

Restrictions on Hazardous Substances

From August 13 EU Member States are required to have in place the regulatory provisions implementing Directive 2002/95 on the restrictions on the use of certain hazardous substances in electrical and electronic equipment (“RoHS”).

Restrictions and Concentration Values

Subsequently, from 1 July 2006, new electrical and electronic equipment (with certain narrow exceptions) put on the European Community market will not be able to contain:

- lead
- mercury
- cadmium
- hexavalent chromium
- polybrominated biphenyls (PBB)
- polybrominated diphenyl ethers (PBDE)

Maximum concentration values for these substances have recently been agreed. The Technical Adaptation Committee (“TAC”), comprising Member States and the European Commission, decided on 20 July that a maximum concentration value of 0.1% by weight in homogeneous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) and of 0.01% weight in homogeneous materials for cadmium will be tolerated.

The TAC defines homogeneous material as ‘material that can not be mechanically disjointed into different materials’. The term “homogeneous” is understood as meaning ‘of uniform composition throughout’. Examples of homogeneous materials given by the TAC are ‘individual types of: plastics, ceramics, glass, metals, alloys, paper, board, resins, coatings’. The term “mechanically disjointed” has been defined by the TAC as meaning that ‘materials can be, in principle, separated by mechanical actions such as for example: unscrewing, cutting, crushing, grinding and abrasive processes’. For example, a plastic cover is a homogeneous material if it consists of one type of plastic that is not coated with or has attached to it or inside it any other kinds of materials. In this case the limit values of the RoHS Directive would apply to the plastic. An electric cable that consists of metal wires surrounded by non-metallic insulation materials is an example of a non-homogeneous material because the different materials could be separated by mechanical processes. In this case the limit values of the RoHS Directive would apply to each of the separated materials individually. A semi-conductor package contains many homogeneous materials which include; plastic moulding material, tin-electroplating coatings on the lead frame, the lead frame alloy and gold-bonding wires. The TAC’s views are not legally binding but its agreement is aimed to assist in the implementation of RoHS. This does not rule out the possibility that different approaches will be taken by individual Member States so monitoring of implementation in key markets will remain essential.

Exemptions to RoHS

The TAC has also carried out a first review of the results of the recent [RoHS Public Consultation](#) on exemptions. A total of 91 responses were received. 56 of the responses relate to exemptions already under examination in the context of a technical study recently commissioned by the European Commission's DG Environment. The TAC members decided to postpone voting on the proposed exemptions until after the results of the technical study are available (in October, when the TAC is next due to meet). A vote is anticipated before the end of 2004. The European Commission has also decided to carry out a full technical study (the details of which will be announced at a later date) into the requirement that medical devices and monitoring and control instruments be included within the scope of the RoHS Directive by 13 February 2005.

California Registration Program Streamlining Aims to Improve Review Times and Cut Costs

In the wake of huge budget shortfalls and Governor Schwarzenegger's Performance Review initiative, numerous changes are underway within the California Department of Pesticide Regulation (DPR) and more are being considered. The California Performance Review (CPR), which has produced recommendations for the abolition or consolidation of many state offices, has recommended that DPR be maintained as one of six functional divisions within the California Environmental Protection Agency (Cal-EPA). Although DPR will maintain its separate identity and functions within Cal-EPA, the CPR has recommended significant changes to how it operates.

Letters of Authorization Blamed for Program Inefficiencies

The CPR, in Resolution 16 of the CPR's Final Report, reserves its harshest criticisms for the current requirement mandating that applicants for state registrations must submit all required data or obtain a letter of authorization (LOA) from the owner of data already in CPR's files. Resolution 16 states that the current process "requires staff time and resources for activities that primarily protect the business interest of data owners, duplicates federal registration processes that already provide adequate protection to data owners, and creates marketplace barriers for pesticide products." The Resolution adds that "this duplication of effort does nothing to improve public health or the environment."

The Resolution recommends that the Governor work with the Legislature to repeal Section 128115 of the Food and Agriculture Code, which prohibits DPR from considering data it has already reviewed unless it has the written permission of the original data submitter. The CPR has set the stage for the repeal by making very strong arguments that the current law diverts resources from the government's core obligations of protecting public health and the environment and wastes significant government and industry resources in the process. Nonetheless, there is likely to be opposition from pesticide registrants that have invested considerable time and money in data packages on file with the state. Consequently, changes to the LOA process may be a future possibility at best and not offer opportunities for near-term streamlining.

Efficacy Data Reviews to Be Eliminated for Some Pesticides

DPR requires that registrants submit efficacy data to support every use site claimed for its California registration. The requirements have been stringently applied, with an onerous degree of specificity applied to the data mandated for non-agricultural use sites. One of the main results of the efficacy requirements has been a bottleneck in the registration review process. The CPR views efficacy reviews as a consumer protection function, which has diluted DPR's mission to protect public health and the environment. In fact, the CPR charges that California, by continuing to require efficacy reviews, has resisted the trend in pesticide regulation to evolve from consumer protection to environmental protection.

