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HEALTH AND SAFETY COMMISSION

Subtilisins

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Issue

1. Agreement to a Maximum Exposure Limit (MEL) for subtilisins.

Timing

2. Routine.

Recommendation

3. That HSC agrees the following Maximum Exposure Limit :

Subtilisins	0.00004 mg.m^{-3} (40 nanograms.m^{-3}) (8-hour time-weighted average)

Background

4. Subtilisins are proteolytic enzymes of bacterial origin and come in the form of light-coloured, free-flowing powders. They are derived from *Bacillus subtilis* by a fermentation process and are readily soluble in water. They are not manufactured in Great Britain but are imported for use in the manufacture of detergents and animal feeds. They are also used for food and leather processing. They are recognised as being respiratory sensitisers and are classified under the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 to be labelled with the following risk phrases:

R37/38	Irritating to the respiratory system and skin
R41	Risk of serious damage to the eyes
R42	May cause sensitisation by inhalation

5. About 100 people are potentially exposed to subtilisins during the handling of dry concentrate and dry detergent product in the soap detergent industry. Up to 1,000 people

may be potentially exposed to the 0.5% subtilisin concentrate during weighing and tipping operations during the preparation of animal feeds, while a further 15,000 people are potentially exposed to downstream animal feed containing subtilisin at a concentrate of about 0.0005%.

6. In 1995 a safety management consultant wrote to HSE asking why subtilisins did not warrant a Maximum Exposure Limit (MEL), given that they were recognised as respiratory sensitisers. He also queried the level at which the OESs had been set. At that time subtilisins had Occupational Exposure Standards (OESs) of 0.00006 $mg.m^{-3}$ (60 $ng.m^{-3}$) (8-hour time-weighted average (TWA) and short-term exposure limit (STEL)). Subtilisins were considered by the Advisory Committee on Toxic Substances' (ACTS) Working Group on the Assessment of Toxic Chemicals (WATCH) at its meeting in September 2000. WATCH agreed that the key health concerns for subtilisins were their potential to cause occupational asthma and allergic rhinitis. Subtilisins are also toxic by inhalation, causing direct effects on the lungs, haemorrhage, congestion and oedema, and there is clear evidence to show that subtilisin enzyme preparations are irritant to the eyes. Subtilisins can also irritate damaged, but not intact, skin.

7. On the basis that it was not possible to establish exposure-response relationships for the induction of occupational asthmas or allergic rhinitis by subtilisins, or to determine where the threshold might lie, WATCH concluded that subtilisins met the criteria for the establishment of a MEL. ACTS agreed in 2001 that HSE should pursue the development of a MEL for subtilisins and withdraw the existing OESs, following public consultation (Consultative Document 182), in January 2003.

8. In April 2003, HSC endorsed a proposal from ACTS that consultation should go ahead on the establishment of a MEL for subtilisins. It was agreed that this consultation should ask consultees' opinion on a MEL set at 40 $ng.m^{-3}$ (8-hour TWA) and a short-term (15 minute) MEL set at the same value. A Consultative Document containing these proposals was published on 2 June 2003 (CD 187) with a consultation period lasting until 1 September 2003.

Argument

9. HSE reported the results of the consultation exercise to ACTS at its meeting on 8 July 2004. Based on the comments received during the consultation exercise, and on subsequent discussions with the detergent industry, HSE recommended to ACTS that they agree a MEL for subtilisins set at 40 $ng.m^{-3}$ (8-hour TWA). This proposal was agreed.

10. The Consultative Document included a proposal for a STEL set at the same level as the 8-hour TWA limit, with consultees asked specifically whether they considered such a limit to be measurable. Consultees who made reference to the issue in their responses suggested that it was not possible to measure such a small quantity of enzyme in a sufficiently accurate way. Moreover, the Health and Safety Laboratory had concerns over setting a STEL at 40 $ng.m^{-3}$ because it would then be necessary to have a lower detection limit, in the region of 0.2 ng/ml. This is far below the detection limits currently used in the measurement assay. In the light of these difficulties, ACTS endorsed a recommendation from HSE not to proceed with the proposed STEL, but suggested that HSE provide advice on the prevention of peak exposures.

11. HSE is in the process of establishing a new occupational exposure limit (OEL) framework, which was agreed by ACTS at its meeting on 8 July. The new framework will introduce a single type of limit – a Workplace Exposure Limit or WEL – which will replace the existing MELs and OESs. Rather than publish the new limit under the old system, HSE intends to publicise the new limit as proposed in para 13, creating a transitional period, with the new limit coming into force with the new OEL framework, expected to be around the end of the year. When publicising the new limit, HSE will remind employers of the requirement to reduce exposures to a level that is as low as reasonably practicable (ALARP).

Consultation

12. Extensive consultation on usage of subtilisins was carried out by HSE during the preparation of the Regulatory Impact Assessment, which informed the decision to consult formally. HSC consulted widely on this proposal between June and September 2003. The Consultation Document was sent to over 250 recipients in other Government Departments, Public Bodies, Local Government Organisations, employer organisations and trade unions, trade associations, health and safety specialists and individual companies. It was also placed on the Internet. Fourteen organisations and one individual commented on the subtilisins proposal. Following formal consultation, HSE officials held further discussions, including a meeting, with representatives of the detergent industry.

Presentation

13. HSE plans to publicise the new limit by publishing the information on the HSE website, and by means of a letter targeted at known users of subtilisins. The information will remind duty holders of the need to reduce exposures ALARP.

Costs and Benefits

14. The costs of compliance with the new MEL for subtilisins were considered in detail in the Regulatory Impact Assessment prepared by HSE and considered by ACTS prior to consultation. Total compliance costs to industry were estimated as being £120,000 in the first year of compliance with ten-year discounted costs of between £542,000 and £593,000. The bulk of these costs would be met by the millers of animal feeds, representing approximately 100 businesses. Costs for small firms would not be disproportionate.

Financial/Resource Implications for HSE

15. No further additional costs are anticipated.

Environmental Implications

16. None.

Other Implications

17. None

Action

18. The Health and Safety Commission is asked to agree to the establishment of the following exposure limit:

Subtilisins	0.00004 $mg.m^{-3}$ (40 $ng.m^{-3}$) (8-hour TWA)

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