Concerns over Chemical Safety in the Great Lakes Region

Establishing some Important Context

Concerns regarding chemical safety are understandable. The chemical substances that we encounter in our daily lives all have properties that we must be aware of and take into account when we make use of them. The subject of "chemical safety" is treated ambivalently in the popular press and in our society. We all want protections and services that chemical products provide, but seek absolute elimination of hazard and potential for risk associated with chemical use.

These concerns result in calls for "safer" chemicals, or no chemicals at all. In truth, no chemical is truly "safe." All must be chosen and used keeping in mind a number of important factors. Prudent uses of chemicals enhance our health, safety and quality of life. When addressing chemical safety questions, the context of chemical use is extremely important. The same is true when looking at commonly raised chemical use questions.

How many chemicals are in use and what do we know about them?

Understanding the context around statements regarding the number of chemicals in production is very important. It often said that there are over 80,000 chemicals in use, but we have little or no information about these materials. It is also said that the safety of producing or using these substances is unknown.

Let's take a closer look. The U.S. Toxic Substances Control Act (TSCA) requires that all chemical substances must be listed, or registered, on EPA's TSCA data base whether or not they are actually in production or use. Consequently, there are more than 80,000 chemicals on this list. However, only about 7,000 of these are actually "in commerce" – being produced and distributed in commercial quantities of 25,000 lbs. per year or more.

Of these, 2,200 are produced in "high volume" quantities– more than one million lbs. per year. Companies provide toxicity data to U.S. EPA regarding "high volume" chemicals.

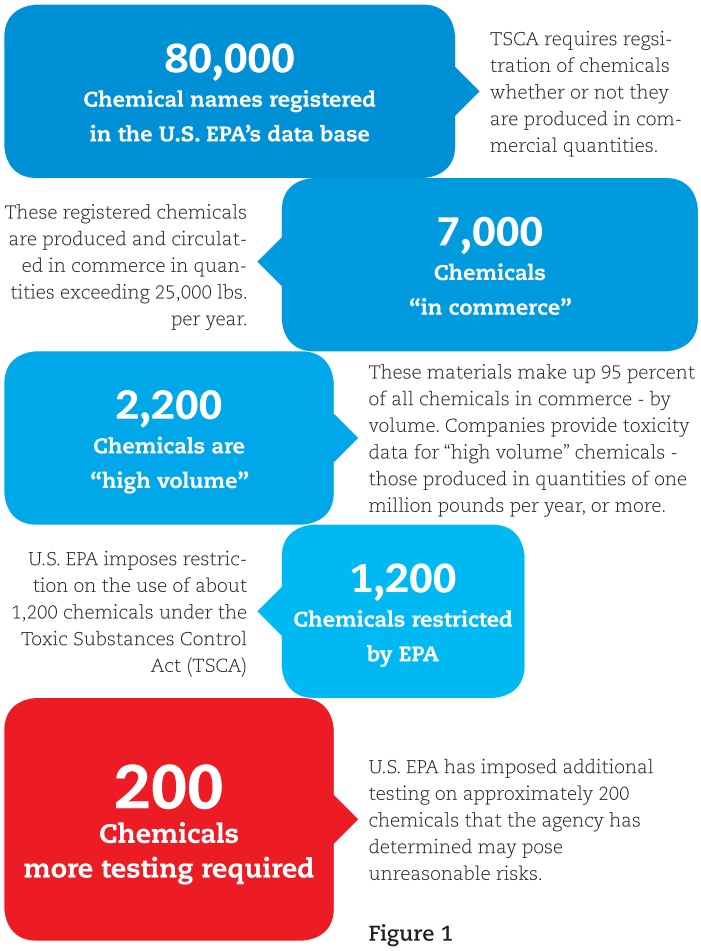

Figure 1

The agency has imposed use restrictions on about 1,200 of the "high volume" compounds. Of those 1,200, the agency has asked producers to conduct more tests and provide data on 200 compounds[I,II,III,IV]. Thus, the claim that we do not have safety information on 80,000 chemicals is false. U.S. EPA does have information and regulates these materials. Often detailed information is supplied to the agency as confidential business information and is therefore not available to the general public. This may give the impression that information is lacking, but authorities do have and use this information to make decisions about how a chemical should be regulated. As shown in Figure 1, a small subset of these materials is being more closely evaluated to establish whether or not they pose unreasonable risks.

To what extent are chemicals regulated in the U.S.?

In the U.S., chemicals are regulated based on how they are produced, used, and released into the environment. News media and others often state that the U.S. government does not have chemical regulations comparable to other countries. Such statements are incorrect and fail to provide clear context relating to how the U.S. chemical regulatory program has been developed.

