



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

GUIDING PRINCIPLES FOR THE SAFE HANDLING OF ENZYMES IN DETERGENT MANUFACTURE

Version 2 - December 2014

-SUMMARY -

ENZYMES Safety task force

1. Introduction

Enzymes are important constituents of modern detergent products. They are proteins which catalyse chemical reactions. They break down soils and stains and thus achieve improved washing performance. The major types of enzymes used are proteases (to remove proteinaceous stains), amylases (for starch removal), lipases (for fat removal) and cellulases (for general cleaning and to remove cotton fuzz).

Enzymes were first introduced into detergent washing powders in the mid-1960s. Unfortunately the potential adverse health effects of enzymes, particularly the induction of respiratory conditions, including asthma, were not recognized at that time and the enzymes used were in a dusty form, resulting in significant exposure to workers handling them. Within a few years, reports were published indicating many workers handling enzymes had developed respiratory disease symptoms and a few sporadic cases in consumers were also reported. Recognition of these adverse effects led the detergent industry and enzyme manufacturers to take steps to reduce exposure. Major reductions in the dustiness of enzymes, achieved by granulation and changes of product form, the introduction of process and equipment control measures and safe-handling procedures to reduce exposure, and improved monitoring methods led to virtual elimination of occupational respiratory disease due to detergent enzymes. At the present time, such effects are only found when process or equipment controls are inadequate or when failure to comply with recommended safe practice occurs.

A.I.S.E. has produced a document which provides detailed guidance on procedures and equipment recommended to achieve safe handling of enzymes. The present document is a shortened version of the guidance which summarizes the principles which guide the safe use of enzymes in detergent manufacture. Both documents are intended for use by detergent manufacturing facilities and by third-party co-packers. They gain even more additional value in the light of REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals, (EC) No 1907/2006). REACH requires demonstration of adequate control of risks for identified uses and exposure scenarios should be communicated to ensure implementation of risk managements through the supply chain. The guidance documents support both the enzyme manufacturers/importers as well as the detergent manufactures so that they can meet the REACH obligations managing the adequate control of risks of enzymes.

2. Health hazards

The main safety concern associated with enzymes is the potential development of respiratory allergies. When allergens such as enzymes are inhaled in the form of dust or aerosols they may give rise to the formation of specific antibodies. This process is called sensitisation and is a response of the immune system to the foreign protein. People who are sensitised do not experience any signs of illness and sensitization does not predict the likelihood of respiratory symptoms occurring. A low number of sensitised individuals may be found in all enzyme handling facilities but past experience in facilities which handle enzymes safely shows that these low incidences are not associated with the presence of individuals with clinical symptoms. However some sensitised people may upon a further exposure to the enzyme develop respiratory allergy with symptoms similar to those of asthma and hay fever. These may be itching and redness of the mucous membranes, watery eyes/nose, sneezing, nasal or sinus congestion, hoarseness or shortness of breath, coughing and tightness of the chest. The symptoms may develop during or after working hours, and will normally disappear within hours or a few days after exposure ceases.

There is no clear scientific evidence that enzymes are skin sensitisers or cause sensitisation by ingestion.

Enzyme preparations containing proteolysis enzymes are capable of causing eye and skin irritation. Other enzymes such as lipases, cellulases and amylases are not likely to cause irritation. Other components of a liquid or encapsulated enzyme may also contribute to skin and eye irritation.

3. Occupational Exposure Guidelines

Under new EU legislation (REACH), there is a requirement to define safe conditions of use for a substance for which human exposure is expected. This is based on setting a derived no-effect level (DNEL) for the substance. Where a DNEL cannot be established, e.g. for respiratory sensitizing substances, then a derived minimal effect level (DMEL) is recommended. For the bacterial and fungal enzymes a DMEL of 60 ng/m³ has been proposed and is used in the detergent industry but applies to all industries handling enzymes.

Decades of experience demonstrates that enzymes can be used safely by ensuring that the exposure is strictly limited. Occupationally, a DMEL of 60 ng/m³ provides an excellent starting point for safety assessment, with experience showing that downward adjustment of this value may be necessary to take account of particular circumstances to ensure safe working practice. In the detergent industry it is recognized that co-exposure with surfactants may enhance the allergenic effect of the enzyme.

