5.3 Personal protective equipment (PPE):

Enzymes are not skin sensitizers, but proteases are skin irritants. Therefore skin and eye contact with enzymes, or bakery products containing significant enzyme dosages, should be avoided by the use of suitable personal protective equipment such as goggles, gloves, and work clothes that are protecting against dust (cf. EN13982). Whenever RPE needs to be used protective clothing should also be used, as secondary exposure very often occurs in this way.

- Under normal operating conditions all employees, bakers, contractors, visitors, maintenance and cleaning operators, etc., should use the relevant personal protective equipment and work clothing appropriate for the areas they visit or for the tasks they undertake. In industrial environments, this will be mandated by site policy.
- The contact surfaces of gloves should be impermeable for handling enzymes and enzyme containing products, Safety shoes, whilst not related to enzyme safety, should also be used by all persons on site as is appropriate.
- Decontamination facilities such as showers; and a change of protective clothing / work clothing should be available for employees in the event that personal contamination occurs.
- Under emergency conditions the appropriate personal protective equipment should be identified from a risk assessment for each task that has been undertaken previously.
- Normal work clothing should be changed / laundered as per site policy, and contaminated work clothing should be changed as soon as is possible depending upon the degree of contamination, and in accordance with the following guidance for personal decontamination.
- 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 to staff outside of the manufacturing / process area. For maintenance or high risk tasks, where personal contamination is likely, disposable workwear is a good option.
- The wearing of safety goggles is recommended as a general precaution in handling enzyme products.

5.4 Personal Decontamination

- Ideally, the plant or bakery lay-out should allow the most convenient and shortest distance from potential exposure areas to personal decontamination facilities.
- Showers should be available for personal decontamination at the end of shift or after undertaking abnormal tasks e.g. the clearing up of spillages.
- Emergency eye wash stations should be in place where they may be easily accessible.
- Documented procedures should be available for personal decontamination after undertaking abnormal tasks where the potential for personal contamination is high.
- Following high risk tasks, contaminated clothing should be removed whilst respiratory protection is still being worn. Clothing should be placed into a plastic bag for disposal or laundering. Special water soluble bags for contaminated clothes are available.
- Following decontamination, clean work clothing should be available for use.

Useful Links

1. AISE: Guidelines for the safe handling of enzymes in detergent manufacturing (version 2.1, 2015). https://www.aise.eu/documents/document/20150603154418-aise-enzymes_safe_handling-v2-1-june_2015.pdf
2. Blij met stofvrij! – Handboek Stofbeheersing – Result of Arboconvenant, 4 June 2003 – Dutch Authorities & Sector Organisations. www.blijmetstofvrij.nl.
3. A Bakers Dozen. 13 Essentials for Health and Safety in Bakeries. <http://www.bakersfederation.org.uk/wp-content/uploads/BAKERS-DOZEN-April-2016.pdf>

6. Instructions and behaviours

It is widely recognised that all employees are responsible for the safeguarding of their own health and safety at work, and also that of their colleagues. This applies not only to obvious physical hazards such as trips, slips and falls; but also to less obvious risks, such as the exposure of the workforce to any toxic or otherwise hazardous substances such as dust.

A thorough risk assessment and analysis goes a long way towards identifying such hazards; and these assessments are used to develop Company policies, procedures and operating practices that mitigate against these hazards as far as possible. It is imperative that these policies, procedures and practices are adhered to by **all** staff in the interests of the health and safety of the whole workforce; including protecting against dust exposure. As systems and methods of working continually evolve it is vital that they are periodically reviewed to ensure that they are still relevant and fit for purpose. Any changes must be effectively communicated to all staff by the most effective means available: through training programmes, poster campaigns, Staff Handbooks, etc.

Company policies, procedures and operating practices can be lengthy and getting staff to read and abide by them is often challenging. It may be necessary to adopt several approaches to ensure the understanding and compliance of the whole workforce in order to foster a safe working environment, such as training, posters, etc.

6.1 Standard operating procedures, practices and instructions

- i) SOPs, practices and instructions need to be **clear** and unambiguous. It is important to remember that staff who must abide by them may be reading them in their non-native language. The use of pictograms, graphics and photographs can help to communicate health and safety messages more clearly.
- ii) It is often helpful if staff can understand the reason **why** the instruction must be heeded. It is much more likely that an instruction will be followed if the consequences of **not** doing so are clearly explained and/or demonstrated.
- iii) Make sure that instructions are **easily accessible**. Staff members are more likely to learn and follow a procedure if they do not have to search a complicated computer system in order to find it.
- iv) **Keep them short**. If this is not possible, use short phrases in a bulleted list as a reminder sheet that can be easily referred to by staff members.
- v) **Show and tell**: it is easier to explain a work instruction or procedure by practical demonstration of how it must be done. The lesson is doubly learned if the demonstration also illustrates the **consequences** of doing something **incorrectly**.

- vi) Consider the use of mentoring, shadowing and performance reviews to give staff members the best opportunity of learning the healthiest, safest, and most effective way of working.

6.2 Staff behaviours

SOPs, procedures and instructions are the best way to guide the workforce into safe working practices; but it is equally important to ensure that they continually adhere to them. The ideal is to create and foster an environment in which the regard for health and safety is so ingrained that it becomes the normal and natural way of working for every member of staff. This ideal takes time to achieve, and there are various ways to encourage commitment to continual and improving safe working practices regarding dust exposure.