In the U. S. chemical regulatory programs have been in place for a very long time. President Theodore Roosevelt signed the Food and Drug Act in 1906. This was the beginning of U.S. regulatory programs pertaining to chemical substances.

The number of programs has grown substantially over the years. At least 21 federal legislative and regulatory programs now in place that require registration, reporting of use and release information, and data on environmental fate and effects associated with chemicals. This set of U.S. chemical regulatory programs is illustrated in Figure 2.

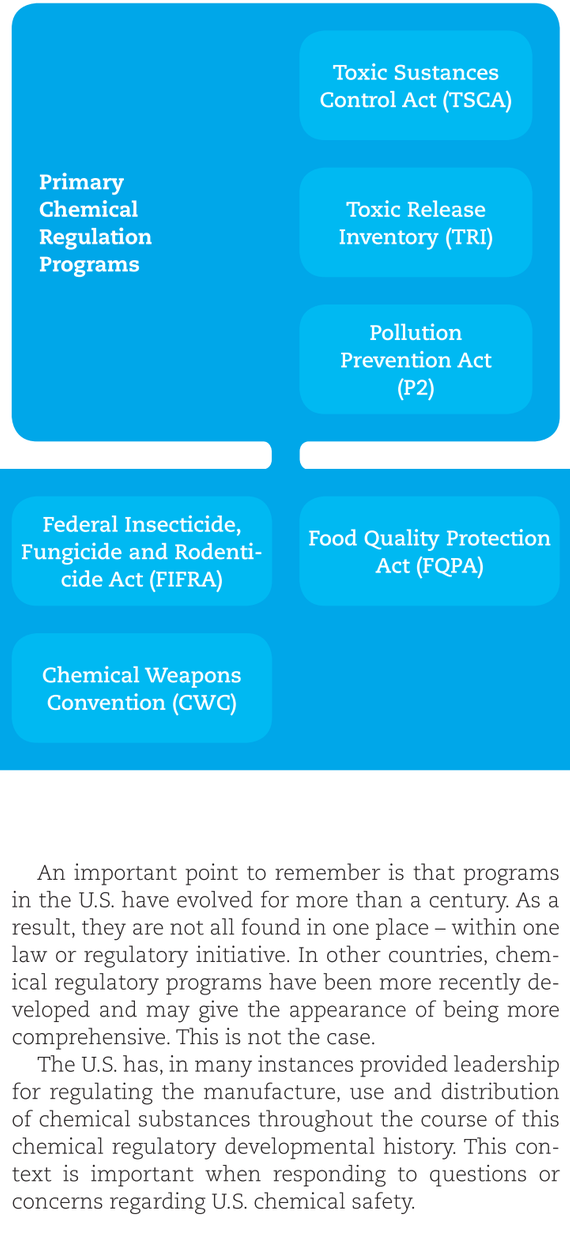

Figure 2 - U.S. Chemical Regulation Programs

An important point to remember is that programs in the U.S. have evolved for more than a century. As a result, they are not all found in one place – within one law or regulatory initiative. In other countries, chemical regulatory programs have been more recently developed and may give the appearance of being more comprehensive. This is not the case.

The U.S. has, in many instances provided leadership for regulating the manufacture, use and distribution of chemical substances throughout the course of this chemical regulatory developmental history. This context is important when responding to questions or concerns regarding U.S. chemical safety.

Does this mean that U.S. chemical regulatory programs are fragmented?

Chemical regulatory programs in the U.S. provide substantial overlap. Many programs can apply to the same substance and uses or production scenarios regarding that substance. Suggestions that U.S. programs are too fragmented to provide effective protection do not take the context of this overlap into account.

Number of regulatory programs	
Category	**Programs**
Releases of chemical to air water and soil	10
Human health and safety	15
Manufacture of:	
Pesticides	13
Pharmaceuticals	13
Commercial Products	14
Consumer Products	19
Support of industrial processes:	
Basic process operation	12
Make other products	20

Figure 3 - U.S. Chemical Regulatory Program Overlap

A number of programs apply to releases of chemicals to air, water and soil. Many apply to the human health and safety of chemicals. Specific regulations apply to the manufacture of different categories of chemical products. Others also apply to how chemicals are used to support industrial processes – from the generation of electric power, to process operation, as well as packaging, storage, transportation to market, and end of life management or disposal. In short, as shown in Figure 3, many different regulatory programs can apply to a single chemical substance.

When viewing the chemical regulatory structure in the use, it is necessary to do so from a perspective of the entire landscape of programs that have been developed over a very long period of time. Only then can such an assessment of how the system works be placed in proper context.