Consistent with the CPR recommendations, DPR on July 27 announced its intention to amend its regulations to provide "more discretion and flexibility on reviewing efficacy

data.” Presumably, its proposed regulatory changes will be consistent with the CPR’s, which would be to review efficacy data only for public health pesticides, described in Resolution 16 as “sanitizers, disinfectants, and sterilants.”

The Resolution further recommends that DPR should review EPA evaluations of efficacy data for public health pesticides and refer to the data only when there are questions about the EPA evaluation. In fact, consistent with this recommendation, DPR issue California Notice 2004-6 in June, encouraging applicants to submit EPA evaluations of all types of data, not just efficacy data. In that notice, the department committed to limit its routine reviews to the evaluations, and to refer to the underlying data only on an “as-needed” basis.

DPR Commits to Register Pesticides in 60 Days

According to Resolution 16, “DPR’s goal and commitment to the pesticide industry is to register pesticides within 60 days of receiving the registration application.” This would be a significant change, given that registration delays of six months are typical and delays of a year or more are common. However, the CPR Resolution notes that DPR management estimates that 75 to 90 percent of all product registrations and label amendments could meet the 60-day turnaround goal, *but only if* the LOA requirement is eliminated and efficacy review regulations are amended.

But Only After Regulations Are Revised and Laws Repealed

DPR management reportedly is working on a proposal to amend its regulations on efficacy data reviews. Even if this process is expedited, it is likely to take at least six months and probably longer before revised regulations are promulgated. Any change in the requirement for LOAs is dependent on repealing an existing provision of law, which is dependent on cooperation between the Democratic-controlled Senate and Assembly and the Republican Governor. Interested parties will be staking out their positions and seeking to influence the upcoming debates on these issues.

The BPD in Germany

June 2004 saw the publication by the Federal Institute for Occupational Safety and Health (BAuA) of the “Guidance for authorisation of biocidal products.” Although the BAuA is the authorising authority, the review and authorisation of biocides involves a number of departments including:

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU).
Federal Environmental Agency (UBA)
Federal Institute for Risk Assessment (BfR)
Federal Institute for Materials Research and Testing (BAM),
Robert-Koch Institute (RKI)

The Guidelines provide information on a number of key topics.

Frame-formulations

This allows authorization of a group of biocidal products that are essentially the same and are to be used in the same use categories. Changes in formulation are allowed where there is :

- a reduced concentration of the active biocidal substance
- a change in the ratio of substances which are not active biocidal substances
- changes in the pigment, colouring agent or fragrance used. Any substitution must have the same or a lower risk and should not have an adverse effect on the efficacy of the product.

Data Protection

A letter of access is necessary where a second applicant requires use of protected data owned by the original registrant. Anyone planning to start a new toxicity study involving vertebrate animals must first send an enquiry to the authorities to determine if that data already exists.

Where the data is still protected, the authorization unit will inform both the data owner and new applicant of the requirement to use the data and pass on contact details of both parties.

Financial compensation is payable to the data owner for use of such studies and is set at 50 % of the costs saved by the new applicant.

Should the owner refuse to allow the use of their data, the registration process will be placed on hold until the applicant is able to produce the necessary study reports.

Classification, packaging, labelling and advertising

As of 30 July 2004, all active biocidal substances and products must be classified, packaged and labelled in accordance with:

[Directive 1999/45/EC](#) - the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations (New Preparations Directive).

Ordinance for the Protection against Hazardous Substances (Hazardous Substances Ordinance – GefStoffV) (§§ 12 Section 11, 54 Section 7 Hazardous Substances Ordinance).

Phrases considered to be misleading, e.g. "low-risk biocidal product", "non-toxic" or "harmless," cannot appear on the label or in supportive literature

The label must also include the name of the active substances, an authorization number, type of preparation, use categories, instructions for use and any direct or indirect side effects. Where possible, reference should be made to an enclosed information sheet.

All advertising must include the phrases: "Use biocides safely; Always read the label and product information before use." Both must stand out from all other wording.

Fees for the authorization of biocidal products

A range of fees payable for the authorization of active substances and biocidal products are described in the guideline document.

Key are the fees for the assessment of a biocidal active substance which range from 75.000 € to 100.000 €, whilst authorization of a biocidal product will cost between 10.000 € and 45.000 €. Where the biocidal product is the subject of a frame formulation, the fee is reduced to 750 €.

Poisons Information

Information about biocidal products on the market must be passed on to the BfR. This includes, the trade name, composition, labelling and emergency measures in case of accident.

\$160,000 Civil Penalty for FIFRA Violation Reinstated Upon Landmark Appeal

In a landmark enforcement case, the Environmental Appeals Board (EAB) reversed a liability decision and assessed a \$160,500 civil penalty on Microban Products Co., a North Carolina plastics manufacturer, for violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (*In re Microban Products Co.*, EPA EAB, No. FIFRA 98-H-01, 5/12/04).

Microban produced a product called Microban Plastic Additive “B,” which was registered by the EPA in 1983 and later sold to toymaker, Hasbro Inc., for incorporation into certain plastic toys, games, and juvenile products. Pesticide Enforcement alleged in its December 5, 1997 Complaint against Microban, that the company had committed thirty-two violations of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B) by shipping products that the company claimed had antimicrobial effects.

