Creation of European standards in biotechnology

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The Technical Committee CEN/TC 233 "Biotechnology" of the Standards Institute (CEN) has been charged by a mandate of the Commission of the European Communities to consolidate three European Guidelines (90/219/EEC; 90/220/EEC; 90/679/EEC) which directly affect the area of biotechnology. The performance criteria for microbiological safety workbenches (Swb) were formulated by the CEN Working Group 4 "Equipment" of the Technical Committee and the Subcommittee 4 "Devices and Equipment" of its national counterpart "DIN/NAL-BT" "Biotechnology" (Fig. 1).

With the issuing of the EN 12469, all concerned will have a set of generally valid technical guidelines at their disposal. Adoption of these standards – as for all other standards – is basically voluntary. Experience has shown, however, that because third-parties demand it (customers, insurers, watchdog authorities etc) use generally becomes mandatory. For example, from 1 April 2000 onwards, § 10 of the "Biostoffverordnung" (Regulations for Biologicals) in Germany requires that protective measures relating to the safety and health protection of employees must be brought into line with the latest standards. The Regulations on Biologicals embody the Guideline 90/679/EEC on the protection of employees against harm from biological substances in national law.

In accordance with the EC Charter Article 118a, the national standards valid at present for Swb in England (BS 5726 Parts 1–4), France (NF X 44-201) and in Germany (DIN 12950 Part 10) must be superseded by conversion of EN 12469 to national law (Fig. 2). The aim of standardising these technical regulations is, amongst other things, to establish minimum requirements for employee protection. Barriers to trade in Europe which exist because of different standards, testing and certification procedures must be broken down in order to ensure the free exchange of goods. In concrete terms, this means that in future in Germany, instead of DIN 12950 Part 10, DIN EN 12469 will be the binding standard, in

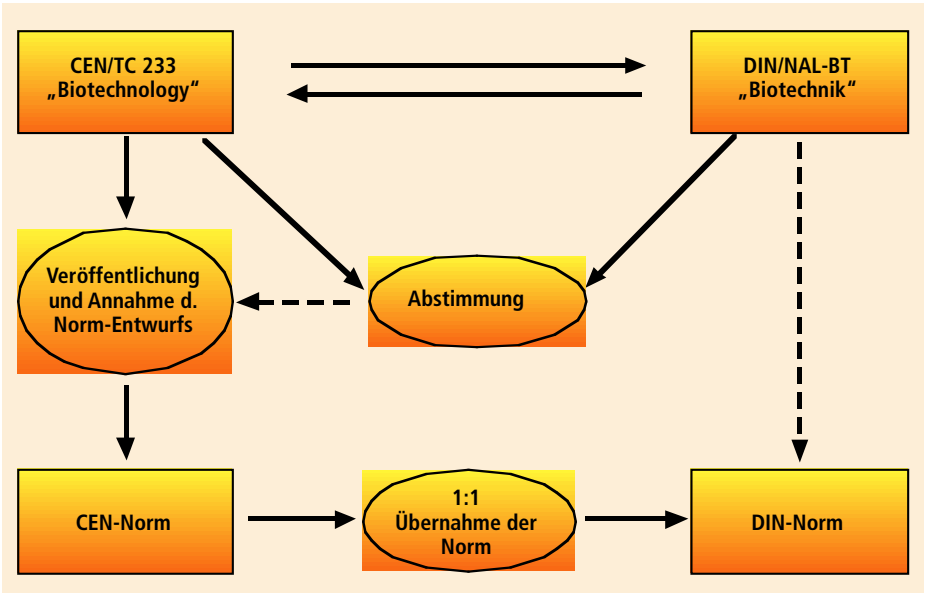

Fig. 1: Procedure for compilation and agreement of European Standards in the CEN/TC 233 Biotechnolgy Section

England, instead of BS 5726 Parts 1–4, BS EN 12469 etc. Many others countries affected will have to deal with a set of standards for Swbs for the first time and are bound by the EC Charter to secure this in national law.

Changes from present standards

Table 1 shows the actual changes from the present standards in Germany (DIN 12950 Part 10).

Probably the most far-reaching changes are those affecting manufacturers of Swbs. The changes which have to be made can be split up into technical changes and changes in documentation. Technical means that structural changes have to be made or new tests have to be performed, of which a few examples are given here.

Leakproof housing

A pressure test (Fig. 3) has to be conducted on the housing of an Swb. To do this, the exhaust and working aperture are hermetically sealed, the Swb is brought up to a pressure of 250 Pa, and a soap solution is applied to all joins, joints and welding seams, through which leakage into the environment might occur. No visible soap bubbles may develop. If the housing does not pass the leak test, presumably changes in design with regard to structural elements and/or sealing techniques will be necessary. It is worth noting here that this requirement ("soap bubble test") has been standard for many years in the American Standard NSF 49 for American Swbs.

