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Protecting workers against unseen hazards

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TSCA & Exposure Assessment: Overview

TUNAR/E+/GETTY IMAGES

By Morgan Bliss

PART ONE

How much do you know about the changes to the Toxic Substances Control Act (TSCA)? Volumes of information are available, most of it by the U.S. EPA, but it can be a time-consuming venture to synthesize all the material. This is Part 1 of a multi-part series on TSCA.

The revised regulations for toxic substances control are found in Chapter 53 of Title 15, and the text of the new requirements is in Subchapter I, "Control of Toxic Substances."

15 CFR 53 Part 2601(a) explains the focus of Subchapter I, "Control of Toxic Substances," is on chemical substances and mixtures that are manufactured, processed, distributed in commerce, used or disposed, and which "may present an unreasonable risk of injury to health or the environment."

Unreasonable is the key word here, and it is not defined. All the regulation says is that the administrator (of the U.S. EPA) will determine whether a chemical poses an unreasonable risk based on scientific information or testing. In Part 2603(b), it expounds upon what could be considered an unreasonable risk: health and environmental effects including carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect that could present an unreasonable risk of injury to health or the environment.

By this definition, were you to bottle sunlight as a new product, it could easily constitute an unreasonable risk, due to the ultraviolet radiation and potential for cancer.

This regulation puts into policy a requirement for the development of adequate information about the health and environmental effects of chemical substances and mixtures, and places the responsibility for developing this information on the manufacturers and processors of chemical substances and mixtures per 15 CFR 53 Part 2601 (b)(1).

The key word in this section is *adequate*. Who decides whether the information provided by a manufacturer is adequate? How do they think manufacturers and distributors will find the funding, technical specialists and content experts to develop this information? Many manufacturers are still not in compliance with the 29 CFR 1910 Part 1200 Hazard Communication requirements; many safety data sheets (SDS) in circulation today do not meet the requirements or intent of the standard.

The EPA administrator is responsible for considering the environmental, economic and social impacts of actions associated with TSCA. This is a strange statement, and puts the administrator and the EPA in an unenvi-

able position of trying to please everybody.

Some interesting definitions for industrial hygienists and safety professionals to consider:

•**"Conditions of use"** means the circumstances [. . .] under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.

•**"Environment"** includes water, air and land and the interrelationship which exists among and between water, air, land and all living things.

•**"Health and safety study"** means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.

•**"Potentially exposed or susceptible subpopulation"** means a group of individuals within the general population [. . .] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

One item of concern is the definition of "health and safety study." It does not seem to require that the stud(ies) be peer-reviewed to be used, per the definition. Does this mean the U.S. EPA is encouraging and will support citizen science? How will the submitted studies be evaluated for scientific accuracy and validity?

Part 2625(h), Scientific Standards, provides some clarification:

•The administrator will make a decision based on science.

•The administrator will use scientific information, technical procedures, measures, methods, protocols, methodologies or models [. . .] consistent with the best available science.

•The administrator will consider the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models are reasonable, consistent with, and relevant for the intended use of the information.

•The data, assumptions, methods, quality assurance and analyses employed must be documented and will be evaluated for clarity and completeness.

•The variability and uncertainty of the procedures, measures, methods, protocols, methodologies or models will be evaluated and characterized.

There is such potential for bias and lazy science with the explosion of interest in occupational and exposure science, and recognizing this seems to be up to each individual industrial hygienist or safety professional.

•The "extent of independent verification or peer review" for the procedures, measures, protocols, methodologies or models will be evaluated.

•The administrator will make decisions based on the "weight of the scientific evidence."

This language is troublesome and does not appear to require peer-reviewed science. As William Watt said, "Do not put your faith in what statistics say until you have carefully considered what they do not say." Results can be manipulated using complex statistical analyses until they say (or do not say) whatever the author's hypothesis may have been.