Occupational Exposure Guidelines (OEGs) for enzymes are established in order to provide guidance on exposure levels which are not associated with clinical symptoms (although a limited degree of sensitisation may occur at these levels). In well-controlled facilities an incidence of 3% new sensitisations amongst its workforce per annum represents a pragmatically acceptable upper limit, and one which is not associated with the generation of clinical symptoms, either in newly sensitized workers or in those that have been sensitized for some time.

There is only one occupational exposure limit established by regulatory agencies for enzymes. This is for Subtilisins (proteolytic enzymes derived from *Bacillus subtilis* or related species). A limit of 60ng/m³, based on at least one-hour sampling, was set by the ACGIH. This limit has been adopted by several countries.

In addition to the levels set for enzymes, an industry guidance value for the overall detergent dust levels is recommended as 1 mg/m³ to avoid respiratory irritation from the detergent formulation.

4. Management and Supervision

4.1 Responsibilities

As with any other workplace activity, employers of those handling detergent enzymes have a responsibility to ensure that the health and safety of their employees is protected. This duty necessitates a full understanding of the potential risks that are present in the workplace and requires arrangements to be put into place to mitigate those risks. The duty of care of employers extends not only to direct employees (line operatives, maintenance staff, engineers, laboratory staff etc) but also to contractors, agency staff, cleaners, visitors and others who may be affected by the activity in question. Each individual employee is also under a legal duty to safeguard their own health, and that of others, by complying fully with safe working practices prescribed by the employer.

Management is responsible for ensuring risk assessments are performed, appropriate risk management procedures are put in place and risks communicated to the workforce (see below). Additionally, they should ensure that suitable equipment is available for safe-handling of enzymes, procedures are in place to minimize exposure of employees and that monitoring and audit systems are in place to check compliance with these procedures.

4.2 Risk assessment

Accepted best practice is to conduct a risk assessment on every activity in order to determine what safeguards need to be put in place to ensure safety. This is also a legal requirement for Manufacturers/Importers under the REACH regulation which demands that adequate control of risks be demonstrated and exposure scenarios be communicated to downstream users for all identified uses of substances, if the tonnage is equal to or more than 10 tons per year. Each operation in which an employee (contractor, visitor etc) can potentially come into contact with enzymes should be identified and evaluated for potential exposure (this is often done by a task analysis, i.e. breaking down the process into individual actions). Similarly, the consequences of exposure should be considered in terms of their severity. Exposure to high levels of airborne enzyme may be considered to involve severe consequences (occupational asthma), while skin contact to proteases would result in mild consequences (possible skin irritation) and ingestion would carry negligible consequences.

Combining the probability of exposure to the hazard and the health consequences of exposure to that hazard allows prioritisation of activities into high, medium, low and negligible risks.

4.3 Risk management

Having characterised and prioritised the risk involved in a given activity, it is then necessary to use the information generated to manage or control that risk. Those risks identified as high obviously require immediate attention and the greatest degree of control. Risks can be controlled using a well-accepted hierarchy of approaches.

Prevent exposure

- Eliminate the hazard
- Substitute the hazard by a less hazardous substance

Control of exposure

- Isolate the hazard to prevent exposure
- Reduce exposure by engineering means
 - partial enclosure and exhaust ventilation
 - local exhaust ventilation
 - general and forced air ventilation
- Reduce exposure by use of safe procedures and working practices
- Reduce exposure by personal protection (only if other approaches not feasible).

Risk management also involves ensuring that the controls put in place to manage the risk are effective. This will involve inspection of engineering controls, monitoring of airborne levels of enzymes to confirm efficiency, auditing of procedural controls and observation of the behaviour of operatives involved in enzyme handling, but also the health surveillance of potentially exposed employees. The risk assessment will determine the frequency and extent of monitoring and procedures in the event of monitoring results exceeding pre-determined action levels.

4.4 Risk Communication

Having completed a risk assessment, and established risk management measures, those potentially affected must be informed of the risks and measures taken to control them.

