PLASTICS MONITOR: PRODUCERS ACHIEVE JUNE HIKES

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Chemical trespass

Will biomonitoring put chemicals on the defensive?

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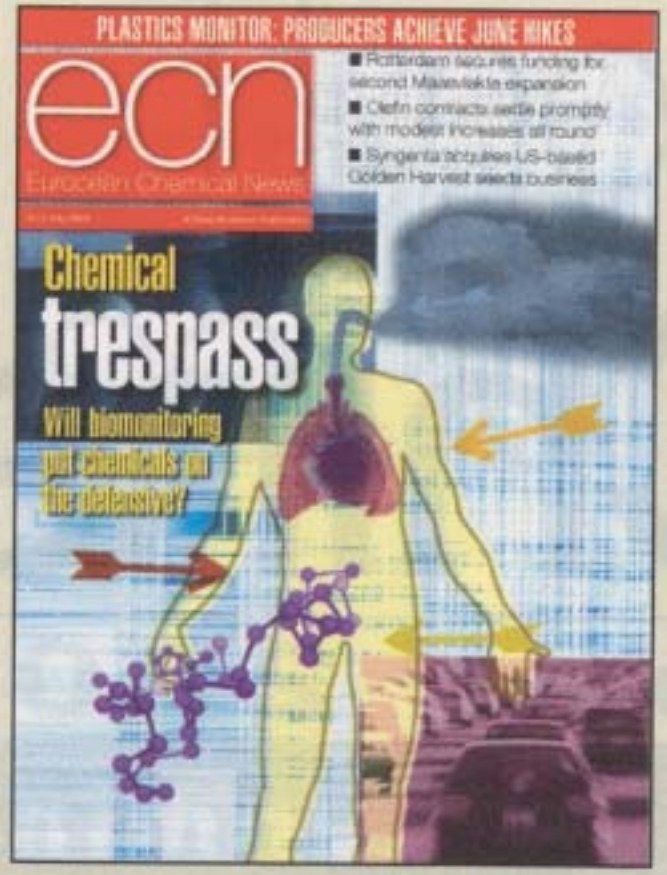

Cover story

Worried by the prospect of being sued for chemical trespass? Perhaps you ought to be, as biomonitoring of chemicals in the human body becomes more prevalent and easier to carry out. Who is responsible for the growing burden of chemicals in our bodies and are there legal and ethical issues over and above the risk of actual physical harm? *ECN* examines an issue that is set to intensify as biomonitoring becomes commonplace.

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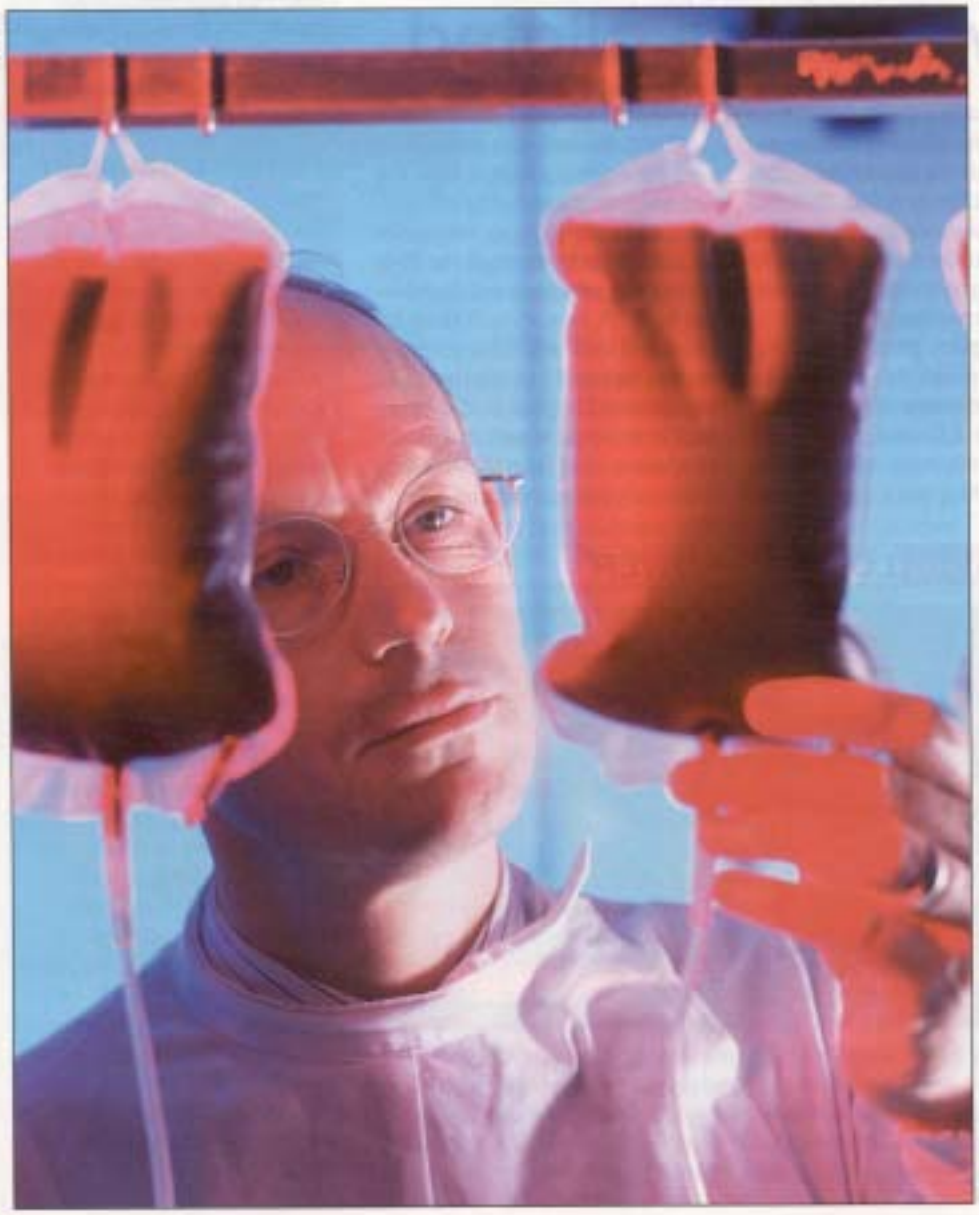
Assessing the risks

