Disinfectant products for today's regulations

If you are a producer of disinfectant chemicals, there are some big changes coming along that will affect your business.

The Biocidal Products Directive (BPD) (98/8/EC) came into force in 2000 and set out a 10 year timetable for review of existing active substances used in biocides.

It was implemented in the UK as the Biocidal Products Regulations in 2001 and the next phase of the legislation will have a significant impact on the use of biocides throughout the EU.

Stricter rules

There can be few products on the market subject to more regulation and scrutiny than disinfectant chemicals, as manufacturers and governing bodies strive to ensure public safety. The rules surrounding the sale of such products are about to get even stricter, prompting a renewed interest in testing procedures.

From 2010, manufacturers of both disinfectant formulations and the active compounds on which they are based must be able to substantiate their safety and efficacy product claims.

This will involve detailed technical dossiers, signalling an end to exaggerated or untested product claims.

A recent example of the dangers of such false claims emerged when vehicle cleaning detergents were found being used for cleaning in a meat plant. This situation resulted in products being contaminated with E. coli O157, because the cleaning agent was ineffective against it.

Reputable manufacturers will welcome the move towards more stringent procedures. However, the sheer cost of producing such in depth documentation could see a dramatic reduction in the number of disinfectant products available on the shelves as producers decide it is just too costly to bring each of their products into line with the new regulations.

As it stands, the regulation of biocide products in the EU operates at a national level. But with the introduction of the BPD, to help ensure free trade and harmonisation across all EU member states, as well as a high level of protection for man and the environment, all products will now face the same rigorous regulations, regardless of their country of origin.

Transition period

This harmonisation is sure to help chemical manufacturers in the long term, particularly those who sell their products internationally, but such complex changes could also lead to confusion during the transition period. The UK's transitional arrangements for producers of biocidal products are three-fold, and involve:

- Informing the National Poisons Information Service.
- Checking liability for the General Industry Charge.
- Compliance with advertising requirements (Reg. 33), which will involve use of warnings such as 'use biocides safely'; 'always read the label before use'.

Yet more disruption will be caused by the necessity of formulation changes, withdrawal of chemicals and disinfectant testing.

To help manufacturers through the minefield of the complexities, there are a number of specialist testing facilities, such as the food and drink research centre at Campden BRI, which are able to offer an independent disinfectant testing service.

Such services will aid those companies required to submit dossiers to the Health and Safety Executive from the beginning to the end of the process. Assistance will include undertaking laboratory tests, advising on the range of tests available and, where required, undertaking field trials to assess the product's efficacy in practice.

Companies will need to provide evidence to substantiate their biocidal claims. For example, if the claim is 'kills 99.9% of E. coli' then a disinfectant test report supporting this claim will need to be provided. It has not yet been confirmed which tests will be formally required by the HSE, but UK specialists recommend that the minimum for the food industry would be EN 1276 to confirm bactericidal activity and EN1650 for fungicidal activity. Some countries also insist on the surface test EN13697.

Independent service

Campden BRI, which is the largest membership based food and drink research centre in the world, offers customised services tailored to the requirements of each individual business, and gives companies access to research worth over £2 million a year.

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The organisation's long standing knowledge of assessment of disinfectants in factories and its close contact with the food and drink industry, has enabled scientists to formulate a full range of suitable tests, all of which are carried out in a purpose built laboratory and on an independent and confidential basis. Whilst the organisation is not able to advise on changes to chemical formulations, it can test/screen trial formulations.

Chemicals that can be tested include disinfectant formulations and their active compounds, bactericidal soaps, barrier creams and hand rubs, disinfectant wipes and whole room disinfectants.

Screening can also be performed to aid with formulation development, as well as taint tests of disinfectants.

Recognised standards

A series of standardised tests has been developed under the European Committee for Standardisation (CEN) that has resulted in an EU wide recognised standard to ensure mutual acceptance of the chemicals that are approved. CEN recruited a number of international experts, including representatives from Campden BRI to develop these.

The minimum standard for disinfectant testing laboratories required by many European countries is likely to be the equivalent of the UKAS (ISO 17025) accreditation.

So a disinfectant supplier will not only be able to achieve European wide recognition of the results of the tests against the CEN norm but also be assured that the test was carried out competently.

The new legislation is intended to harmonise UK law with the rest of Europe to simplify the testing procedure for manufacturers who sell their products internationally.

Table 1. Examples of standardised tests for disinfectants.

BS EN number	Name
BS EN 1040	Basic bactericidal
BS EN 1275	Basic fungicidal
BS EN 1276	Bactericidal
BS EN 1650	Fungicidal
BS EN 13697	Surface bactericidal
BS EN 13697	Surface fungicidal
BS EN 13610	Viricidal
BS EN 13704	Sporicidal
BS EN 1656	Veterinary bactericidal
BS EN 1657	Veterinary fungicidal
BS EN 1499	Hygienic handwash
BS EN 1500	Hygienic handrub

That said, it is sure to bring some disruption while it is in the process of being introduced. Campden BRI's aim is to make the transition as easy as possible for those manufacturers affected by it by putting their wealth of knowledge and expertise to the best possible use.

Under the directive, with its 10 year timetable for the review of existing active substances used in biocides, each reviewed substance has to be cleared by the EU before it can be used in biocidal products.

The products themselves are then authorised in each member state where they are used in a system of mutual recognition through a positive list.

Essentially, this means that if a product has been submitted and authorised by the competent authority of one country, it will be recognised as being approved in the other member states of the EU where the chemical is sold and used.

According to the directive, such products are defined as 'active substances or preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means'.

As well as disinfectants and general biocide products, the directive also covers other products such as pest control agents and embalming and taxidermist fluids.

In the UK, this means that anyone planning to place a biocide on the market must inform the National Poisons Information Service and check their liability for the General Industry Charge.

They must also comply with all advertising requirements with regard to advice to use biocides safely and to always direct users to read the label and product information before use.

No reference likely to mislead in respect of the risks, such as terms like 'non-toxic', should be used. Among the information which has to be supplied for product authorisation is a letter of access to the dossier on active substances, the product dossier itself, which includes information on efficacy, toxicology, environmental fate, ecotoxicology and physical chemistry.

All data points have to be addressed, either by data or arguments and raw data, robust study summaries and a risk assessment also need to be included.

The requirements are undoubtedly complicated, so Campden BRI advise extensively on what is required, which tests are available and which are appropriate for specific products.

Keep up to date

With the emphasis of responsibility now firmly placed at the door of the manufacturers, they must ensure they keep up to date with all the active substances in their products and whether or not they have been supported.

They also need to keep abreast of the timings and procedures involved so they know when to submit their product dossiers and think about their products and the data requirements.

Suppliers and users also need to be aware of the new requirements and keep up to date with their products to determine whether they will be able to remain in use.

Despite the huge changes to the industry, Campden BRI are confident that disinfectant manufacturers can make a smooth transition.

It is a difficult period, but if manufacturers take advantage of the services offered by organisations like Campden BRI, they can be sure that their products comply with the legislation and need not worry that they have missed something. ■

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