



Webinars on Safe Handling of Enzymes in the Bakery Supply Chain:

Q&As

April 2020

In 2019, AMFEP, the Association of Manufacturers and Formulators of Enzyme products and FEDIMA, the Federation of European Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery and Patisseries Industries, hosted a series of [webinars](#) to present the [Guidelines on the Safe Handling of Enzymes in the Bakery Sector](#) jointly developed in 2018. This document outlines all the questions asked during the Q&As sessions of webinars, as well as answers provided by the AMFEP and FEDIMA experts.

WEBINAR 1 | Introduction to safe handling of enzymes in the bakery supply chain, including regulatory aspects

<p><u>1.</u> Mixes being designed for home baking may contain enzymes. How did you evaluate that this poses no risk to consumers?</p>	<p>A comprehensive answer to this question can be found in the Guidelines, where the assessment process is described very well. In short, our technicians took several packages of such products and poured them into a bowl, where they stirred it very vigorously into a dry product (the task was carried out in a safety hood). Then, they measured the exposure by collecting air through pumps, that were equipped with filters. These pumps with filters were put in the safety hood and directly placed above this bowl. Technicians carried out the mixing for about 15 minutes. They simply set up a study where they tried to mimic the worst-case scenario for the consumer and, in this way, they did not measure any enzyme levels above the limit value.</p>
<p><u>2.</u> We need to measure the concentration of subtilisin in the air, but we cannot find any laboratory. Do you know any</p>	<p>AMFEP and FEDIMA recommend that you contact your enzyme supplier, who can help you find an appropriate laboratory.</p>



laboratory in Spain that could measure concentration of subtilisin in the air?	
3. Can you suggest a maximum concentration level to reduce the handling risk for the clients?	If you keep levels below the recommend limit value of 60 ng/m ² , which is the DMEL value in the EU, then the risk of sensitisation and allergy is very low. This DMEL value was established based on 40 years of historical data from the enzyme manufacturing industry. If you keep the exposure below 60 ng/m ² , then the incident rate per year (which would be new cases of allergies among the workforce) would be extremely low, i.e. 1 in 1000 exposed workers.
4. When is a safe OEL of 60 ng/m ² accepted for subtilisin? Can we safely assume this limit also holds for other enzymes?	40 years monitoring and health surveillance suggest that there is no significant variation between enzymes or enzyme classes in terms of potency.
5. What has led the Dutch Authorities to introduce an OEL of 10 ng/ m ² ?	AMFEP and FEDIMA are not in the position to comment on intentions of regulatory authorities.
6. Why is everyone only talking about amylases? Is that because it is not (yet) possible to analyse other enzymes in dust?	Fungal amylases are widely used within the bakery industry. This has also led regulatory authorities to give more attention to alpha-amylase, for example in The Netherlands. Nevertheless, it is possible to measure the exposure of many other enzymes by health monitoring and airborne exposure.
7. Am I correct in concluding that enzymes as a sensitising agent is the only significant health hazard for workers in the bakery sector?	The focus of our webinars was on the health hazards of enzymes. We cannot make statements regarding the allergenic potential of other ingredients in bakery wares. But for enzymes, the answer is yes. If we assess the toxicological profile of enzymes, the only health hazard for workers is sensitisation by inhalation. This also applies to the group of enzymes that are proteases, i.e. those enzymes that are able to break down proteins. If the skin comes in contact with high concentrations of proteases for a long period, the skin can be irritated. However, this is a temporary effect, which will disappear in the absence of exposure to proteases. Skin irritation must not be confused with skin sensitisation. Skin irritation is temporary, whereas skin sensitisation is a permanent condition.



WEBINAR 2 | Control of exposure during handling of enzymes in bakery sector: Artisan bakeries, Bakery Schools & Demonstration Bakeries

<p><u>1.</u> Do you always have to wear respiratory protection when working with products containing enzymes?</p>	<p>No, not always. The best thing to do is to assess the risk of dust formation. If there is no dust, then it is not always necessary to wear the respiratory protection. However, this is also dependent on how the working space is set up. A good ventilation system, that extracts the air away from the operator will already significantly reduce exposure to enzymes. Due to the low limit value of enzymes, it is recommended to determine the efficiency of the local exhaust ventilation and the need to wear respiratory protection with workplace air measurements. Respiratory protection equipment is needed for trouble shooting, maintenance and cleaning activities.</p>
<p><u>2.</u> The use of the explosion proof vacuums was not mentioned in the webinars. Should this not be considered when working with combustible dust?</p>	<p>AMFEP & FEDIMA webinars are specifically addressing the health hazards of enzymes in flours and in dust. That is why subjects like combustible dust were not dealt with. Of course, the use of the explosion proof vacuums is something to consider, but this would be independent on whether the enzymes are present in the dust.</p>
<p><u>3.</u> Most North American bakeries use corn meal as anti-dusting agent, rather than wheat flour. Besides the difference in particle size, how does corn meal compare to wheat flour in terms of endogenous enzymes with regard to health/allergy implications?</p>	<p>In principle there are differences between corn flour and wheat flour regarding the number of enzymes present in the flour itself. In general, it is recommended to deal with both flour types in the same way. It is advisable to follow the suggestions reported in the Guidelines and try to limit exposure, to limit the risk. That is independent of which flour is used. Risk is limited in any case.</p>
<p><u>4.</u> When using a vacuum cleaner with HEPA filter, is RPE protection still needed during a clean-up of spillage?</p>	<p>Yes, there is always higher risk of exposure during the clean-up, therefore respiratory protection is always necessary.</p>