Simon Oxenham at Big Think explored this in the article, "**Believe It Or Not, Most Published Research Findings Are Probably False.**" He gave a quick synopsis of key factors for scientists to consider:

•The smaller the study, the less likely the findings are to be true.

•The smaller the effect size, the less likely the findings are to be true.

•The greater the number and the lesser the selection of tested relationships, the less likely the findings are to be true.

•The greater the financial and other interests and prejudices, the less likely the findings are to be true.

•The hotter a scientific field, the less likely the findings are to be true.

The last two points are especially worrisome for the state of exposure assessment today. Significant costs are associated with determining exposure concerns for TSCA, and a lot of money is involved in developing newer, faster and more specialized tests for chemicals. There is such potential for bias and lazy science with the explosion of interest in occupational and exposure science, and recognizing this seems to be up to each individual industrial hygienist or safety professional.

A similar concept was explored by Veritasium in a video, "**Is Most Published Research Wrong**?" Part of this article covers testing requirements for chemical substances per TSCA. ■

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TSCA & Exposure Assessment: Testing Chemical Substances

By Morgan Bliss

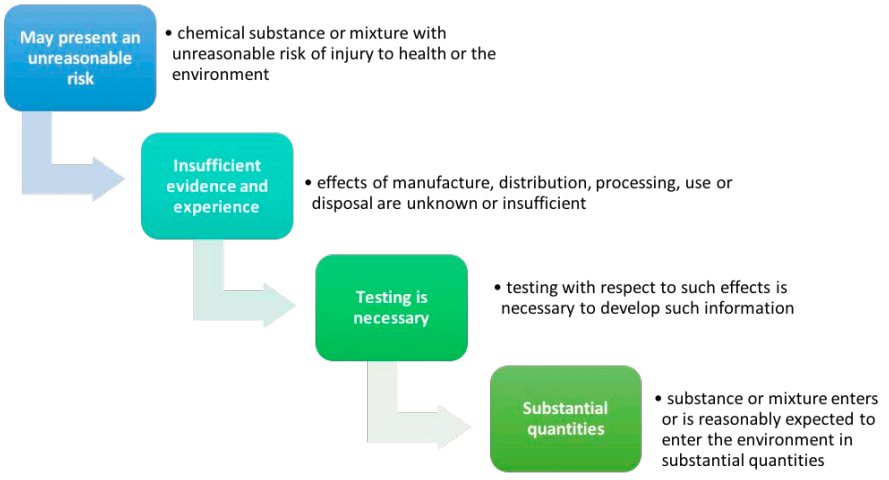
PART TWO

Continuing the series on TSCA and exposure assessment, this article addresses the testing requirements for chemical substances. This is Part 2 of a multi-part series on TSCA.

15 CFR 53 Part 2603(a) explains the testing requirements. This is best explained in a graphic:

If a chemical fits the requirements explained in the image above, the Administrator (of the U.S. Environmental Protection Agency) will call for testing to be conducted on the substance or mixture. The testing must show whether the manufacture, distribution, processing, use or disposal (or any combination of these activities) does or does not present an unreasonable risk of injury to health or the environment.

FIGURE 1
TSCA Testing



The administrator can also require the development of new information relating to a chemical substance or mixture. It is at the EPA administrator's discretion to establish the priority (either high-priority or low-priority) of the substance or mixture. This prioritization is established to rank substances or mixtures for risk evaluation by the EPA.

A high-priority substance is one that presents an unreasonable risk of injury to health or the environment because of a potential hazard or a potential route of exposure under normal conditions of use. However, the definition for high-priority substance has more worrisome language. The administrator can conclude that a substance is a high-priority substance without consideration of costs or other non-risk factors, and the Administrator decides which potentially exposed or susceptible subpopulation is relevant in determining whether the substance poses *an unreasonable risk*.

A low-priority substance is anything that the administrator deems not to be a high-priority substance, based on information sufficient to establish this designation, without consideration of costs or other non-risk factors. "Information sufficient to establish" is not defined.

