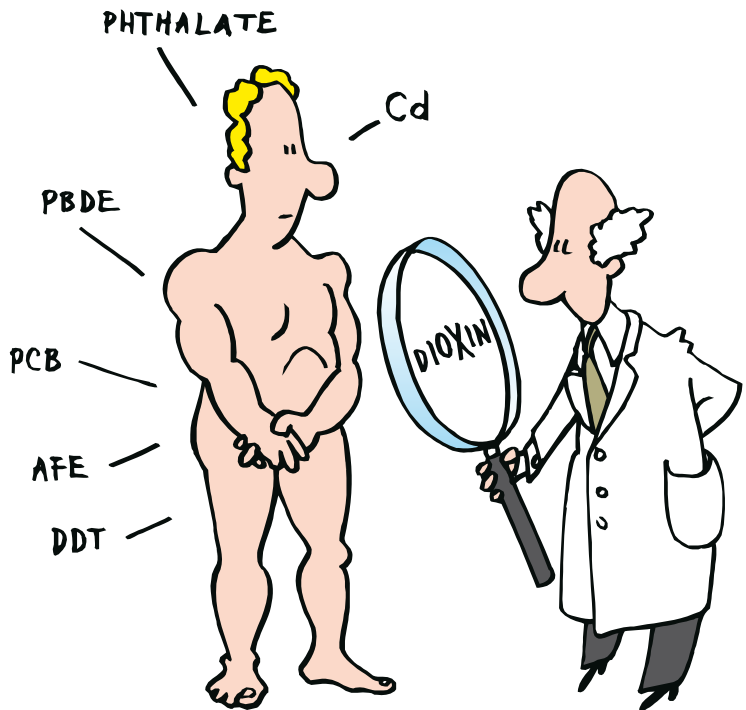


# Toxic Chemicals – WHAT IS THE PROBLEM?



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# Introduction

*Chemicals are immensely useful in our daily life, from medicine to agriculture to construction of homes. Innovations of chemicals have been a key factor of today's welfare in the industrialised world. As a result, the use of chemicals has grown exponentially over the past half century.*

*Unfortunately, this development is not without severe problems. Chemicals pose a major threat to workers' health on many work places. The use of pesticides causes severe poisonings and even deaths in some parts of the world. Chemicals used in consumer products, agriculture, and industry eventually end up in the environment and in the bodies of people and wildlife. Some chemicals persist for long periods in the environment. Others break down rapidly to other molecules with characteristics that differ from the original chemical. Chemicals can interact with each other and with substances that occur naturally in the environment or in our bodies. They can be transported along complicated pathways through the environment.*

*At each stage from manufacture to disposal of a product, chemicals may enter the environment by contaminating air, water, sediments, or soil.<sup>1</sup> Some chemicals can cause illnesses and disabilities in humans and animals.*

*To exemplify with one well known substance: Lead. This heavy metal has been recognized as a poison since the 19th century. By the 1930s, most medical and scientific experts agreed that lead was harmful to both children and adults, although there were still many questions about the exact nature of the damage. Despite this knowledge, lead was used in paint and in gasoline, exposing everyone to this potent toxic chemical. We now know that lead damages the brain, lowering IQ and causing learning disabilities and behavioural problems. Research on exposed children has shown that lead can damage the brain of a fetus, infant or child at extremely low levels.<sup>2</sup> Millions of children have suffered and continue to suffer the consequences of lead exposure.*

# Chemicals in large numbers...

The problem of lead exposure and risk has been scrutinized and researched for decades. Much less is known about other chemicals. Despite our impressive scientific capacity to develop new and useful chemicals, we still lack a good system to ensure that chemicals can be used without harm.

We are constantly being exposed to a large number of chemicals. About 70 000 chemicals are currently in commercial use in the European Union. About 2 500 of them are produced or imported in quantities over 1 000 tonnes per year. Some 30 000 substances are marketed in volumes exceeding 1 tonne per year (per manufacturer).<sup>3</sup> The number of chemical products (mixtures of chemicals) is unknown, but certainly orders of magnitude higher.

## The trespass to humans and wildlife

Tests of human blood and tissues show that people's bodies are contaminated with a range of industrial chemicals. Many of these are known to be harmful. Others have unknown health effects.

Blood from volunteers have been tested in various studies<sup>5</sup>, and shows that each person's blood contains multiple industrial chemicals. In fact, more than 100 such chemicals have been found in people's blood, urine, and body tissues. One study tested chemical levels in the blood of three generations (grandmother, mother, and daughter)



in families from twelve European countries. The study showed significant levels of toxic chemicals in all the study participants. The study also showed that some children had even higher exposures to some chemicals than their parents or grandparents.<sup>6</sup>

Children's exposure to chemicals is a cause for particular concern because they are more vulnerable than adults to the effects of many toxic chemicals. Their greater vulnerability is in part because of their smaller size and different metabolisms. Children breathe more air, drink more water, and eat more food than adults per unit of body weight. Thus, for a given level of contamination, a child's exposure may be greater than an adult's. Children are also at risk because of their habits. Children are more likely to put objects into their mouths, to put their hands in their mouths, and thus ingest contaminants in the environment around them. In addition, children's organ systems are developing rapidly. A small toxic exposure during a critical period of organ development can create life-long, irreversible damage.