What are the important elements of chemical safety assessment processes?

All chemical substances should be considered hazardous. What is important is how they are handled, stored, and used. It is essential to know and understand the hazards, potential for exposure and how these factors contribute to risks associated with each chemical use situation. Hazard refers to the inherent properties of a substance that make it capable of causing harm to the health of humans and/or the environment. Exposure describes both the amount of, and the frequency with which, a chemical substance reaches a person, group of people, or the environment. Risk is the possibility of a harmful event arising from specific uses and circumstances of exposure to a substance.

Scientists and health professionals in government, industry and research institutions examine all three of these factors when assessing the safety of a chemical through a process known as a "chemical risk assessment." A typical frame work for risk management is shown in Figure 4 adapted from Canadian Standards Association protocol Q-850 (1997).

Starting with a hazard assessment, a preliminary analysis of degree of hazard, use characteristics, and exposure elements are made to produce an estimation of risk. This estimation is further evaluated to determine control elements needed to bring the risk into acceptable limits. In follow-up to the use decision, monitoring and evaluation continues for use in periodic reassessments that guide management of residual risks. Essential to this chemical use and risk management process is the risk communication efforts that must be taken at each step and include full engagement with stakeholders. It is essential that all parties understand how chemical uses are managed to have the ability to view the hazards within a context of managed risk.

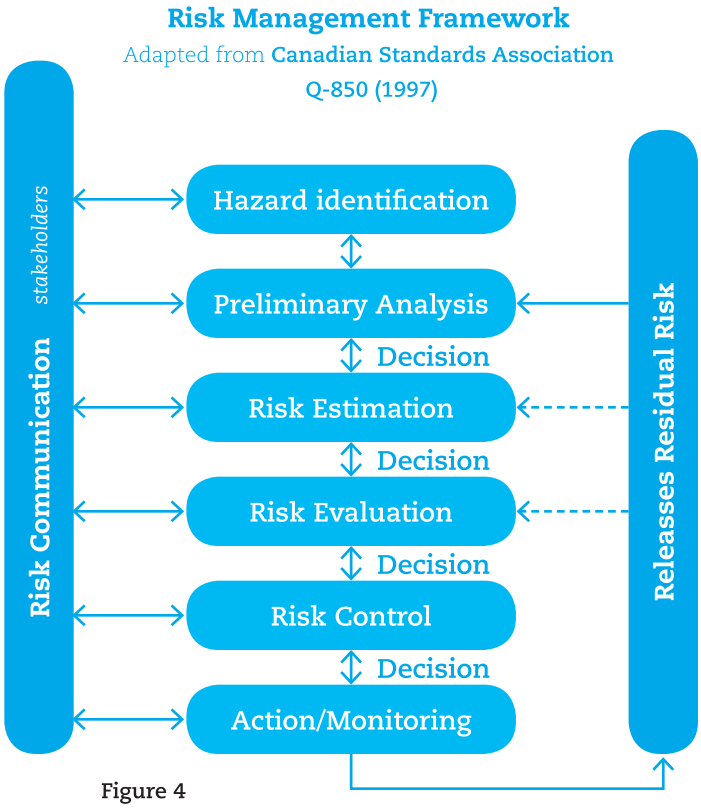

Figure 4

The importance of context in Great Lakes chemical management policy development

Viewing chemical management needs and options within the context of existing regulatory structures, the management actions that are in place and a risk characterization and communication framework will be extremely important as policy makers and government agencies work to implement the provisions of Great Lakes Water Quality Agreement (2012) Annex 3. Nominating, selecting, and managing Chemicals of Mutual Concern will be a challenge for the region that can only be successful through understanding and application of all of these elements.

I Myth Versus Fact About Chemical in Commerce, Society of Chemical Manufacturers and Affiliates,
http://www.socma.com/GovernmentRelations/index.cfm?subSec=26&articleID=3259
II U.S. EPA 2006 Inventory Update Reporting Summary,
http://www.epa.gov/cdr/pubs/2006_data_summary.pdf
III National Pollution Prevention and Toxics Advisory Committee report, October 6, 2005,
http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf
IV U.S. EPA, 2012 Chemical Data Reporting Rule Summary,
http://www.epa.gov/oppt/cdr/index.html

CGLI Council of GREAT LAKES INDUSTRIES
3600 GREEN COURT, SUITE 710
ANN ARBOR, MI 48105-1570 • USA
TEL: 734-663-1944 • FAX: 734-663-2424 • WEB: WWW.CGLI.ORG