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| <b>Health and Safety Executive</b> |               | <b>Sector Information Minute</b>               |                               |
| <b>Agriculture and Food Sector</b> |               | <b>SIM 01/2003/56</b><br>(formerly 05/2003/14) |                               |
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Target Audience:

FOD Inspectors responsible for the food industries

Specialist Inspectors (Occupational Hygiene)

## **OCCUPATIONAL EXPOSURE TO FOOD ADDITIVES: MANAGING HEALTH RISKS**

This SIM gives information on the potential for health effects resulting from occupational exposure to food additives during food manufacturing and processing and advises on an approach to inspection. This is an area where current knowledge is limited and the Sector welcomes receiving information on examples of good and poor practice when working with additives.

### INTRODUCTION

1 What is a food additive? The Food Safety Act 1990, in Section 1, defines food as including articles and substances used in the preparation of food, drink, etc. The definition therefore includes food additives within the provisions of the Act. Spices and seasonings are food ingredients and in food law are not additives. Guidance on managing health risks from the use of spices and seasonings is given in **SIM 1/2001/51**. Food additives can be grouped into the following categories based on their function:

- Antioxidants
- Colours
- Emulsifiers, Stabilisers, Thickeners and Gelling agents
- Preservatives
- Sweeteners
- Others, eg enzymes

2 To protect consumers, food legislation in the UK defines which substances can be used as food additives. In most cases the legislation also lists the foods in which each additive can be used and the maximum concentrations allowed. There are about 300 permitted additives, although this number includes many 'duplicates' where additives can be used in more than one form.

3 Each permitted additive is assigned an E number, signifying that it has been approved as safe for food use, usually by the EU Scientific Committee on Food. A list of current permitted additives is available on the web at [The Food Standards Agency Website](#).

4 Occupational vs Consumer exposure: Food additives are only permitted if there is no health risk to the consumer at the proposed level of use. However, for certain additives there may be an occupational health risk associated with the way they are used during food manufacture and processing.

## HEALTH RISKS

5 The potential for occupational ill health depends upon the hazard from the substance and the nature and extent of exposure. This is related to the quantity used, the physical form, eg powder, granules, liquid, and the method of handling. The main routes of exposure are inhalation or skin contact with typical adverse health effects including respiratory and dermal irritation and sensitisation.

6 For additives that can cause sensitisation it is the overall amount of exposure to the sensitiser that matters. Both high exposures over short periods and lower concentration exposures over long period are important. There is some evidence that transient high (peak) exposures such as those arising from handling powders, spillages, machinery breakdowns, etc may cause sensitisation.

7 Food additives known to be associated with sensitisation (including asthma), include proteolytic enzymes such as bacterial and fungal alpha amylases, papain and bromelain, and antioxidants particularly gallate based. Sodium metabisulphite and other sulphates/sulphites emit an irritating gas (sulphur dioxide) that may make asthma worse. Appendix 1 [internal link to Appendix 1 when set up] is a non-exhaustive list of additives that have resulted in adverse health effects through occupational exposure.

## INFORMATION FOR USERS ON HEALTH RISKS AND CONTROLS

8 For many food additives there is little knowledge on occupational health effects, safe levels or actual workplace exposures. The HSC has not published occupational exposure limits. To enable users of food additives to assess potential health risks and to develop effective control strategies, they need to receive information on the hazards associated with the food additive. The usual route for receiving this information is by safety data sheets (SDS) provided by the supplier.

9 The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002, CHIP specifically exempt any substance or preparation in a 'finished state intended for the final user and intended for use as food within the meaning of the Food Safety Act 1990', so in some circumstances food additives may be exempt from the requirements of the regulations. Consequently there may be no legal requirement under CHIP 2002 to provide

an SDS and the main duty to supply information will be under the Health and Safety at Work, etc Act 1974 Section 6. This requires the supplier to provide adequate information about any risks to health that may result from the inherent properties of the substance. Inspectors will find that the Safety Data Sheets ACoP (L62) still provides a useful framework. If inspectors are considering taking action under CHIP 2002, Food Section should be consulted. Food Section will liaise with CFPD6 Chemicals International on the legal application of CHIP and advise accordingly.