<p>5. Why should the local exhaust be placed preferably behind the mixing bowl?</p>	<p>The reason is that in this way you can extract air and dust away from the breathing zone of a person.</p>
<p>6. Can waste bags containing enzymes be provided to third party waste companies?</p>	<p>Yes, but the third party needs to be warned about the possible presence of the enzymes, so that they can take precautions. If you have specific questions about products containing enzymes and how to handle enzymes-containing waste, you should contact your enzyme supplier, who will be able to provide you with clarifications.</p>
<p>7. Are bread improvers the only potential hazard or can premixes with higher dosages pose a hazard too?</p>	<p>In principle, the handling of all different products containing enzymes can be a potential health hazard. Therefore, you have to be careful with all of them. Make sure you follow the Guidelines for all products containing enzymes to be sure you limit the risk of exposure. If you limit the risk of exposure, then you limit the overall risk.</p>
<p>8. In webinars 2 and 1 you talked about flour dust and enzyme dust only. But there are other ingredients that may give dust problems. Do all controls, filters and RPE also work against dust from other ingredients?</p>	<p>Yes, they work against dust in general. However, you should be aware that workers will not be 100% protected using controls and RPE (respiratory protective equipment). Therefore, it is advised to check your local regulations on the assigned protection factors (APFs) of your RPE. In most cases, engineering controls and RPE that are applied to control enzyme dust would also be effective to control dust from other bakery ingredients.</p>

WEBINAR 3 | Control of exposure during handling of enzymes in bakery sector: Flour millers, Industrial bakeries & Ingredients manufacturers

<p>1. For spillage cleaning, can a normal vacuum cleaner be used, if the operator uses protective equipment?</p>	<p>No, it is recommended to avoid doing this. The exhaust from a normal vacuum cleaner may contain very fine enzyme dust, which is not held in the vacuum cleaner by the dust bag. Subsequently, dust can be redistributed into the workplace environment. Operators are possibly protected by a respirator during the clean-up, but anybody else coming into the workplace environment can automatically be exposed to the dust.</p>
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<p>2. Are the suggestions provided for enzyme dust control also effective for other allergens present in the used products?</p>	<p>The measures are recommended for dust, including flour dust. In terms of other allergens, that would depend on the particle sizes of the allergens concerned. But the general recommendation also applies to other ingredients.</p>
<p>3. Can you estimate how much dust formation can be reduced when working in the way described?</p>	<p>Although dust formation can be reduced when you work in the way described in the Guidelines, some dust formation will always occur.</p>
<p>4. Should protective equipment always be worn when working with enzymes?</p>	<p>The best thing to do is to assess the risk of dust formation. If there is no dust, then it is not always necessary to wear the respiratory protection. However, this is also dependent on how the working space is set up. A good ventilation system, that extracts the air away from the operator will already significantly reduce exposure to enzymes. Due to the low limit value for enzymes, it is recommended to determine the efficiency of the local exhaust ventilation and the need to wear respiratory protection with workplace air measurements.</p>
<p>5. What enzymes does flour contain?</p>	<p>All flours contain enzymes of different kinds, as they are naturally-occurring biocatalysts. The exact composition will vary from flour type to flour type and from country to country. In general, flour contains naturally-occurring enzymes such as alpha- and beta- amylases. There are providers that add enzymes to flour as it is being milled, but this varies from country to country. It is advised to check the composition of your flour with your flour supplier, to see if there are any added enzymes and if so, which ones.</p>
<p>6. Regarding waste, can't bakery powders be put in paper bags instead of polyethylene bags?</p>	<p>Yes, in principal they can. Normally, the paper bags used are covered with a polyethylene inner liner. They are typically a combination of paper and polyethylene. This will prevent penetration of moisture from the outside air, which could lead to lump formation. Moreover, bakery powders may contain fats and if you only have a paper bag it will be absorbed by the bag and be visible on the outside.</p>
<p>7. Can we adapt packaging so that it prevents spillage?</p>	<p>The packaging of enzyme-containing products is constantly improved to ensure the safe handling of these products. However, the enzyme and bakery industry need to rely on the solutions currently provided by the packaging industry, which reflect the cost structure of the bakery industry.</p>