Table 1: New requirements or changes in requirements in EN 12469 as compared to DIN 12950 Part 10

Requirement of EN 12469	New	Changed
Housing leakproof		X
Working aperture leakproof		X
HEPA Filter leakproof		X
Ease of cleaning	X	
Sterilisability	X	
Working materials,		
construction, manufacture		X
Sealing of apertures		X
Alarm display system		X
Safety of surrounding area		X
Reverse system		X
Filter system		X
Ventilation Class III Swb		X
Marking	X	
Documentation	X	
Airflow volume or		
speed of flow		X
Decontamination	X	
Types of test		X
Model test	X	
Installation test	X	
Routine maintenance	X	

Ease of cleaning

To comply with EN 12469, the ease of cleaning (Fig. 4) of all areas users can easily access and which may possibly be contaminated, such as the working area, working surface, collecting basin, has to be demonstrated in a model test. The cleaning class has to be tested by introducing a defined indicator substance, quantitative sampling and then cleaning in accordance with the manufacturer's instructions. A Cleaning Index B at least must be achieved, which means that the ease of cleaning has been tested under controlled conditions and quantitatively determined, or the construction of the Swb was tested in accordance with defined criteria.

If the above requirements are not met, structural changes are necessary. This applies to corners and edges in the working area, and those of the working surface and collecting basin.

Vibration

A model test has to be conducted on the vibration at the centre of the working surface. This test determines the oscillation amplitude at target current speeds in a frequency range between 20 and 20,000 Hz. The threshold value of 0.005 mm may not be exceeded. Testing the oscillation of the working surface has also been standard for many years in the American NSF 49. If the threshold value is exceeded, the result will probably have to be structural changes and new methods of fixing and stabilising the working surface and the fan.

Documentation

The amount of documentation required in model tests will be considerably greater in the future. All significant tests must be documented in writing together with the measuring devices used, the results, and methods etc. In addition to the instructions for operation and a binding certificate in accordance with EN 12469, this documentation on the model tests conducted must also be given to the customer.

For example, it is necessary for every Swb construction series to document in detail that the housing is leakproof, the Cleaning Index B at least has been achieved, that there are protective functions with regard to persons, products and carry-over effects, that all filters are le-

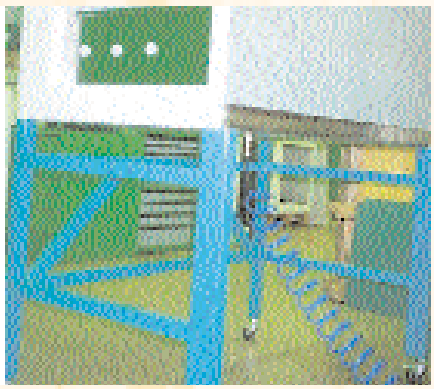

Fig. 2: Comparison of standards for microbiological safety workbenches at present and in the future

Fig. 3: Leak test on housing in accordance with EN 12469

Fig. 4: Testing for the Cleaning Index of the working space, working surface and collecting basin in accordance with EN 12469

akproof and sit firmly, that the air can move freely and that the equipment can be sterilised. For the manufacturer this means that considerable amounts of information must be revealed to the customer.

Future outlook

Final agreement on the draft standards has already been reached. The technical content has therefore been confirmed and can no longer be changed. Ratification of the standards is in the hands of the French TC-233 Secretariat. At present, it looks as though the standards will come in to force in Autumn of 2000. After a short transitional phase of about 6 months, the European Norm must be converted into national law.

Manufacturers

It will be particularly easy for manufacturers of Swbs who already work together with an experienced and neutral instance. Swbs which have already been tested and certified in accordance with DIN 12950 Part 10 under the terms of the Safety of Devices Act ("GS Mark"), fulfil the principal requirements of EN 12469. Their conformance with EN 12469 in the form of a certificate can be very quickly and efficiently secured by conducting a few additional tests and compiling comprehensive documentation. From the point of view of the manufacturer, this is very important in terms of product liability.

Operators

Operators of laboratories dealing with pathogenic biological materials must conform with regulations and minimise any potential dangers by using Swbs, amongst other measures. The protective work devices must correspond with standards in force. In future, they will have comprehensive information and documentation at their disposal (see 1. Documentation) to assist them in their choice of a new Swb. Proof of conformance is easy to establish in the form of a certificate from an authorised body. It is the responsibility of the operator to ensure that the staff employed receive adequate practical and theoretical training. One useful source of training is the practice-based seminar "Safety Training for Biological Materials", in which participants receive detailed and practice-orientated instruction.

The operator must also ensure that the installation tests and routine maintenance tests (usually once per year) are conducted and documented. When choosing a company offering service and maintenance, care should be taken to ensure that the employees of the company have the necessary expertise and that this is documented. Attention has been drawn to this problem area many times in the past.

Fig. 5: TÜV-Mark for products and management systems 8915 1672 10587 202 555.5

New concept: "TÜV-Mark" (TÜV = Technical Surveillance Association)

Because of continuing globalisation and ever increasing competition, it is of decisive importance to bring new developments in shorter and shorter times to market. Particularly from the point of view of the customer, it is difficult to gain clarity with the large number of different standards marks in the international market place. Even within individual testing institutes, many different standard marks are used, both in appearance and type, which is often irritating. To counter this trend, TÜV Product & Management Service have developed a test mark with a worldwide patent – the TÜV-Mark (Fig. 5). The TÜV-Mark offers convincing and visible advantages. It uses a modular concept, which means that one mark can be used to convey information on different product tests and certified management systems (e.g. ISO 9001). In one mark, understood throughout the world, manufacturers can make product- and system-specific statements and signal this to their customers in a mark. The customer can rely on the quality and reliability of the product and/or management system.

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