- i) **Make it easy to comply:** ensure that there are plentiful supplies of any necessary equipment for reducing dust exposure, e.g. gloves, goggles, face masks, respirators, etc.; and that these are **available in appropriate areas** of the factory. Staff members are less likely to use equipment if they have to waste time searching for it.
- ii) **Lead by example:** make sure that **all** staff members are aware of the risks and their own responsibilities to follow correct procedures.
- iii) **Instigate a 'challenge' policy** that allows **any** member of staff to challenge the working behaviour of **any other** member of staff, **regardless of their seniority.**
- iv) **Monitoring:** Senior management should show their commitment to the health and safety of the workforce by setting up a regular health screening/monitoring programme for all staff who may be particularly at risk from exposure to dust and/or enzymes.
- v) **Communication and feedback:** foster a working ethos that allows **any** member of staff to make constructive comments or feedback on current working practices, and to suggest improvements.
- vi) It is also important for staff members to be able to **report unsafe practices without fear** of stigmatisation or reprisal. This can be facilitated by using Suggestion Boxes or having a line manager Open Door policy.

6.3 Practical steps for reducing dust exposure

Purchasing: wherever possible, source and select raw materials that are non-dusty. For example; use liquids, pastes or grades of powdered ingredients that have large particle sizes; or have been treated in such a way that their capacity for dust-creation has been minimised.

Goods inwards: if possible use enclosed pipes for the intake of dusty raw materials. Otherwise, take care not to puncture/rupture packaging of powdered materials. Ensure that storage pallets are undamaged and free from splinters.

Un-bagging/de-boxing: train and encourage staff members to unpack powdered materials in such a way that they do not create dust clouds. E.g. bags of powdered ingredients/flour should not be shaken at height.

Part-used bags: make it a standard operating procedure to carefully close, reseal and store partly used bags of enzyme containing ingredients in such a way as to minimize dust formation. Ensure that all such bags are stored in an area with easy access for the safe cleaning of any accidental spillage.

Use of face masks, safety goggles, gloves, respirators, etc.: make staff members aware that the use of PPE *does not* excuse them from being careful when they are handling powdered materials. PPE is intended to minimise risk, not protect from clouds of dust that are created by careless handling.

Extraction and ventilation: make appropriate use of extractors and ventilators in areas that may be particularly susceptible to a dusty atmosphere; e.g. weighing, mixing and blending areas.

Spillages: use vacuum cleaners fitted with appropriate HEPA filters on spillages of dusty materials and make sure that these are emptied in such a way that the vacuumed contents do not create dust clouds.

Where dust is required during a process, e.g., when producing bread or pastry on an automatic line; use equipment that drops flour only where it is needed. If excess flour dust needs to be removed at any stage, install an extraction unit over the line or suitable guards to prevent dust from being discharged into the atmosphere. If possible, use 'non-dusty' flours for this purpose (see previous section 'Dough Handling')

7. Occupational exposure assessment by air monitoring

This chapter focuses mainly on enzyme exposure monitoring and less on total dust monitoring, and especially chapters 7.4 to 7.6.

The objectives behind airborne dust and enzyme levels monitoring are clear:

- It enables the quantification of employee exposures
- 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 should be worn.
- The results may also be used to identify where working practices may need to be reviewed in order to make them less hazardous; i.e. less prone to being dusty.

7.1 When should air monitoring be conducted?

Monitoring should be prioritized based on the risk of exposure to workers. The basis for the sampling strategy in workplace air is the EN689 standard. To begin with there should be a qualitative assessment of the risks as this will define the ultimate air monitoring strategy for the site. The strategy may also depend on the outcome of medical surveillance: for example, if immunological testing reveals that there is a changing trend in the incidence of sensitization. Moreover, the strategy will also depend on the outcomes of performance assessments of the equipment, work practices and behaviours of the workforce.

Routine air sampling 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.

Area sampling is used to evaluate the effectiveness of control measures and trends in performance, and is typically done at a fixed location; it can readily provide an indication of employee exposure. Though static sampling cannot be compared with current limit values; it gives a useful indication of background exposure in a specific workplace. The personal exposure level is typically a factor 2 to 5 higher, depending on the direct tasks.

Personal sampling involves a sampling train (pump-tubing-sampler-collection substrate). Low volume devices are primarily used but there are also high flow pumps on the market that are wearable. These devices are worn by the operator and can be used to evaluate individual employee exposure according to job description or as total cumulative exposure where job rotation applies. However, the use of personal sampling is limited by the limit of quantification of the methodology (sampling and analysis combined).

It is good practice to measure both total inhalable dust and enzyme airborne dusts in the bakery supply chain. Only enzyme aerosol levels are measured in liquid operations. As the limit values are mainly for the inhalable fraction, an inhalable aerosol sampler should be used. Your enzyme supplier can be contacted for advice on measuring inhalable enzyme dust.