4.5 Training

All potentially exposed employees, contractors and other visitors to the site should have appropriate training in the safe handling of enzymes and the risks involved so that the need for compliance with control measures is fully understood. Employees should also be trained in the use of contingency measures so that they know immediately what to do in the event of spills or other incidents. All employees need to be trained for the tasks and responsibilities they undertake.

5. Control of exposure during the handling of enzymes and the manufacture of enzymatic detergents

5.1 Introduction

To prevent the exposure of employees to enzymes during the manufacture of detergent products, there is a series of well-established engineering controls and operational procedures that have been developed over many years by the industry.

The key strategies are:

- The prevention of dust or aerosol formation by using plant and equipment designed to minimise damage to enzyme encapsulates, and to minimise the formation of airborne dust or aerosol within the process.
- The containment of dust or liquid aerosols at source using closed process equipment maintained under negative pressure.
- The avoidance of routine or uncontrolled spillages.

In broader terms, control of airborne enzyme centres around the following aspects:

- General Building/ plant and equipment design via hygienic design principles
- Enzyme quality and form (use of low dust encapsulates)
- Enzyme supply units (ensuring direct connection of packaging with the process and safe disposal)
- Engineering controls for manufacture and packing (isolating, enclosing and ventilating potential sources of enzyme exposure)
- Operational, maintenance and emergency procedures
- Personal and respiratory protection

5.2 Enzyme Quality & Form

Encapsulated enzyme must be used for the manufacture of detergent powders or tablets. Encapsulated enzyme must meet a suitable quality specification with respect to the level of free enzyme dust present in the encapsulate or that remains associated with the encapsulated enzyme after the manufacturing process.

5.3 General Building / Plant and Equipment Design

Buildings, plant and equipment should be designed as far as is possible to provide an environment that is easy to maintain in terms of hygiene and which minimizes damage to encapsulates in powder plants or which minimizes the generation of aerosols in liquid plants by avoiding splashing.

The interface of employees with the manufacturing plant, and in particular with packing machinery, is a great potential source of personal exposure to dust and enzyme. The design intent should be to eliminate or reduce spillage and to facilitate cleaning with the use of a vacuum tool.

Process and packing equipment design should eliminate external spillage and reduce liquid splashing by:

- Designing efficient enclosures to contain spillage and liquid splashes within the equipment
- Using internal spill pans/trays to collect and maintain spillage within the equipment
- Designing access doors that can be opened without causing spillage to the floor
- Incorporating product reject positions within the enclosure
- Incorporating proper quality assurance sampling points into plant and equipment.

In addition, process and packing equipment design should minimise the need for internal

access by:

- Elimination / reduction of internal spillage through good material handling design
- Automated collection and removal of internal spillage to reduce cleaning
- Improved mechanical reliability
- Use of “Cleaning in place” (CIP) technology
- Use of remote cleaning facilities (i.e. from the outside)
- Using external spill pans/trays to keep the product off the floor where the source of spillage has not yet been eliminated

Vent pipes on any tanks, vessels, hoppers etc should be protected by filters, or vented to a suitable local exhaust ventilation system. For liquids, aerosols can be vented outside without a filter at a suitable location to prevent re-entry to the building.

Pumps should be leak-free mechanical seal designs. Diaphragm pumps and air-driven pumps should be designed and installed to ensure there is no significant risk of aerosol generation as a result of even a minor fault.

Equipment which is likely to give rise to spillages (e.g. dip pipes) should not be used.

5.4 Discharge Process

The discharge of enzyme supply units should provide operator safety by appropriate containment (use of downflow air, use of an enclosed room, secondary containment for liquid dispensing etc). There should be local exhaust ventilation around the discharge unit to ensure containment throughout the discharge operation. Details of the safety aspects of the discharge of different supply units are given in the guidance document.

The safety of dispensing and disposal should be considered in choosing the type of supply unit to be used. The options for disposal are return to the supplier, incineration or land-fill. Contaminated packaging waste must be safely contained within another closure to ensure safe handling at all downstream stages of the disposal operation. Packaging returned to the supplier must be in a safe condition, with no external contamination, and no risk of loss of integrity during the return trip. The preparation of packaging waste for disposal should be carried out in the isolated discharge area under controlled conditions, by operators wearing suitable respiratory and personal protection.