The use of biomonitoring to detect levels of chemicals in the human body is about to proliferate and, at the same time, larger numbers of chemicals are being examined for their health risks. **Julia Hatcher** and **William Rawson** look at the effects this biomonitoring increase will have on the chemical industry



Increased attention has been given recently to the detection of commercial chemicals in the human body. In the US, federal and state governments are making significant investments in biomonitoring programmes designed to assess the body burden of commercial chemicals in the general population.

Some non-governmental organisations point to chemicals found in the body as evidence of ineffective government regulatory programmes and inadequate product stewardship by industry. Industry, in turn, points out that the mere presence of chemicals in the body does not demonstrate a health risk.

Indeed, traditional risk assessment principles assume that the body takes in some amount of a chemical, which then moves through the body via the blood to various organs. Thus, every external exposure to a chemical deemed safe based on animal or human testing should have a corresponding internal 'safe' exposure level as well.

Looking for chemicals in the body is not a new concept. Biomonitoring has served as an occupational health protection tool for many years. Biological exposure indices (BEIs) (typically safe levels in blood or urine) have been established for some industrial chemicals, and are used by industrial hygienists to ensure that workplace exposures are maintained at safe levels.

Levels of lead in blood have been monitored in the general population in the US for many years, and a demonstrated decrease in blood levels was cited as a principal reason for not allowing lead back into gasoline in the 1980s.

It is fair to say that although not a new concept, biomonitoring has been used historically on a limited and discrete basis. That is about to change. The next few years will bring a much expanded scope of biomonitoring – both in terms of the number of programmes and the number of chemicals covered.

Improvements in analytical methods and lower-cost techniques now make it possible to screen for many more chemicals in much larger populations. Biomonitoring programmes, both public and private, will proliferate not only in the US, but also around the world, particularly in Europe and Japan.

As one example, the US Centers for Disease Control has a long-standing biomonitoring programme, dating back to the 1980s, that will be extended over the next few years to cover scores of additional chemicals. It will also be extended to collect information in a manner that allows for greater public access to correlations of biomonitoring data with subpopulation information, such as age, sex and geographic region.

The proliferation of biomonitoring data

raises potentially significant challenges for companies that manufacture, process and/or use chemicals. These challenges include the need to place the data within a health-risk framework and otherwise to explain their significance to industrial customers, consumers, regulators and the public and the need to anticipate the potential vulnerabilities that could result from opportunistic use of biomonitoring data in litigation.

Biomonitoring data unequivocally document exposure to a specific chemical in a specific compartment of the body (eg blood, urine, breast milk). The data make it easier to focus on chemical body burdens in potentially sensitive subpopulations, such as children or women of child-bearing age. Certainly, the presence of a chemical in the body does not mean that one has suffered (or will suffer) adverse effects. However, without toxicology and other sufficient data that could place the biomonitoring data in a health-risk framework, it becomes difficult for regulators as well as the chemical industry to respond to customer and public concerns. Conversely, it becomes easier for various stakeholders to make unsubstantiated claims of harm.