In cases where there may be a lack of available qualified internal resources, a certified consultant (industrial hygienist) should be contracted to conduct the air monitoring; and a laboratory employed to carry out the air monitoring analysis. For those entities where resources are available for an air monitoring program it is important to follow the elements listed in sections 7.2-7.6

7.2 Components of an air monitoring program

7.2.1 Training

A trained and competent person should oversee the air monitoring program. This individual will be responsible for establishing the sampling plan (e.g. sampling frequency, location and sampling time); selection of air monitoring equipment, data evaluation, assessment of the adequacy of control measures, and training of individuals who are collecting the samples. The individuals performing these tasks should be adequately trained in the operation of the sampling equipment.

The collection of reliable and accurate air sampling data requires training in the following:

- Operation and maintenance of the sampling equipment
- Calibration of sampling equipment
- Data collection (e.g. sample time, flow rate, location, operations, employee work practices)
- Sampling plan and sample type
- Understanding of the basic analytical requirements, including handling, storage and transport of filters
- Maintenance of sampling equipment
- Hygienic practices: the biggest risk here is the contamination of samples. It is important to remember that:
 - The objective is to measure nanograms of enzyme protein (billionths of a gram)!
 - High flow sampling filters are especially susceptible to contamination because they are not housed in a cassette, and have a large surface area that is exposed to the environment
 - Tweezers and filter housings of high flow sampling units should be cleaned between uses. Studies indicate that the use of ethanol to remove enzyme residues from a hard surface may not be as effective as using a detergent solution. On the other hand, ethanol is excellent for the removal of potential microbes.

Training should involve a practical demonstration of sampling and equipment calibration. A practical demonstration of this skill should be assessed at least every 12 months to ensure continuing competency.

7.2.2 Air sampling equipment

High flow samplers are commonly used for enzyme air sampling. These typically operate at 300-600 litres/minute and sampling/monitoring times of up to 4hrs may be necessary to demonstrate compliance with internal occupational exposure limits. Some new high volume samplers have flow rate controllers, which allows the flow rate to be adjusted according to the target flow.

Experience has shown that liquid aerosols may pass through the filter material if the sampler volume is too high. GF/C glass fibre filter pads are generally used for high volume sampling.

Low flow samplers can be used for personal or area sampling. These have a flow rate of 2-3 litres /minute for personal sampling, or 20-30 litres/min for area or targeted sampling.

They can use glass fibre, polypropylene, PVC, MCE or Teflon filters. It is also important to select the right pore diameter, as this is key to giving an indication of the back pressure. High back pressures mainly indicate an underestimation of the exposure. Based on the experience of your enzyme supplier, different filter types may be recommended to measure different types of enzyme.

There are advantages and disadvantages for both types of samplers.

High flow samplers: These are used where large volumes need to be collected within in a short period of time. Some analytical methods may have high limits of quantification which may negate the use of low volume samplers.

Low flow samplers: These are easier to calibrate and, if they are used for personal sampling, their pumps may not require an external electrical source for operation. They are often used where more sensitive analytical methods are available, and explosion-proof samplers are available for use in areas where there may be flammable solvents. Low volume samplers with a flow rate of 20-30 litres/min are a good option for both area and targeted sampling; and this consideration is particularly important when potential exposure sources are being mapped and identified. In this respect, direct reading devices may be a valuable option for dust mapping and task exposure determination. The results can also be used when training people for certain tasks.

It is important to keep air samplers very clean to avoid sample contamination. The filter holder should be protected from contamination when it is not in use and cleaned before each sampling

campaign. It is advisable to clean with a substance that will denature any protein contamination but also dries out quickly, e.g. ethanol. The equipment should be allowed to dry completely before sampling because moisture can weaken the filter and increase the risk of damage to the filter pad during handling.

7.2.3 Air Sampling Strategy

Each site should have a protocol that ensures the air sampling program is representative of the overall operation. The air sampling strategy should be developed based on data collected from the qualitative assessment (outlined in section 7.1) to derive a sampling plan that addresses the specific objective of the sampling plan (for example, to measure worker exposures, to test effectiveness of controls, etc.). The purpose of the monitoring exercise is to determine the choice between High and Low flow sampling. If the purpose is to establish baseline airborne enzyme concentrations in an area where the process conditions are stable for a couple of hours; low flow samplers can be allowed to run for about 8 hours in the operator's breathing zone. The limit values are mainly 8 hours TWA concentrations, hence a sampling time close to the 8 hours is recommended. Conversely, if the process varies in a manner that could create peak exposures over a short period of time; e.g., transfer of enzyme-containing raw materials at non-dedicated facilities; the use of a high flow pump might be more appropriate.

Different sampling approaches may be used; although it may be necessary to follow local authority regulations or the guidance of EN standards (EN 689:1995 and EN 482:2015, Council Directive 98/24/EC (07/04/1998); ECHA Guidance, Part R.14: "Occupational Exposure Assessment").

EN482 and EN689 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.

However, the "personal breathing zone" sampling method for enzyme exposure monitoring has some limitations, namely:

- Firstly, personal samples will not necessarily identify peak concentrations: high volume area or static sampling and point source sampling are better methods for this purpose.
- Secondly, in modern manufacturing operations, personnel are often working outside controlled rooms and may be multitasking. Therefore, they are not necessarily staying at the defined sampling location for a long enough period to obtain a representative reading.
- Finally, personal monitoring may not provide a sufficiently representative reading that truly reflects the effectiveness of engineering controls such as containment and LEV.