5.5 Enzyme Transfer and Dosing

Transfer of enzyme encapsulates and liquids may be achieved by gravity or by powered systems, such as conveyor belts, dense phase vacuum transfer, or pumps. Containment can be achieved either by the use of a closed system or partial enclosure and ventilation control.

When enzyme encapsulates are transferred it is essential that the plant and equipment is designed to minimise any damage to the granules, thus maintaining their integrity. Thus, equipment which should not be used for transfer of enzyme encapsulates includes screw conveyors, disk conveyors, brush conveyors, and drag conveyors unless an evaluation of encapsulate damage using a suitable method as described in Chapter 10 of the guidance document shows the equipment does not cause significant physical damage.

Dosing of enzyme encapsulates should be undertaken at the latest possible point in the production process, so as to minimise the amount of equipment that will be contaminated with enzyme, and reduce the distance that enzyme will be conveyed, thus minimising the potential for encapsulate damage. Belts and conveyors used to transfer encapsulates (and transfer points between different conveyors) should be fully enclosed and placed under adequate ventilation control.

Dosing should only be carried out using contained and controlled dosing systems. Manual dosing of enzymes must never be carried out by open tipping, or pouring, through the manway, or over the side, of any mixing vessel.

For liquids, there are design guidelines that can help to prevent exposure occurring in the event of a leak (e.g. use welded, threaded, or flanged pipework connections, cover flanges with flange protectors) or during normal operation (e.g. vent piped outside or into the local exhaust ventilation system). Pumps used for liquids should have a minimum leakage design.

Liquids dosing plants should be sited in a contained [authorised access] area, under negative pressure with respect to the building, and controlled with a high level of dilution ventilation.

5.6 Mixing / Blending / Fluidising

There will be a large variation in the standard of enclosure, and containment of plant for mixing the post-dosed formulation ingredients. For some plants containment is implicit in the design, as with continuous dosing plants for liquids for example, but in others there may be a risk of dust and/or aerosol release, particularly at the loading transfer points. In all instances, transfer points should be enclosed as far as is practicable, and the containment assured by the application of ventilation control to the enclosures to maintain an inward air velocity of ≥ 1.0 m/s at all gaps and openings, or by the provision of local exhaust ventilation.

The transfer and distribution of the product after mixing, either by conveyor belt, or by any other means, should be subject to the same controls as already discussed.

5.7 Bulk or Intermediate Storage

Following the mixing operation there are several possibilities for the storage and distribution of product, both powders and liquids. Filling should occur without the release of dust or aerosol. This will necessitate specific equipment design features for both powders and liquids, depending on the container type. Vents from storage tanks or silos should be filtered to prevent the release of airborne dust or aerosol.

The filling station should be fully enclosed and ventilated by a combination of local exhaust ventilation at the filling head, and enclosure ventilation to maintain the overall integrity of the filling operation.

Exterior surfaces of storage containers should be cleaned frequently to prevent significant build-up of dust.

5.8 Packing of Finished Product

Filling containers with powders or liquids by gravity or force will result in the generation of dust and/or aerosol. Manual packing of enzymatic products therefore carries with it a very significant risk of exposure to dust and/or aerosols and must not be undertaken.

Packing machines should be enclosed as much as is practicable. All major openings in the enclosure should be minimised, and all doors or other such access points should be fitted with effective seals. Sufficient extract ventilation should be provided to ensure that an air velocity of ≥ 1.0 m/s is achieved at all gaps or openings in the structure.

The ventilation control should always be interlocked with the operation of the packing machine to ensure that the machine cannot be operated if the ventilation is not operating, or the efficiency has dropped to a level at which control has been lost.

When filling packs with powder, direct local exhaust ventilation of the dusty air displaced from the carton or bag is the best practice to contain a major source of dust.