Specifically, Pesticide Enforcement alleged of each of the thirty-two shipments of Additive “B” that Microban “in each instance sold or distributed a registered pesticide with claims that were substantially different from claims made in connection with its registration.” The relevant section of FIFRA provides that it is unlawful to distribute or sell a pesticide if any claims made as part of its distribution or sale differ from the approved claims under the product’s registration statement.

Pesticide Enforcement’s case centered on three questions: whether Microban’s claims differed from those made in the registration statement, whether the unapproved claims were made “as part of” the distribution or sale of Additive “B,” and whether the unit of violation and penalty assessment were appropriate and proportional to the gravity of the violation.

Three documents were at the heart of the EAB’s finding that Microban’s antimicrobial claims about Additive “B” substantially differed from claims made under its registration: 1) a document memorializing a Presentation to Hasbro, Inc. including the statement that Additive “B” was “the ultimate in germ-fighting protection”; 2) a draft toy label by Microban suggesting that the Hasbro toy labels state, “Only Playskool has the exclusive Microban germ-fighting technology built right into the toy. This unique technology inhibits the growth of germs on toys to help provide a healthier (or better) environment for your child”; and 3) a Questionnaire about Microban stating “Microban protection has been shown to be effective in virtually eliminating the growth of most common household germs, including E. coli, Salmonella, Staph. and Strep. as well as mold and fungus.”

Based on these documents, the appeals board found that EPA had produced sufficient evidence of a violation. Microban’s human health related antimicrobial claims differed from EPA’s explicit statement made in a July 1987 letter to the company regarding registration stating: “the data which you have submitted do not support health-related efficacy claims. The only claim which may be made is that the product is bacteriostatic with respect to bacteria not infectious to man.”

The second central question, whether the unapproved claims were made “as part of” the distribution or sale of Additive “B,” was more contentious. On remand, the Administrative Law Judge (ALJ) concluded that Pesticide Enforcement had not demonstrated a particularized link between the thirty-two shipment invoices and the unapproved claims in the Presentation, the Q&A document, and the Draft Label, thus finding no violations of FIFRA section 12(a)(1)(B).

On appeal, however, the EAB found that the fact that the sales agreement was entered into sometime after the presentation, and the shipments resulting from the agreement occurred sometime after that, does not change the underlying fact that a connection existed between the unapproved claims and the “distribution or sale” of the pesticide.

Resolution of the final question regarding the unit of violation and penalty assessment was also reinterpreted upon appeal. Microban argued that, when there is a sale and later shipments made pursuant to that sale, unless the unapproved claims physically accompany the subsequent shipments, there can only be one violation of FIFRA for the sale. Microban emphasized the fact that none of the documents at issue were sent with the thirty-two shipments to any of Hasbro’s contractors.

In his 1999 decision, the ALJ decision concluded that Microban had committed five violations of FIFRA section 12(a)(1)(B) based upon five documents in which he found Microban to have made unapproved claims. In the current decision, the EAB held that the ALJ had erred in his interpretation of section 12(a)(1)(B) of FIFRA because a unit of violation “must be based, not upon the number of documents containing unapproved pesticidal claims, but rather upon the number of proven distributions or sales of the pesticide, which in turn must be shown to be ‘linked’ to one or more of the unapproved claims.”

The appeals court found the gravity of the violations to be significant because Microban’s culpability was high and the company’s claim violations were blatant. The Board thus assessed the statutory maximum penalty per violation, which resulted in a total civil penalty of \$160,500.

The Appeal’s Board’s decision has several lasting implications. The Microban decision reinforces a broad interpretation of evidence demonstrating the existence of a nexus between unapproved claims and the distribution or sale of a pesticide. The penalty assessment also demonstrates the EAB’s willingness to issue the statutory maximum fine per FIFRA violation, especially in the case of a claim that “blatantly” departs from the scope of EPA’s approval.

In the current decision, the Board found that the language of FIFRA authorizes the Agency to consider each shipment as a violation of the Act, stating, “under the plain language of the statute, each shipment of Additive “B” constitutes one violation of FIFRA.” In the case of a FIFRA section 12(a)(1)(B) violation, the EPA is authorized to charge violations of either the sale(s) or the shipment(s) of a pesticide (but not both).

Thus, any egregiously written pesticide claims that depart from the scope of a pesticide's registration will meet a potential maximum statutory fine based on either the number of sales or shipments of the pesticide.

EPA penalty policy for assessment of administrative penalties for violations of FIFRA (Five-Stage Process):

- (1) Determine the gravity of the violation;
- (2) Determine the size of business category for the violator;
- (3) Use the FIFRA penalty matrices to determine the dollar amount associated with that gravity level and that size of business category;
- (4) Further adjust the gravity of the base penalty by considering the specifics of the pesticide involved, such as toxicity, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator;
- (5) Consider the effect of the calculated payment on the ability of the violator to continue in business.