10 The Sector considers that for the information to be adequate it should include:

- details on nature of the hazard, which may include the COSHH Essentials Hazard Group;
- safe means of storage, handling and disposal;
- appropriate controls during use such as LEV and/or PPE including RPE.

11 The enzyme additives bacterial and fungal alpha amylase are currently under review by HSE's Advisory Committee on Toxic Substances (ACTS). Alpha amylase is used to break down starch into fermentable sugars and can cause asthma and allergic rhinitis. Bacterial amylase is used to extend the shelf life of bread. In June 2001, Chemical Hazard Alert Notices (CHANs) were issued to announce that ACTS is considering setting a maximum exposure limit (MEL) under COSHH. Interim guidance is given on bacterial alpha amylase in **CHAN 21** on fungal alpha amylase in **CHAN 22** and in EH 40 Occupational Exposure Limits 2002, Table 4.

## CONTROL

12 The approach to control should follow the risk assessment hierarchy of protection measures under the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and the COSHH Asthmagens ACoP. Where risk is identified substitution with an alternative substance is only feasible if the substitute is listed as an additive under food safety legislation. However, substitution by changing the physical composition of the additive may be practicable, eg using granular or liquid forms instead of a fine powder or using dust-suppressed batch pre-mixes in place of neat additives.

13 **Appendix 2** sets out the priority areas for effective exposure control of sensitisers, including asthmagens. **Appendix 3** is a detailed guide that can be used as an aide-memoire for implementing a food additives management system. It can be used as a guide to inspection or copied to duty holders to aid compliance. It is based on the information contained in the Asthmagens instructions in the **FOD Inspection Pack**.

14 It is important for users to ensure they have introduced effective control strategies. In-house occupational exposure limits are likely to be in the

microgram/m<sup>3</sup> range for total enzyme protein, or nanogram/m<sup>3</sup> range for active enzyme by assay. Setting in-house occupational exposure limits may be beyond the competence of SMEs. In seeking to reduce exposure the main areas to consider include changing the physical form, (eg granules not powder), engineering controls (LEV), containment, prevention of spread, good housekeeping, specific cleaning procedures and RPE and gloves for respiratory and dermal risks respectively. If the employer must use latex gloves, these should be low-protein and non-dusted gloves.

15 When developing suitable control strategies the employer should consider the possible health effects from exposure to the food additive (the hazard), the amount used together with its dustiness (solids) or volatility (liquids) to determine the likely risk and types of controls that should be applied.

16 HSE guidance, [COSHH Essentials](#) provides easy step-by-step method of selecting appropriate controls. However, this system cannot be directly used for food additives, as it requires information on the risk phrases provided by the supplier under CHIP. This information will not be available as foodstuffs, including ingredients such as additives, are exempt from the requirements of CHIP (**para 9**). Where details of the potential health effects are known a notional risk phrase could be applied by a knowledgeable user and this would enable a COSHH Essentials approach to be followed.

Note: Where a substance is a respiratory sensitiser COSHH Essentials currently defaults to the instruction 'seek specialist advice'

17 Where the food additive may cause sensitisation by inhalation or skin contact the control approach should normally be by engineering means (eg LEV) or containment (eg sealed process) unless the amount of additive used is very small, ie grams or millilitres and not kilograms or litres of additive.

18 Notable successes in reducing exposure to asthmagens in the baking industry are the addition of a very small percentage of vegetable oil to amylase-flour mixtures to create low-dust mixtures that are supplied in sachets for one-shot addition in a bread recipe and the substitution of enzyme powders with granulated enzymes or liquid formulations.

## HEALTH SURVEILLANCE AND ILL HEALTH REPORTING

19 In deciding whether health surveillance is legally required and the form it should take, the strength of evidence linking the substance to the risk of developing sensitisation, including asthma, is crucial. The precise form of surveillance chosen will depend on the particular circumstances of exposure - level, frequency and duration. Responsible suppliers consider all enzymes to be respiratory sensitisers, and people working with such additives should be under health surveillance for asthma.

20 Companies should identify potential respiratory or skin sensitisers from the suppliers' information on potential health effects. It is particularly important

that employers monitor sickness absence for signs of respiratory problems and take positive steps to enquire about both respiratory or skin problems. Suspected/reported cases should be referred in the first instance to an occupational nurse or doctor. Employees should be provided with appropriate information in such cases. If inspectors are not satisfied with the standard of health surveillance then they should consider involving specialist group medical and occupational health inspectors.