Spillage Recovery in Packing Machines

Spillages may be removed safely by constructing spillage trays, or hoppers, beneath the filling heads that can be designed to be emptied without the need for an operator to open the machine enclosure, by using a portable vacuum cleaner fitted with a HEPA¹ filter, the ventilation control system, or a separate vacuum transfer system, or in the case of liquids, by the use of a sump from which the product is pumped for rework or disposal.

Spillage recovery using the ventilation control system requires very careful design to ensure that the system does not become blocked and lead to a loss of containment / ventilation control. There are two approaches that can be adopted:

- Design the ventilation control system with sufficient airflow to ventilate the filler cabinet and the spillage hoppers. The powder carrying capacity of the available air stream should be sufficient to prevent blockages occurring in the hoppers and ductwork due to spillage. Incorporate a powder separation facility to remove excess powder from the ventilation system prior to the filtration unit, or
- Provide separate ventilation control and spillage recovery systems to the packing machine enclosure.

5.9 Tableting

Tableting involves the application of force to the detergent powder and as a result encapsulated enzyme may be damaged. This can, by design, be minimised. Because of the higher risk of damage, a higher degree of control may be needed for the tableting process than for powdered products. The spillage, dust, and debris which builds up within the tableting machine will contain a higher proportion of damaged encapsulate than would be encountered in a normal packing machine. The same constraints should apply for access into, cleaning and maintenance of this equipment as would apply to other enzyme process plant. Tablet-conveying systems must be fully enclosed and ventilated as per the general requirements for transfer systems. Tablets should only be handled using fully enclosed and controlled systems until packed into sealed retail packs.

Tablets rejected because they are damaged, not correctly formed, or underweight should be collected under controlled conditions. It is essential that the equipment or process used to break down reject tablets minimizes the amount of enzyme released. Carefully managed trials on the reclaimed powder using the analytical methods described in Chapter 10 of the guidelines can be used to guide process improvements to minimize release of enzyme dust. As there is the potential for the powder to contain some damaged encapsulate, or at least more than normal finished powder, the handling, transfer, and dosing of the reclaimed powder should be carried out by fully contained processes, and preferably automated to remove any manual interface.

5.10 Product Reclaim, Rework & Trade Returns

Reclaim of packed product is often a manual operation. 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. The whole reclaim process should be carried out within the containment of a booth controlled by ventilation. The booth design should facilitate the safe collation and disposal of packaging. Because of the inherent potential for exposure due to handling a large quantity of leaking product containers, larger volume central rework or scrapping stations should be isolated from other operations.

¹ High Efficiency Particle Absorption filter, generally made of fan-folded glass-fibre paper which typically removes >99.995% of particles

Operators undertaking manual reclaim of powders must always use suitable respiratory protection as secondary protection. Whilst full control of the actual reclaim process is possible, there is a risk of exposure from handling packs that may be damaged, open, or externally contaminated, when handled outside of the reclaim booth.

Waste packaging will contain some traces of enzymatic powders, or enzymatic liquids. Therefore it should be handled carefully to avoid exposure to dust or aerosol.

Containment and control of automated compaction units should follow the same basic principles as process plant.

Third party waste recycling companies must be informed of the hazards and risks associated with the handling and processing of packaging that is potentially contaminated with enzymatic product.

5.11 Filtration of Extract Air

Air contaminated with enzymatic dust and/or aerosol should be cleaned prior to discharge to the environment. Air that is to be returned to the working environment must be filtered to HEPA standard, to at least EU13.

5.12 Dealing with Spillages

Spillage of enzyme encapsulates and liquids, and spillage of enzymatic products, must be removed with the use of a vacuum cleaner fitted with HEPA filtration. There are several types of vacuum equipment, including central vacuum systems, portable vacuum systems and mini-central vacuum systems. The advantages and disadvantages of these are dealt with in section 5.13 of the guidelines. Brushes, brooms, and compressed air **must not** be used for cleaning spillages, as these will generate significant airborne dust. Smaller spillages may be removed by a soft water hose. Respiratory protection must be used for all cleaning operations as the risk of exposure is high.

5.13 Personal & Respiratory protection

The protection required from respiratory protective equipment (RPE) will depend upon the task, the potential level of exposure, and whether the RPE is required for primary or secondary protection. The filtration efficiency that is required to provide the necessary protection should be determined by undertaking a risk assessment for the particular task.