<p><u>8.</u> How can we verify/measure the presence of enzyme concentration?</p>	<p>There are dust regulations available, which are different for enzymes and for flour dust. It is possible to measure both enzyme concentration and total dust/flour dust concentration in the air. These topics are covered in the 4th webinar. A comprehensive answer to this question can also be found in the Guidelines.</p>
<p><u>9.</u> What are the potential health issues caused by enzymes?</p>	<p>In general, enzymes have an excellent safety profile, with little ability to cause adverse responses in humans. However, enzymes are proteins and like many other proteins they are potential inhalation allergens. They can provoke allergies, i.e. hypersensitivity reactions of the body to foreign substances. Furthermore, the inhalation of enzyme dust or aerosols may provoke the development of respiratory symptoms like hay fever or asthma.</p>
<p><u>10.</u> Is there any dust concentration limit?</p>	<p>Yes, there is. It is advised to check local regulations, which differ from one country to another. For a large number of countries, general dust limits are listed in the Guidelines.</p>

WEBINAR 4 | Health surveillance and air monitoring

<p><u>1.</u> We do not use pure enzymes; enzymes are always diluted/in mixes. Should we conduct a medical screening as well?</p>	<p>Yes, it is known that certain operations, even though they use diluted enzymes or mixes that contain enzymes, can result in exposures of over 60 ng/m³. It is recommended to determine all working locations where there is a high risk of getting exposed to enzymes and carry out exposure measurements at these locations. On the basis of these air monitoring data, you are advised to contact your enzyme suppliers to discuss whether a medical screening programme would be beneficial.</p>
<p><u>2.</u> The MICT is calibrated only for fungal alpha-amylase, what are the options for other enzymes or other alpha-amylases?</p>	<p>MICT uses antibodies which are specific to only one alpha-amylase. It will detect other alpha-amylase as well, but with lower accuracy and precision. This means that the MICT needs to be validated for each commercial fungal alpha-amylase separately. For other amylases and other enzyme classes it is advised to contact your enzyme supplier, who can help to determine an appropriate analytical method.</p>



<p><u>3.</u> Can liquid enzymes cause allergy?</p>	<p>Liquid products can, for example when they are transferred or mixed, release aerosols containing enzymes. These aerosols can be inhaled – just like dust – leading to the same adverse health effects as described for products in powder form.</p> <p>The risk management measures, air monitoring and health surveillance in principle do not differ from products containing enzymes in powder form. However, exposure to enzymes from liquid products is typically much lower compared to products in powder form. Hence it is easier to control exposure to enzymes in liquid products.</p>
<p><u>4.</u> Can one become allergenic by eating bread made with enzymes?</p>	<p>No, as allergenicity of enzymes is eliminated during the production of bread. There are studies concluding that even if you have a respiratory allergy to alpha-amylases, eating bread with high doses of that same alpha-amylases will not lead to allergic reactions. Therefore, there is no risk for the consumer.</p>
<p><u>5.</u> Can a potential new employee be hired if he is sensitised?</p>	<p>Yes, if the workplace exposure is below the limit value, then it has been shown that even sensitised workers can safely work in such workplace environments without developing allergy symptoms. Regular health checks, for all employees working with enzymes, are advised.</p> <p>Furthermore, preventing sensitised people to start working is illegal, in almost all national legislations.</p>
<p><u>6.</u> Does an employee who gets sensitised have to stop working with enzymes?</p>	<p>Depending on the local regulation, it is typically up to a medical professional to decide whether removing the worker from his/her workplace is necessary.</p> <p>In most European countries, the employer is not informed by the medical professional about the identity of the employee that got sensitised. It is up to the employee, together with the medical professional, to decide which approach is in the best interest of the employee.</p>
<p><u>7.</u> Do you need to monitor all different enzymes used?</p>	<p>Not necessarily. The exposure profile for the different enzymes used in the bakery sector are similar. Thus, the data generated for one enzyme can often be used for other enzymes. However, the read-across needs to be justified (i.e. based on the task, product, enzyme concentration, working environment, etc.) and should reflect a worst-case scenario.</p>



8. What is the approximate cost of an air monitoring equipment?

It depends on the type of equipment, and if only low-volume sampling pumps are required or also high-volume sampling pumps (see [Guidelines](#)). Generally, a basic sampling equipment set (1-2 sampling pumps, sample heads and calibrator) may be in the price range of several thousand Euros. However, this value does not include the costs of the analytical work.

As this equipment needs to be maintained, e.g. regular calibration of the calibrator, changing of batteries, etc., it is recommended to invest in air monitoring equipment only if it is used on a regular basis and one has the internal expertise to use the equipment. If this is not the case, then it is advised to turn to external companies that are specialised in occupational hygiene. They have the air monitoring equipment and hence can be engaged to do the air monitoring. Some of these companies also rent the air monitoring equipment on a per day basis, in case one still wants to do the actual air monitoring in-house.

In case you have to do a first quick exposure assessment to better understand your situation and evaluate if you should invest in your own air monitoring equipment, then it may be possible to request help from your enzyme suppliers.