21 COSHH Essentials guidance sheets 402 'Health surveillance - lower level' and 403 'Health surveillance - higher level' are due to be published in the Autumn.

22 A report of ill health under RIDDOR is required for all cases of:

(1) occupational dermatitis, where the work activity involves any known irritant or sensitising agent including in particular any chemical bearing the warning "may cause sensitisation by skin contact" or "irritating to the skin"; and

(2) occupational asthma, where the work activity involves a proteolytic enzyme or any other sensitising agent, including in particular any chemical bearing the warning "may cause sensitisation by inhalation".

#### ACTION BY INSPECTORS

23 No special action or visits are required by this SIM. However, when visiting suppliers of food additives, inspectors may wish to check that the suppliers is providing the information required by HSW Section 6 to assist users in carrying out risk assessments.

24 The Food Section would welcome any information on:

(1) good and bad practice in the use of additives and in particular, examples of effective substitution with non dusty forms of additive; and

(2) copies of RIDDOR reports and/or investigations that are of particular interest.

#### ENQUIRIES

25 Inspectors wishing information on suitable control strategies should contact their local specialist group occupational hygiene inspector and for information on health surveillance contact the specialist group EMAS section.

26 If any enquiries are received on food safety issues the enquirer should be informed that food safety issues are not dealt with by HSE. In the case of a specific product that is being complained about the complainant should be

referred to the local authority that have responsibility for environmental health and consumer safety.

#### FURTHER INFORMATION

27 Food Safety Act 1990.

28 **SIM 1/2003/55** Chloramine: exposure and control in food processing.

Date first issued: 21 May 2003

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APPENDIX 1  
(para 7)

INFORMATION ON POTENTIAL SENSITISING ADDITIVES, LIST NOT  
EXHAUSTIVE, BASED ON LIBRARY SEARCH

| ADDITIVE   | EFFECT                                      | ACTIVITY/JOB (where known)                              |
|--|---|---|
| <b>Baking</b>  |   |   |
| Cinnamic Aldehyde  | Chronic urticaria                           | Pastry maker  |
| Alpha Amylase  | Asthma,<br>Rhinoconjunctivitis              | Baker, work with flour and additives                    |
| Foodmuls-E-3137<br>Emulsifying agent   | Contact dermatitis                          | Baker, work with dough improver                         |
| Alpha amylase  | Contact dermatitis                          | Baker - flour additive                                  |
| Alpha amylase  | Asthma, rhinitis, conjunctivitis,<br>eczema | Bakers  |
| Alpha amylase  | Respiratory sensitisation                   | Bakeries  |
| Aspergillus derived enzymes as<br>additives  | Respiratory allergy                         | Bakers  |
| Soyabean flour and aspergillus<br>enzymes  | Asthma                                      | Bakers  |
| Proteolytic enzymes  | Contact Dermatitis                          | Bakery mixer  |
| Flavouring agents Vanilla,<br>Balsam-of-Peru, Isoengenol   | Contact Dermatitis                          | Cookie Factory Worker                                   |
| Gallates   | Allergic contact dermatitis                 | Bakery workers  |
| Various proteolytic enzymes,<br>sodium sulphite phospholux<br>gelatine                             | Palm (contact) dermatitis                   | Bakery worker   |
| Various: persulphates<br>benzoylperoxide, iodates,<br>azodicarbonamide, soy and<br>broad bean meal | Allergic dermatitis                         | Bread and paste production                              |
| <b>Meat</b>  |   |   |
| Proteolytic enzyme meat<br>tenderisers, eg papain  | Respiratory symptoms, asthma                | Meat portioning workers                                 |
| Proteolytic enzymes, spices,<br>papain, bromelain and ficin  | Asthma                                      | Meat workers  |
| <b>Fruit and vegetables</b>  |   |   |
| Sodium metabisulphite  | Asthma                                      | Potato preserving                                       |
| Pectinase  | Asthma                                      | Fruit processing  |
| Glucanase  | Asthma                                      | Fruit processing  |
| <b>Other</b>   |   |   |
| Sodium nitrite and p-nitre-<br>dimethylaniline hydrochloride                                       | Contact Dermatitis                          | Manufacture of vanillin                                 |
| Do decyl gallate (anti oxidant)  | Skin sensitiser                             | Washing powder manufacture but<br>used as food additive |