Primary control of exposure during normal manufacturing operations should always be achieved by means other than the use of respiratory protection. It still has a role, for example in cases where a secondary safeguard is required, or in the event that emergency or maintenance situations arise. Examples are: "On-line" maintenance, access into filling machine enclosures, product reclaim, dealing with small spillages, cleaning, quality sampling. In abnormal situations RPE may be required as primary protection e.g. /Major spillage of enzyme raw material or product /Dealing with, and repair of, damaged enzyme supply units /Gross failure of containment or control /Maintenance or repair of contaminated plant & equipment /Decontamination of plant & equipment.

Some enzymes are skin irritants. Detergent products are usually high pH and are also irritants, or may also contain other irritant materials. Therefore skin and eye contact with enzymes, or enzymatic products, should be avoided with the use of suitable personal protective equipment.

Under **normal** operating conditions all employees, contractors and visitors should use the relevant personal protection equipment appropriate for the areas they visit and the tasks they undertake.

Showers must be available for personal decontamination at the end of shift, after undertaking abnormal tasks, or in the event of an emergency.

6. Assessment of equipment performance and behaviour

It is essential to ensure that the controls and procedures put in place to limit enzyme exposure are working effectively.

Objectives of monitoring are to look for trends in results that will:

- Confirm that existing controls are adequate
- Confirm compliance with operational procedures
- Confirm a good margin of safety when engineering or operational changes are introduced
- Indicate when control measures are deteriorating so that action can be taken to rectify deficiencies before there is a problem
- Reassure employees and others that working conditions are safe
- Indicate the scale of a problem in the event of a breakdown or other control failure and confirm when the issue has been brought under control.

It is important to set limits for those items being monitored. Operational procedures are needed to ensure that deviations from predetermined acceptable levels are communicated to an appropriate person so that remedial action can be taken. The essential elements of a monitoring programme are sampling of airborne dust and enzyme, monitoring to ensure that equipment is functioning properly and visual assessment of containment. Compliance with operational guidelines can also be monitored e.g. by a Behavioural Observation System, inspections of tidiness and housekeeping.

6.1 Semi-Quantitative Assessment of Containment

Visual assessment is an effective and simple tool to help detergent manufacturing sites identify areas where containment has been lost and take corrective action. No visible powder/liquid should be present outside of dust/aerosol control containment or enclosed spillage containment and there should be no recurring spillage outside of dust/aerosol control and spillage containment. If there is visible dust or liquid aerosol (either visible to the naked eye or as seen by backlighting) then it should be assumed there is an exposure above the OEG.

Each operating department where enzyme exposure could occur should have a survey process to gather and document performance data. Initially, surveys should be completed in each operating department according to an agreed schedule and should be completed at random points throughout the shift. Surveys should also be completed after maintenance activities but **prior** to start-up to ensure that no enzyme spillages have occurred during the maintenance procedure.

6.2 Assessment of Equipment Performance and Maintenance

Without routine maintenance attention, the performance of equipment such as local exhaust ventilation systems degrades over time. Spills of enzyme containing product occur due to equipment leakage, operating procedure or process malfunctions. The causes of recurring spillage need to be identified and corrected to minimize enzyme exposures. There should be clear accountability in the plant organization for hygiene equipment performance results.

A monitoring and maintenance plan should include:

- Daily visual checks of the system
- Scheduled airflow and static pressure measurements to ensure operation within baseline conditions which are documented at system start-up
- Scheduled duct and equipment inspections and cleaning
- Scheduled mechanical lubrication and maintenance for the fans, filters and airlocks
- Record keeping requirements

6.3 Peak Exposure Detection

It is believed (although not yet proven) that sensitisation occurs predominantly as a result of “peak” exposures above the OEG, rather than maintained low level exposures around the OEG level. The background level of exposure is the average of large and small peak exposures and exposure from continuous sources. Therefore a monitoring programme should prioritise areas and tasks which are likely to give rise to higher peak exposures, based on risk assessments, air monitoring data, incident investigation reports, health surveillance data and worker input.