The following factors should be in place to ensure that the programme delivers accurate data that is representative of the operation.

7.2.4 Sampling Schedule

The system for data tracking should verify that samples are taken at random times during all shifts (day and night). The only exception to this is 'targeted sampling' (see 1.3.6). It is also recommended that samples are taken when there is no manufacturing in progress. This will establish background dust levels in the workplace which serve as the baseline for comparison with the air sampling results obtained during production.

7.2.5 Sampling Frequency

Representative area samples should be taken on a regular basis for each unit operation where enzymes are involved, and rotated around the shift pattern. Sampling frequency should be based on the results of previous measurements, any initial risk analysis, and the outcome of the medical surveillance (if conducted).

7.2.6 Sampling Duration

Sample duration may vary depending on the objective (up to 4 hours for high volume sampling and 8 hours for personal monitoring), and the variability within the process.

Sampling duration should also reflect the sensitivity of the analytical method i.e., the limit of quantification of the enzyme in question; enzyme levels in the facility; and the air sampling rate of the equipment (type of sampler).

7.2.7 Sampling Locations

Areas with the highest potential for exposure should 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.

Inhalable dust (EN481 and/or ISO7708) in the atmosphere of the enzyme producing industry, bakeries, flour mills and manufacturers of dough improvers is the main source of occupational exposure to enzymes. Enzymes such as fungal alpha-amylase are usually associated with flour dust in bakeries and related facilities because they may be added to flour that has been finely milled or otherwise processed from cereal grains.

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

- Dispensing
- Sieving
- 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

7.2.8 Sampler Positioning

Air samplers are so designed that dust samples are collected in the same way that an operator would inhale dust.

The monitoring head of the high flow sampler should be placed in a position equivalent to the operator's breathing zone (typically 1.5 meters above the floor). The filter head should be designed or modified to give the needed speed of air flowing into the filter for the relevant particle fraction (cf. EN 481: Workplace atmospheres "Size fraction definitions for measurement of airborne particles"). Exact sampler locations, in terms of distance from the source, should be determined on a case-by-case basis following the outcome of the risk assessment and the location of any potential peak exposure sources. The position of the samplers can be clearly marked on the floor to ensure that they are always placed in the same location.

7.2.9 Targeted Sampling

Some operations have a relatively high potential for generating dust or aerosol, such as cleaning, maintenance, rework, troubleshooting, etc. Where such operations are part of the routine air monitoring program, samples should be taken during periods of activity.

7.2.10 Sampling Procedure

Filters should be weighed before and after taking the air sample to determine the inhalable dust fraction before conducting the analysis for enzymes. Care must be taken not to damage or contaminate the filter before or during analyses.

Filters should be removed from the sampling device in a clean environment as soon as possible after the sampling process is completed.

7.2.11 Sampler Calibration and Maintenance

Calibration of the equipment (Figure 32) is crucial for the reliability of the results: pumps must be calibrated before and after sampling, with the sampling media in place, to verify that the sampling rate remained constant during the test measurement. (cf. EN 13137 – Workplace atmospheres: pumps for personal sampling of chemical and biological agents – requirements and test methods)

Sampling pumps should be calibrated according to the manufacturers' instructions and recommended frequency.

Primary Calibration Standards (examples: soap-bubble meters, spirometer, Gilibrator, Buck Calibrator, Defender, etc.) take direct measurements of the flow of the device.

Secondary Calibration Standards (e.g., precision rotameter) are calibrated against a primary standard.

Low flow pumps should be calibrated before each use and the primary calibration device sent for certification once a year. Calibration of high flow pumps should be checked at regular intervals. Modern high volume samplers often have calibration facilities built into their electronics.

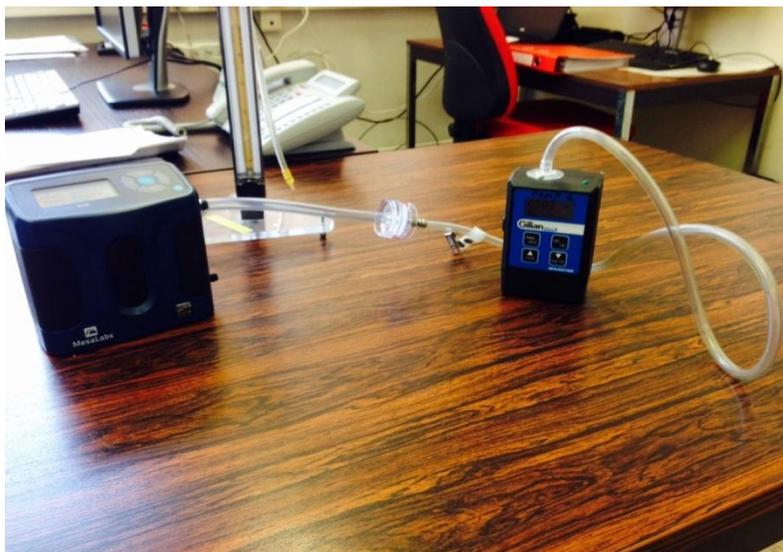


Figure 32. Calibration set-up for air sampling equipment.