| <b>ADDITIVE</b>   | <b>EFFECT</b>  | <b>ACTIVITY/JOB (where known)</b> |
|---|--|-----------------------------------|
| Various: nickel sulphate, sodium bisulphate, allyl disulphide, fresh garlic, thiuram mix, Peru-Balsam | Irritant contact dermatitis, allergic contact dermatitis, protein contact dermatitis | Food service workers              |
| Hexamethylene tetra amine (preservative)  | Dermatitis, respiratory allergies  | Not specified                     |
| Octyl gallate (anti oxidant)  | Contact dermatitis   | Food worker                       |
| Antioxidants: nickel sulphate, propylgallate  | Allergic contact dermatitis  | Food handlers                     |
| Papain (proteolytic enzyme)   | Asthma   | Food technologists                |
| Proteolytic enzymes, bromelain  | Asthma   | Food production                   |
| Sulphites and sulphates including sodium metabisulphite   | Contact dermatitis   | Food industry                     |
| Stafac  | Airborne irritant contact reaction   | Food additive production          |

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APPENDIX 2  
(para 13)

RISK CONTROL INDICATORS

1 Three indicators have been selected against which performance should be measured:

**Sensitiser/Asthmagen Management System**

Effective organisation and arrangements including adequate COSHH assessment, provision of information, instruction, training and supervision. Evidence of management commitment and arrangements for review.

**Control Strategy**

Substitution considered and effected where possible. Adequate engineering controls provided, used, maintained, examined and tested at suitable intervals. Suitable PPE is provided, worn and stored correctly, suitably cleaned and well maintained. Appropriate instruction and training in proper use of engineering controls and PPE.

Substitution should be the first consideration by all duty holders where employees are exposed to sensitisers/asthmagens. Where substitution is not possible control should be achieved by engineering means including containment, so far as is reasonably practicable. PPE should be considered as the last line of defence because its effectiveness is highly dependent on correct selection and use including its suitability for the wearer. In particular for RPE the need for fit testing of tight fitting facepieces, eg half masks.

There may be situations where some elements of the risk control indicator are not relevant. For example where **full** control has been achieved by engineering means, eg containment, PPE may not be required except for cleaning and maintenance.

**Health surveillance**

Suitable health surveillance is provided by a competent person, everyone requiring it has been included, it is repeated as necessary and health records are kept. Cases of occupational asthma or occupational dermatitis are reported under RIDDOR.

This performance indicator should NOT be used when the control strategy is such that there is not a reasonable likelihood that occupational asthma may occur under the particular conditions of work.

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APPENDIX 3  
(para 13)

AIDE-MEMOIRE ON EFFECTIVE CONTROL STRATEGIES

**1 SENSITISER/ASTHMAGEN MANAGEMENT SYSTEM**

*Management commitment:*

Has responsibility for the management system been accepted by a senior manager? HSW Act s.2

*COSHH assessment:*

Has a suitable and sufficient assessment been made by a competent person? COSHH reg.6(1)

A suitable and sufficient assessment should include:

an assessment of the risks to health:  
what substances employees are liable to be exposed to;  
what are the hazardous properties of the substance;  
what effects these substances can have on the body;  
where substances are likely to be present and in what form;  
ways in which employees could be exposed;  
an estimation of exposure;  
comparison of the estimate with any occupational exposure limits;  
the effect of preventative and control measures;  
the results of relevant health surveillance;  
where work involves exposure to more than one such substance, the risks presented by exposure to such substances in combination;  
any additional information necessary to complete the risk assessment.

Has the assessment been recorded? (more than five employees) COSHH reg.6(4)

Have employees been informed of the result of the assessment? COSHH reg.12(2)

Is the assessment reviewed regularly (when no longer valid or there has been significant changes to the work) COSHH reg.6(3)

*Information, instruction, training and supervision:*

Have employees been provided with suitable and sufficient information, instruction and training? COSHH reg.12(1)

This should include:

the names of the substances and the risk created as a consequence of exposure;  
access to any relevant material safety data sheet;  
the appropriate precautions and actions to be taken in order to safeguard himself and others;  
training in the proper use of PPE including requirements in relation to cleaning, storage and disposal procedures.  
monitoring procedures and the results of any exposure monitoring;  
the role of health surveillance and their duty to attend, arrangements for dealing with accidents, incidents and emergencies.