If the administrator requires the development of new information, the administrator must write a statement of need. This statement must include: 1) the need for the new information; 2) how information reasonably available to the Administrator was used to inform the decision; 3) explanation of any decision requiring the use of vertebrate animals for testing; and 4) why the issuance of an order is warranted rather than promulgating a rule or entering into a consent agreement.

One big issue here is "information reasonably available" to the administrator. How is this to be decided? What constitutes reasonably available? How substantial of a data search or literature review is this?

Any rule, order, or consent agreement must include the following basic information:

- identification of the chemical substance or mixture;
- protocols and methodologies for the development of information for each substance or mixture;
- a specified time period (which may not be of unreasonable duration) where the person(s) required to conduct the testing must report the information to the administrator.

It also states the administrator's considerations for testing must include the relative costs of test protocols and methodologies, as well

as the reasonably foreseeable availability of facilities and personnel needed to perform the testing. This may require the person(s) or facility to submit preliminary information to the administrator.

In Part One, I discussed the health and environmental effects that would necessitate development of information—carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect that may present an unreasonable risk of injury to health or the environment.

The regulation also calls out specific characteristics of chemicals or substances that would require development of information, such as persistence, acute toxicity, subacute toxicity, chronic toxicity and any other characteristic that may present such a risk.

The inclusion of "any other characteristic" that may present an unreasonable risk is nonspecific and will likely present confusion for manufacturers in evaluating the risks of their substances or mixtures.

Protocols and methodologies that may be prescribed by the Administrator include epidemiologic studies, serial or tiered testing, in vitro tests and whole animal tests. The regulation notes: "before prescribing epidemiologic studies of employees, the administrator shall consult with the director of the National Institute for Occupational Safety and Health" (NIOSH). This proposed practice may lead to privacy concerns for employees who may be required to participate in the epidemiological studies.

A strange phrase in the regulation can be found in Part 2603(b)(2)(B), where it states that "from time to time, but not less than once each 12 months," the administrator must review any protocols or methodologies developed in response to a rule, order, or consent agreement for *adequacy* (emphasis added). Again, the definition of adequate is not provided.

When creating the priority list, the administrator must consider at least the following information:

- quantities of the substance that are or will be manufactured;
- quantities of the substance that are or will enter the environment;
- number of individuals who are or will be exposed to the substance in their place of employment, including the duration of such exposure;
- extent to which human beings are or will be exposed to the substance
- extent to which the substance is closely related to another chemical substance which is known to present an unreasonable risk of injury to health or the environment;
- extent to which testing of the substance may result in the development of information upon which the effects of the substance on health or the environment can reasonably be determined.
- reasonably foreseeable availability of facilities and personnel for performing testing on the substance.

The inclusion of "any other characteristic" that may present an unreasonable risk is nonspecific and will likely present confusion for manufacturers in evaluating the risks of their substances or mixtures.

The delineation of "individuals" who are or will be exposed in their place of employment versus "human beings" is unintentionally funny, as if individuals who work are somehow separate from the rest of humanity.

The regulation requires a committee to be established to make recommendations to the administrator regarding priority substances. The committee must give priority attention, per the regulation, to substances and mixtures that are carcinogens, mutagens or teratogens. If the administrator receives information about a substance that concludes the substance presents a significant risk of serious or widespread harm to human beings, the administrator has 180 days to initiate "applicable action" to "prevent or reduce to a sufficient extent such risk."

Something interesting in the testing section is the requirement to reduce testing on vertebrates, and to use alternative testing methods whenever feasible. This can include:

- computational toxicology and bioinformatics;
- high throughput screening methods;
- testing of categories of chemical substances;
- tiered testing methods;
- in vitro studies;
- systems biology;
- other new or revised methods identified by validation bodies.

In the next article in this series, I will review the manufacturing section, including the requirement for "protection against unreasonable risks" per TSCA. ■

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