Potential sources may be located based on visual examination, backlighting by a high intensity light source, the use of a direct reading aerosol monitor or by air sampling.

6.4 Behaviour Observations

The intent of observing behaviours is to ensure that unsafe behaviour leading to exposure in the workplace is confronted and corrected and safe behaviour is reinforced. This provides a simple and yet a powerful tool to eliminate unsafe behaviour “before the fact”. In well-controlled plants most exposure related incidents are the result of unsafe behaviour.

Critical behaviours are identified e.g. those which have a high potential for exposure to enzymes. Useful sources of information are health surveillance records, safe working practices, air sampling data and worker input. Trained observers then observe these behaviours. Scoring criteria need to be in place to determine acceptable levels of behaviour and action triggers. All levels of the organisation should participate in this monitoring exercise.

7. Air Monitoring

The intent is to monitor the airborne dust and enzyme levels in the workplace. Air monitoring includes area and personal sampling. Area sampling is used to evaluate the effectiveness of plant control measures and trends in performance. It can also provide an indication of employee exposure. Area sampling is normally taken at a fixed location. Personal sampling involves a low volume device which is worn by the operator and which can be used to evaluate individual employee exposure by job description or as total cumulative exposure where job rotation applies. However the use of personal sampling is limited by the lowest limit of detection of the methodology.

Normally, both total detergent dust and enzyme airborne dusts are measured in powder detergent manufacturing operations. Only enzyme aerosol is measured in liquid operations. Evaporation of liquid precludes gravimetric measurement of total liquid detergent aerosol. A trained and competent person - like a qualified health and safety professional - should oversee the air-monitoring program. These individuals are 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 collecting the samples. The individuals performing these tasks should be adequately trained in the operation of sampling equipment.

Air sampling Plan

Each site should have a system to ensure that the air sampling program is representative of the overall operation and covers all enzymes in use. Areas with highest potential for exposure should be chosen as area sampling locations. These are likely to include:

- 1) Where the enzyme tipping or discharge takes place
- 2) Enzyme dosing area at dosing units
- 3) Mixing or blending of finished product
- 4) In the powder / liquid storage area
- 5) Finished product storage / transfer areas
- 6) At the head of each packing machine

- 7) At the packing reject station
 - 8) In the area set aside for recovery of powder.
 - 9) Handling of empty enzyme supply containers
 - 10) And, wherever medical surveillance results indicate some areas/activities of concern.
- Section 6.3 on "Detecting And Ranking Peak Exposure Sources" can be used to help identify additional locations.

The system for data tracking should verify that samples are taken at random times on all shifts (day and night). Some operations have a relatively high potential for generating aerosol. Where such operations are part of the routine air monitoring program, samples should be taken during a period of activity.

The sample duration may vary depending on the objective and on the analytical method (i.e. 15 minutes for peak exposure, 4 hours for long duration and up to 8 hours for personal monitoring). Sampling time should also reflect the sensitivity of the analytical method, enzymes levels in the plant, and the air-sampling rate of the equipment.

There are many methods for analysing results. A frequently used methodology uses a statistical concept called Capability Ratio (Cpk). This measures the variability in the difference between the measurements and the OEG. Trends in the Cpk can indicate gradual changes in control and containment. Action levels should be set for further action on the basis of trend data and absolute comparisons against the OEG levels. Follow-up procedures should be in place for deviations from acceptable performance. There should be an agreed system for reporting compliance results to management.

8. Health Surveillance

A health surveillance programme for workers potentially exposed to enzymes should be in place.

The objectives of health surveillance include:

- protecting the health of individual employees by detecting, at as early a stage as possible, adverse changes which may be attributed to exposure to hazardous substances
- assisting in the evaluation of measures taken to control exposure
- collecting and maintaining objective data to detect and evaluate hazards to health.

Pre-employment screening should include a medical history, completion of a respiratory questionnaire, assessment of lung function, an immunological test and a physical examination in order to make an assessment regarding the individual's fitness to work with enzyme products and of any adjustments or special requirements.