## 2 CONTROL STRATEGY

Has prevention of exposure been adequately considered COSHH  
reg.7(1)

Where prevention not reasonably practicable has substitution been considered. reg.7(2)

Where prevention of exposure not reasonably practicable then: COSHH  
reg.7(3)

design and use appropriate work processes, systems and engineering controls  
control exposure at source, including adequate ventilation systems and appropriate organisational measures.

Where necessary, have employees been provided with suitable PPE: COSHH  
reg.7(3)  
PPE will be necessary when adequate control by other means is not possible eg: where it is not technically feasible to achieve adequate control by process operational and engineering measures alone; as an interim measure when a new or reviewed assessment indicates that it is necessary until control is achieved by other means; during routine maintenance where the infrequency of the activity make process control measures unwarranted; where urgent action is required eg plant failures

*Meaning of adequate control:*

**The asthmagens AcoP that accompanies COSHH 2002 states - Exposure to asthmagens should be prevented, where not reasonably practicable, exposure control should prevent exposed employees from developing occupational asthma (paragraph 12).**

**In practice this means for all asthmagens, including those assigned a MEL or OES, adequate control requires exposure to be reduced to as low a level as is reasonably practicable (not just to the MEL or OES) and where short term MELs or OESs (eg 15 minutes reference period) have been assigned they should NEVER BE EXCEEDED. Controls should prevent or minimise short term peak exposures.**

*Maintenance and use of control measures:*

Are employees given suitable instruction, in the use, cleaning storage and maintenance of control measures COSHH  
reg.12(1)

Is there evidence that control measures and items of PPE are properly used? Evidence may be: COSHH reg.8

records of visual checks;  
personal observation;  
a system for taking remedial action where necessary;  
Provision and use of storage accommodation;  
provision of hygiene facilities eg showers, baths, eating facilities;  
a system for reporting defects in any control measure or item of PPE

Are control measures maintained in an efficient state, efficient working order and good repair, in particular:

COSHH  
reg.9(1)

are engineering control thoroughly examined and tested at regular intervals;  
is LEV plant examined and tested at least once every 14 months;  
is RPE (other than disposable RPE) examined and tested at suitable intervals.

Are records kept of all examinations and tests and repairs

COSHH  
reg.9(4)

NB Records should be kept for 5 years.

### 3 HEALTH SURVEILLANCE

Is suitable health surveillance provided for employees? Is it repeated as necessary?

COSHH  
reg.11(1)

(the level of health surveillance should be decided

in consultation with an occupational health professional)?

Has accountability for the health surveillance programme been accepted by a responsible person who draws on appropriate help?

Are lung function tests undertaken by a competent person?

eg OH nurse or someone suitably trained

Where lung function tests, questionnaires or self tests identify possible respiratory problems are cases always referred to a doctor for further investigation/treatment?

Are suitable health records kept for each individual? Health records should contain:

COSHH  
reg.11(3)

personal details of individual;

date started job;

an historical record of jobs involving exposure to asthmagens (and any other hazardous substances for which health surveillance is required);

conclusions of health surveillance and date on which carried out;

whether individual is fit to return to work including decisions of doctors/nurses/ other responsible persons

Are health records kept for at least 40 years?

COSHH  
reg.11(3)

Are cases of occupational asthma reported under RIDDOR?(This duty comes into effect when the employer receives a written statement from a registered medical practitioner)

RIDDOR reg.5

NB This should be a trigger for the employer to review their system for managing asthmagens.

## 4 TECHNICAL SUPPORT

You may wish to make use of specialist help to assist you in developing and implementing effective control strategies. Specialists can provide the following support:

### **(1) Occupational hygienists:**

An assessment of work practices to determine health risks, appraise adequacy of control measures (including ventilation systems and PPE) and recommend reasonably practicable controls).

Monitoring of personal exposures for comparison to any occupational exposure limits.

A list of occupational hygiene consultants is available from the [British Occupational Hygiene Society](#)

### **(2) Medical and Occupational Health service providers:**

Advice on likely health effects;

Advice on requirements for health surveillance.