7.3 Observations

Operators should record any non-routine conditions and behaviours taking place in the area during sampling that may affect the results; such as spills, maintenance, and intervention

without PPE etc. Observations should be logged along with the results. The requirements for reporting exposure measurements are stated in EN689.

7.4 Data analysis and interpretation

7.4.1 Data interpretation

If there is a national limit value for workers exposure, interpretation should be done according EN689.

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?

There are many methods for analysing results. One example uses a statistical concept called Capability Ratio (Cpk) but is not defined in EN689. A further useful performance indicator is the Upper Control Limit (UCL). This indicator is defined in the EN689 as the upper confidence level of the 95th percentile.

We refer also to the website of the American Industrial Hygiene Association (<https://www.aiha.org/get-involved/VolunteerGroups/Pages/Exposure-Assessment-Strategies-Committee.aspx>) and their tool IHSTAT, developed by the AIHA, which is an Excel worksheet that enables statistical analyses of occupational hygiene measurement data and compliance testing.

7.4.2 Definition and Use of Cpk

$$\text{Cpk} = \frac{\text{OEG Value} - \text{Average Value}}{3 \times \text{Standard Deviation}}$$

Where:

- Cpk = Capability Ratio
- OEG Value = Value of Occupational Exposure Guideline (DMEL is set as 60 ng/m³ for enzymes)
- Average Value (AVG) = Arithmetic mean for data from sampler location
- Standard Deviation = the standard deviation calculated assuming normal distribution of data

If the average of 3 or more measurements plus 3 standard deviations provides a value less than 60 - this means that the CpK is > 1. In this case the dataset can be considered valid and suggests that respiratory protection is not required in that area or for that task.

CpK is a measure of the capability of a system for delivering results below the OEG: the greater the CpK, the higher the capability. Given that the OEG is a fixed value, a lower average value and a lower standard deviation make a system more capable.

The trend in CpK values calculated for a sampling location can be used to indicate if an area is considered to be in control (i.e. $Cpk > 1$) or out of control (i.e. $Cpk < 1$).

7.4.3 Definition and Use of UCL

UCL is a fixed level based on performance of several locations. Typically, it is 50% of the OEG.

7.4.4 Corrective actions and follow-up

Remedial steps should be taken immediately to resolve any exposure conditions leading to an air sampling result out of the OEG limit. When re-sampling confirms the high level, then the use of RPE or stopping production should be considered until appropriate controls can be implemented. The follow-up procedure is defined in EN689.

7.4.5 Feedback to employees

If the exposure in an area is above the OEG limit, employees should be informed immediately and wear RPE until the measurements return to the acceptable limits. When the CpK results are within limits but the air sampling data is above the UCL, then the mandatory wearing of RPE should be considered on a case-by-case basis.

The individual results above the OEG limit or above the UCL, as well as the percentage of routine sampling locations with $Cpk < 1$, should be reported periodically to all employees and shared during the safety meetings. The report should include a summary of the basic causes found during the investigation, any corrective actions that were recommended, and the status of their implementation.

7.5 Limitations of an air monitoring program

Air sampling results, together with the outcomes of the medical surveillance programme, provide valuable information regarding the effectiveness of control measures. However, it is necessary to take into account the limitations of any exposure monitoring program, e.g.:

- No 'real-time' monitoring equipment available currently. This is only available for particles. If the ratio of the enzyme concentration and the inhalable dust fraction for certain products is determined, direct reading devices can be used.
- Are peak exposures adequately monitored?
- When comparing monitoring results with the DMEL, are synergistic effects taken into account? No, but EN689 requires calculating the cumulative exposure index.
- The variable rate of uptake of hazardous substances according to the degree of physical exertion.

- EN 689 allows “health expert advice” based on only 1 data point if the result is less than 10% of the exposure limit.
- Monitoring results that are less than the DMEL do not guarantee zero incidences of sensitization.
- Limits of the assay sensitivity: denatured enzymes (high T°, low pH,) with a largely intact protein structure may not respond to current analytical assays but may still elicit an immunological response

The nature of the sampling regime means that results are always viewed in hindsight so that it might be difficult to trace back to what went really wrong at the time of the sampling. Observations according EN689 should give information during sampling.

7.6 Analytical methods

One aspect of the exposure monitoring is the sampling, but the analytical part is equally important. There are two common methods, of which the activity based assays is still the most practical one. Please contact your enzyme supplier for further guidance on the analytical methods. According EN482, methodologies should be validated between 10% of and 2 times the limit value.

Activity based assays are easy to set up and run, but the higher LOD's may be the limiting factor. The analysis of the so-called ‘blanks’ is important for the validity of the air monitoring results. Blanks are analysed to rule out sources of contamination and analytical error. A buffer blank should be collected on each day that the buffer is used. At least one filter blank should be analysed to rule out contamination of the filter stock.

In addition, air monitoring assays require prompt analysis. Enzyme activity decreases over time so that filters should be preserved in a buffer as soon as practicable after the sampling has been performed. Filter cassettes should be refrigerated if the filters cannot be placed in a buffer on the day of the sample collection. Samples can generally be kept in buffer for a few weeks if they are stored at refrigeration temperatures. This information should be available in the validated SOP's for the air monitoring assay developed by the enzyme suppliers.