Placing biomonitoring data in a health-risk framework may pose special challenges. Notably, most toxicology studies have not been designed to assess the potential health consequences of biomonitoring data. Animal studies typically relate adverse effect levels and 'no adverse effect' levels to external doses (eg milligrams of test substance per kilogram of body weight per day, or parts per million in air).

Health significance

Standard test protocols specified by government agencies typically do not require measurements of internal blood levels (although study sponsors sometimes add such measurements). Studies of workers and other human populations have also, in most cases, focused on external measures of exposure. Thus, much of the available safety data do not speak directly to the question of the health significance of biomonitoring data.

In the future, study protocols are likely to evolve to address biomonitoring data. In the meantime, it may be possible to place biomonitoring data in a health-risk framework by comparing blood-level data with an external exposure (such as a concentration in air) determined by regulatory agencies to be safe. If one can show that blood levels are consistent with what one would predict from external exposures at government-approved levels, then one might conclude that the biomonitoring data are not indicative of significant health risks.

Considered in this way, biomonitoring data might actually be used to confirm that exposures are below levels of concern (which is how biomonitoring data typically are used in occupational settings). This approach, however, requires understanding of a chemical's pharmacokinetics – how the chemical is processed in the body – and that information is not always available.

Moreover, even if available, some may argue that an external dose approach using pharmacokinetics information is not sufficient because it does not involve direct use of the human biomonitoring data itself.

Some may argue further that a more sophisticated, time-integrated understanding of exposure sources and pathways is a necessary component for sufficient interpretation of biomonitoring data. Low levels in blood might come from low-level exposures that occurred on the same day, or high-level exposures that occurred several days earlier.

For persistent chemicals, exposure issues are particularly complicated, as biomonitoring data may reflect exposures that occurred some time ago. In addition, some commercial chemicals are naturally present in the environment. Where that is the case, low blood levels in the general population may reflect natural rather than man-made sources of exposure.

The confirmation of chemicals in the body provided by biomonitoring data converges with other emerging chemical concerns, such as potential health risks presented by persistent or bioaccumulative chemicals, exposure to multiple chemicals, children's health risks, and the potential for unusually sensitive subpopulations.

For at least some categories of chemicals – those with hazard data indicative of possible serious health concerns (eg cancer risk), persistent chemicals and chemicals with widespread exposure potential to subpopulations of concern such as children – biomonitoring data are likely to lead to greater demands for toxicology data, despite the recognition that the presence of a chemical in the body does not necessarily imply a health risk.

Inadequacies

Many non-governmental organisations have recognised the potential impact of biomonitoring data, and have used chemical body-burden data to highlight what they see as inadequacies in chemical testing and regulation, and inadequate disclosure of potential health risks to consumers and the general public. Body-burden data has been used to generate media interest and apply pressure to regulatory agencies, and the theme of chemical trespass has been used to put companies on the defensive.

Biomonitoring may impact tort liability in the US. By unequivocally documenting exposure, biomonitoring data could be used to expand existing causes of action and to press for new causes of action. Although plaintiffs bear the burden of proving harm, biomonitoring data provide a vehicle by which they can attempt to shift the burden of proof to defendants by arguing that a particular defendant's representation of safety of the chemical in question (or of products containing such a chemical) does not adequately take into account biomonitoring data and does not otherwise reflect state-of-the-art health-risk assessment methods. In responding to such arguments, a defendant may be forced to demonstrate the absence of harm to avoid the anger and other prejudicial impacts that biomonitoring data could have on juries and even judges.

Chemical trespass

Moreover, biomonitoring data provide a key element of proof – proof of exposure – and plaintiffs can be expected to rely heavily on this proof in promoting relatively new, but quite powerful and financially significant, causes of action, such as medical monitoring and increased risk of disease. Biomonitoring data can also be expected to spawn, and have already spawned, attempts to create wholly new causes of actions. For example, allegations of chemical trespass are beginning to show up in class action lawsuits against corporate defendants who are responsible for chemical exposures.

Chemicals provide essential benefits in virtually every facet of our daily lives. It is important that these benefits be obtained without posing unreasonable risks to health or the environment, which means that exposures must be maintained at or below safe levels. As the measure of exposure shifts from external dose to internal dose, risks do not necessarily increase, but public concern may, and industry must be prepared to address that concern.

Biomonitoring data should be used to inform, not scare. To achieve that objective, industry in general will need to play an active role in the development of tools and information necessary to understand the health-risk significance of low levels of chemicals found in the human body.

Companies should evaluate what the increased availability of biomonitoring data and the evolution of the health-risk framework for evaluating chemicals to include biomonitoring data will mean for the chemicals they make, process and/or use. Where appropriate, these companies should consider additional testing and other measures to address potential questions and concerns and to minimise litigation risks. ■

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