During the first 24 months of employment, individuals should have six-monthly health surveillance and thereafter every 12 months. The review should include a Respiratory Questionnaire, spirometry and an immunological test (either skin prick testing or serological analysis). Those with normal findings may continue to work until the next examination. Those with abnormal findings which the Occupational Physician considers could be due to enzymes, require immediate further assessment. It is not necessary to remove sensitised individuals from handling enzymes. However individuals showing symptoms may need to be moved, at the discretion of the occupational physician, so that further exposure does not occur.

The results of an individual's immunological tests should be given to each employee. They are of practical relevance for individual employees, since they may permit the identification and correction of individual contributory or causative factors such as failure to follow job safe practices. Nevertheless positive immunological responses are not an accurate predictor of the likelihood that a person will develop enzyme asthma. Group results of immunological test results also assist in the evaluation of workplace control measures.

9. Follow-up procedures

Where deviations from acceptable control is indicated by the results of the assessment of equipment performance, behaviour observations, peak exposure detection, air monitoring or health surveillance, as indicated in sections 6, 7 and 8 above, then an integrated approach is advised to investigate the causes of the deviations and to identify the appropriate corrective action.

10. Analytical Procedures

The capability to analyse for the presence of enzymes is a major aid to process control. Dependent on the purpose of use methods should have the capacity to measure enzyme in the presence of detergent (e.g. in production samples) or at a very low level (e.g. in samples taken from the workplace atmosphere). Manual or automated methods may be used as long as the required sensitivity and reliability are ensured and the method has been validated.

10.1 Methods to Assess Enzyme in Sample Solutions

Enzyme analysis may be performed using activity-based assays or immuno assays, such as ELISA (Enzyme Linked Immuno Sorbent Assay). There are advantages and disadvantages of each method which influence the choice for a particular application.

The activity-based method measures the enzyme catalysed conversion of an appropriate substrate into a product under well-defined conditions. Catalytic activity is followed photometrically by monitoring the change in substrate or product concentration at the appropriate wavelength. The activity method is simple and rapid. Simple basic equipment (manual methods) and advanced autoanalysers are available commercially from laboratory equipment suppliers.

The ELISA method measures immuno-chemically active enzyme, i.e. enzymes being recognised by specific antibodies. Typically, ELISA methods have higher specificity and are less susceptible to interferences, but require a higher level of expertise to perform and require specialised equipment.

10.2 Protein determination

Protein determination is required for characterizing an enzyme sample or product and for setting and monitoring compliance with OEGs. There are many analytical techniques for establishing the amount of protein in a sample.

Activity-based analysis is the preferred technique for the determination of the level of active enzyme in product and enzyme raw materials. A high degree of method sensitivity is not essential as these usually contain a significant amount of enzyme. Methods should be robust and insensitive to interference by detergent ingredients.

10.3 Methods to Assess Dustiness of Enzyme Raw Materials

The first component in a series of primary control measures in the prevention of operator and consumer exposure to enzymatic dust is the encapsulation of active enzyme into granules. Therefore the dustiness of the raw material needs to be assessed. Additionally it is necessary to ensure that the processes (including delivery) do not damage the encapsulates. There are currently two main methods, the Vertical Elutriation test and the Heubach attrition test, used in the detergent industry to ensure that encapsulates meet a certain quality.

10.4 Filter Analysis from Air Sampling

Typically, sampling is carried out in pre-defined sampling locations over periods of 15 minutes to 4 hours. Shorter sampling periods are used when short duration 'peak

exposures' are suspected, while longer periods are used to monitor average airborne concentrations.

Method sensitivity should be sufficient to detect at least 10% of the OEG for each enzyme type. It should also be noted that reduced sampling periods require high sensitivity methods, as the amount of enzyme collected on the filter is significantly lower.

11. Auditing

To ensure the effectiveness of the enzyme programme, regular audits of the operation systems and equipment are necessary to comply with the OEGs. The audit should cover engineering design and construction, operational systems and maintenance and monitoring, analytical records and health surveillance. Standards need to be set for the frequency of auditing and the role of both internal and external auditors in the process. Non-compliances should not just be recorded but action should be taken to rectify the issues identified as soon as possible.