Immunoassays, like Elisa, rely on the binding of the enzyme to specific antibodies in order to quantify protein level. They also provide a more physiologically relevant measurement. Although Elisa techniques are able to measure very low detection limits, they require additional equipment and specialized training, so these are less often used in normal production quality control laboratories.

The air sampling filter needs to be selected and validated for recovery of the enzyme from the filter. The recovery efficiency needs to be determined for each enzyme and filtration material.

8. Health surveillance

This 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 **enzyme-containing dust**. The protocols recommended in this document may be refined by occupational health specialists based on historical results obtained from their specific area of the baking industry.

The content of this 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). It also includes, with the exception of some modifications, recommendations given in that publication.

Other strategies may be used; e.g. the “Application of a prediction model for work-related sensitization in bakery workers”, as referred to in the following link: <https://www.ncbi.nlm.nih.gov/pubmed/20150203>. This strategy was successfully used in the Netherlands, where bakers at high risk of having work-related allergy were identified by use of a questionnaire-based prediction model for work-related sensitization.

It should be emphasized that enzymes generally have a low order of toxicity. There are only two toxicological end points:

- **Respiratory allergy** which is an intrinsic hazard for all enzymes, and
- **Skin irritation**, which is an intrinsic property of enzymes belonging to the class of proteases.

In addition to alpha-amylases and glucoamylases; cellulases, lipases, xylanases and proteases may also be used in the bakery sector.

The main safety concern associated with enzymes is their potential to induce respiratory allergy, as these effects are practically irreversible. Unfortunately, the relationship between airborne exposure to enzymes and the development of sensitization or allergy is still poorly understood.

Although enzyme formulations have been improved in recent times; changing from very dusty powder to less dusty granular, paste-like and even liquid enzyme formulations; there are still situations where the number of enzyme allergies is on the increase due to lack of awareness by workers and management in this sector.

8.1 Definition

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

8.2 Objectives

Health surveillance is highly recommended for all employees in the bakery supply chain, who may be exposed to flour and bakery ingredients; especially enzymes. 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.

8.3 Health effects resulting from occupational exposure to airborne enzyme

Respiratory allergy, which is also called Type 1 allergy, is the only sort of allergy caused by enzyme exposure. Enzymes do not cause allergy via skin contact and, to date, enzymes have not been associated with food allergy.

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

The induction (sensitization) 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 sensitized.

The elicitation stage: A sensitized 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 sensitized person is repeatedly exposed at sufficiently high level and for sufficiently long periods of time, allergy symptoms may develop, and the person is now allergic.

The difference between being sensitized and being allergic is determined by the appearance of allergic symptoms. A sensitized person has no symptoms and sensitization by itself is not a disease, whereas an allergic person will always present allergic symptoms when exposed to the allergen in question. Sensitization is the early warning that an allergy may develop. However, prompt and correct intervention may prevent the development of a full blown allergy.

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*** sensitization. Therefore, it is of key importance to prevent peak exposures.

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 and more severe symptoms may appear, and in some cases these may become chronic.

It is, therefore, vital that swift and appropriate intervention should 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 sensitized and of developing symptoms.

In addition, it appears that individual susceptibility may vary from time to time. For example, returning to work after a recent infection seems to increase the risk of becoming sensitized or of developing symptoms.

Some enzymes are able to 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 localized, 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.

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 enzymes as raw materials in the bakery industry. Several studies have shown that consumers of products that contain enzymes in today’s market 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.

8.4 Guidance for a Health Surveillance programme

8.4.1 Pre-placement testing

A pre-employment or pre-placement testing should always be conducted before starting work in an environment where enzyme exposure cannot be excluded. It is important to emphasize that pre-placement testing cannot be used for discriminatory purposes. Such pre-employment testing should include:

Medical history should be assessed with particular reference to, for example, asthma, allergic rhinitis, eczema, urticaria, allergies, chronic lung disease and any medication.

A respiratory questionnaire should be completed including details of smoking habits. The purpose of this pre-placement questionnaire is solely to detect and thoroughly describe any existing respiratory symptoms. A questionnaire should also be completed at subsequent health screenings to follow up on any changes since the last test. Examples of such pre-employment and periodical questionnaires are given in the AISE Guidelines for the Safe Handling of Enzymes in Detergent Manufacturing. These questionnaires are based on one that was published by the International Union against Tuberculosis and Lung Disease (IUATLD) in 2001. Occupational health specialists should assess the significance of any reported symptoms and should identify any smokers.

Assessment of lung function should be made using a suitable spirometer and following an accepted standardized procedure and protocol in order to minimise measurement errors. A detailed description of such a procedure can be found in the AISE guideline on safe handling of enzymes. Spirometry should be conducted by trained and competent staff, as testing and interpretation require both skill and training. The parameters to be measured are:

Forced expiratory volume in 1 second (FEV1). This is the volume of air that can be forcibly blown out in one second, after full inspiration. The average values of this parameter in healthy people will depend mainly on gender and age, as well as height and mass. Values of between 80% and 120% of the average value are considered normal.

Forced vital capacity (FVC). This is the volume of air that can be forcibly blown out after full inspiration. The ratio between FEV1 and FVC in healthy adults should be approximately 70–85%, and this declines with age. In obstructive diseases like asthma the ratio between FEV1 and FVC is reduced – often down to 45%.

Peak Expiratory Flow Rate, (PEFR). This is the maximal flow (or speed) achieved during the maximally forced expiration. It is measured in litres per minute or in litres per second. A minimum of three trials should be completed to check for reproducibility.

Once acceptable and reproducible spirometry results have been obtained, the results should be interpreted by a trained and competent person.

Immunological Tests e.g. skin prick or serological tests should be performed. The purpose of immunological monitoring is to monitor the appearance of sensitization among the workforce, revealed by the development of specific IgE antibodies. It is important to remember that sensitization is not a disease: it is an indication that a person has been exposed, and may be on their way to developing an allergy. Monitoring the immunological status of the employees makes it possible to prevent the development of an enzyme allergy by appropriate intervention. Two methodologies are generally used for this type of monitoring, namely the Skin Prick Test or the Serological Test, which involves the analysis of a blood sample to identify specific IgE associated with baking enzymes. A detailed description of both methods can be found in the AISE guideline on safe handling of enzymes. Both methods are recognized as being fit for the purpose, but both also have advantages and disadvantages.

The main advantages of **skin prick testing** (Figure 33) are that the result is obtained almost immediately, and that the method is relatively inexpensive.



Figure 33. Skin prick testing

One of the disadvantages of this method is that it requires a high degree of training and skill on the part of the staff who are conducting the test. Another disadvantage is that this method does not produce a quantitative result. The result will be either a positive or negative response in terms of sensitization towards the allergen in question. Typically, a concentration of 50 µg

enzyme proteins per ml of reconstituted material has shown to deliver valid results. The reagent must be sterile.

For **serological testing** the major advantages are that the result obtained is quantitative; that analysis for more allergens can be conducted on the same blood or serum sample; and that the serum sample can be stored for analysis at a later point in time. The latter could be relevant if, at some point, it becomes necessary to test for sensitization towards a different allergen than was previously investigated. The serological testing does not require specially trained nurses or staff on-site, but it will require the serum samples to be transported to an accredited or certified laboratory. This is important to prevent the reporting of false positive or false negative responses. The main disadvantages of serological testing are that the results are not obtained immediately; and that that this method is relatively expensive.

A physical examination may be carried out at the discretion of the occupational health professional who must have approved and certified training in occupational medicine.

Subjects with significant findings such as a history of asthma, allergic rhinitis or other respiratory disease, or poor lung function should be assessed carefully. The Occupational health professional will make suitable recommendations on the basis of medical history and examination findings and in accordance with local legislation; regarding the employee's fitness to work with enzyme products and of any necessary special requirements. Such recommendations should be based on formal risk assessment and sound clinical judgment.

8.4.2 Temporary Workers

In the case of occasional or temporary workers, the medical selection and surveillance procedures will depend on the duration and degree of exposure. Where there is significant exposure for one month or more, the protocol for "new employees" should be applied.

8.4.3 Employees working with enzymes

During the first 24 months of employment, individuals should have six-monthly health surveillance checks and thereafter a minimum of every 12 months.

The review should include (see also under 8.4.1 for the respective methods):

- Periodic Respiratory Questionnaire
- Spirometry
- Immunological Test

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.

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; should have immediate further assessment. They should also be re-tested within one month or at the discretion of occupational health professionals.

Those who show a **continuing downward trend in lung function** should be carefully assessed regarding the need to remove them from further work with enzymes.

Employees with clinical symptoms of enzyme induced respiratory disease should have their fitness to work assessed by an occupational health professional. Workers who regularly deal with enzymes or enzyme-containing materials should be trained to recognize any symptoms that may arise due to the nature of their work; and must be encouraged to report those symptoms to the occupational health centre.

There should be careful monitoring of any absence of enzyme workers due to respiratory problems, with appropriate follow up action by an occupational health professional.

8.4.4 Record Keeping

All relevant records must be kept for a certain period of time according to national legislation, including data protection and privacy regulations after employment has terminated. Clinical information obtained from health surveillance should be maintained in confidential personal medical records.

8.4.5 Data interpretation and follow-up

The results of immunological tests should be given to the individual employee in question. They are of practical relevance for the individual, since they may permit the identification and correction of any contributory or causative factors; such as failure to follow safe job practices. Each case of sensitization should be assessed by a workplace investigation conducted by an occupational health specialist.

Analysis of group results of immunological test results also assist in the evaluation of workplace control measures. Group data should be used to monitor the effectiveness of hygiene and engineering programmes at factories and within individual departments. Such data will help prioritize areas for improvement. However the validity of this type of monitoring is affected by group size.

8.4.6 Benchmark

In 2015 a study conducted by AISE and the American sister organization ACI was published showing exposure and health surveillance data from more than 100 detergent producing factories over a period of 5 years.

From this very comprehensive study it can be seen that when exposure is in control, the incidence rate of new sensitizations, i.e. the percentage of new sensitizations per calendar year, comes down to approx. 1%. Only 10% of those newly sensitized individuals will go on to develop an allergy to enzymes; that is to say only approx. 0.1% of the workforce is at risk of developing an enzyme related allergy.

It has to be highlighted, though, that the detergent industry has, over the last 4 decades, made drastic improvements in the management of enzyme safety. The baking industry can leverage the success of the detergent industry by adopting similar enzyme safety processes.

References

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Useful links

- Example of general information on health surveillance (UK example)

<http://www.hse.gov.uk/coshh/basics/surveillance.htm>

- Application of a prediction model for work-related sensitization in bakery workers (The Netherlands)

<https://www.ncbi.nlm.nih.gov/pubmed/20150203>.

9. Consumer aspects

It is important to emphasize at the outset that the risk of respiratory sensitization to enzymes is solely occupational. Enzymes used in the bakery industry will be denatured during the baking process and thereby lose their potential sensitizing capability. Thus, baked goods do not represent a risk to the general population. Additionally, enzymes are in general not associated with food allergy (allergy as a result of oral exposure): enzymes can only cause sensitization and allergy via respiratory exposure.

The above statement has been validated and documented in two studies (1, 2), in which individuals already sensitized via the inhalation route were challenged via oral exposure.

In the first study (1) 400 atopic patients (i.e. patients having allergy to at least one common allergen) with diagnosed allergy to inhalation allergens, food allergens, bee or wasp were included in the study. All were confirmed as being sensitized to at least one of the mentioned allergens. In the first place the study population was tested for sensitization to 19 different commercial enzymes used in the food industry, including the baking industry. Among the 400 atopic individuals in the study population, only 13 (3%) of them showed a reaction to one or more of the 19 different commercial food enzymes. These 13 individuals were challenged in a double blind, placebo controlled study where they were given 250 ml black- currant juice to which was added either placebo (water) or the maximum allowed dosages (in Denmark) of each of the enzyme products to which they had shown a reaction. The study can be considered a worst case study since the commercial enzymes used in the food challenge were fully active i.e. not denatured and given in a dosage much higher than that which can be expected under normal conditions. Only one positive reaction was seen the food challenge, and this turned out to be a reaction to a placebo. Therefore, since there were no allergenic findings of clinical relevance, the study concluded that ingestion of food enzymes in general is not considered to be a concern with regards to food allergy.

In the second study (2) 18 patients with respiratory allergy to were included. The 18 patients had acquired their allergy to fungal alpha-amylase via their occupation as bakers. In a double-blind, placebo controlled food challenge the patients were given either 100 g of bread baked with a double dosage of fungal alpha-amylase (compared with the normal dosage), or bread baked without enzyme (as placebo). None of the 18 patients with respiratory allergy to fungal alpha-amylase expressed food allergy to bread baked with the double dose of the enzyme. In a parallel study, a screening of 1000 persons from the general population was performed to estimate the frequency of sensitization to fungal alpha-amylase. The screening showed that none of the 1000 persons were identified as sensitized to this enzyme.

It is concluded that food allergic reactions to fungal alpha-amylase are likely to be rare in the general population and, even among patients with respiratory allergy to enzymes it is not commonly accompanied by a corresponding food allergy.

But what about respiratory exposure to consumers when, for example, handling baking mix products that may contain enzymes?

The airborne exposure to enzymes during vigorous handling of such a product has been studied in a non-published study (3). In this study two different commercial enzyme containing baking mix products were each tested as follows:

In a closed cabin without ventilation, 1 kg of the baking mix product was poured into a bowl and afterwards dry-mixed vigorously for 2 min. using a hand mixer at maximum speed, and then discarded. This process was repeated until 10 kg of the baking mix product had been handled this way. During the handling of the 10 kg of baking mix, site directed air sampling was performed using four 25 L/min samplers with their sampling head placed above the bowl at a distance similar to the breathing zone of a person, who would perform such operation, Figure 34.



Figure 34. Consumer aspect test set-up.

The potential airborne enzyme exposure during this exaggerated set-up showed in most cases an exposure below the limit of detection (1 ng/m^3) and in all cases an exposure well below the limit for consumer exposure (DMEL 15 ng/m^3 , (4)), for which reason the investigated products can be considered safe.

However, it should be emphasized that the outcome of such evaluations is highly dependent on the product that has been tested in the investigation. If, for example, the enzyme concentration in the product is increased; this would call for a new evaluation to make sure that the expected consumer exposure would still be below the DMEL; even under exaggerated use conditions.

Generally speaking, it would be prudent to perform a safety assessment in which the level of respiratory exposure is evaluated on all consumer products before launch and, as a general principle, consumers should be advised not to create airborne dust when handling flour products regardless of whether or not they contain added enzymes.

AISE has prepared a slide deck (5) and a guideline which can be useful when such an evaluation is to be undertaken (6).

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5. AISE webinar material on “Consumer Safety”: <https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes.aspx>
6. Developing consumer products containing enzymes, ensuring consumer safety. <https://www.aise.eu/cust/documentrequest.aspx?DocID=2785>

10. Concluding Remarks and Acknowledgments

In this document the authors have shown the importance of minimising and controlling dust exposure throughout the bakery supply chain. This control is achieved by using a holistic approach: from a technical perspective in the form of ingredient format and equipment design for example, through operator behaviours and effective management. The advice and best practices provided in this document should be read in conjunction with local guidelines and regulations where applicable.

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