Industrial chemicals have also been found in the umbilical cord blood of newborn babies.<sup>7</sup> This means that when a pregnant mother is exposed to a toxic chemical, the developing fetus is likely to be exposed as well. Babies also receive chemicals through breast milk.

### **Some Health and Environmental Effects of Chemicals<sup>8</sup>**

Chemicals can cause a wide range of health problems in people.

Examples include:

- Cancer
- Cardiovascular diseases
- Respiratory diseases
- Allergies and hypersensitivities
- Reproductive disorders
- Developmental disorders
- Nervous system disorders

Chemicals can also cause harm to wildlife. Examples include:

- Eggshell thinning in some bird species
- Reproductive problems in seals, otters, mink, osprey, eagles, and salmon
- Spine malformations in some fish.

**FACT BOX**

# A short history of chemicals management

The history of chemicals risk management contains a significant number of unfortunate failures, well known examples being DDT, PCBs, dioxins, CFCs, lead, cadmium, mercury, and asbestos. In many of these cases, it is easy to see with hindsight that better attention to early warnings, and a more precautionary approach, could have helped to avoid human suffering and environmental damage.

The ambitions to reduce the negative impact of chemicals have gradually increased. In the 1960s, the focus was mainly on adverse effects from pesticides, very much due to the debate following the publication of Rachel Carson's "Silent Spring"<sup>9</sup>, but focus has also turned towards more general rules for chemicals. The first chemicals legislation in the EU, setting rules for classification and labelling of dangerous substances, was adopted in 1967<sup>10</sup>. Legislation has expanded significantly since then, but in an ad-hoc fashion that has left many chemicals unregulated. In 2005, there was still no single, overarching system in EU for ensuring that all chemicals are adequately tested and regulated.

The current system of chemicals regulations in the European Union has three main parts. These are firstly the regulations for new substances, which says that chemicals that are to be introduced on the European market should undergo a notification procedure prior to marketing. The procedure includes requirements that the chemical should be tested to enable a simple risk assessment. The second, the existing substances regulations covers over 100 000 chemicals. These are the chemicals that were available on the EU market before September 1981. The existing chemicals have never been submitted to test requirements, risk assessment or notification. According to the existing substances regulations, they are to be risk assessed one-by-one. The risk assessment process in which the existing substances are to be evaluated has turned out to be slow and resource consuming. Since 1993 draft risk assessments have been presented by the EU for a little over 100 chemicals in total.

A number of wider international initiatives were launched from the late 1960s onwards, such as the International Programme on Chemical Safety, (1980), the first OECD test guidelines (1981), and the OECD existing chemicals program (1987). In 2006, a global strategic approach for international chemicals management (SAICM) was adopted, making it the first global treaty to enhance control of industrial chemicals. SAICM is a follow-up to the UN Earth Summits in Rio de Janeiro and Johannesburg.

# A constant lack of data...

In spite of the growing political interest, we still know very little about the industrial chemicals we use every day in industry and in products. For three out of four high volume chemicals on the market, information is lacking to carry out even a minimal risk assessment (see below).<sup>11</sup> About x thousand of the around seventy thousand chemicals in use have been classified as hazardous by the EU. But the reason is not that the rest are non-hazardous. Studies indicate that the number of classified substances would be much higher, if we only have had the capacity to test them.<sup>12</sup>

The problem is even greater when we take into account that many man-made substances are metabolized in both humans and other organisms. This may result in break down products that are even more toxic than the original compound.

Furthermore, we are almost always exposed to chemicals in combinations. Combinations can in some cases result in toxic effects other than the chemicals would produce individually. Since scientists generally study one chemical at a time, we have even less information on effects of chemicals in combination.



# Getting to know the risks

With all scientific capacity and political will, why is the knowledge about chemical risks still so limited? The answer is found in the intrinsic complexity of health and environment interactions. In order to find solutions to the risk dilemma, we need to look at how risks are estimated today.

## \* RISK ASSESSMENT

A scientific tool called risk assessment has been developed over decades as a basis for decision making. The risk assessment process aims at identifying chemicals of concern to human health and the environment, in order to take actions to reduce potential risks. The method relies on scientific data on exposure and effects. Absence of such data makes it impossible to calculate chemical risks.

### FACT BOX

#### Risk Assessment

A risk assessment is only possible if scientific data is available about the substance. Such data is obtained through laboratory experiments and, in some cases, epidemiology or field studies. When data is available, risk assessment is usually performed through an evaluation of available data in four steps:

1. Hazard identification is the effort to determine the inherent ability of a substance to cause harm. (Such knowledge is usually obtained from animal experiments.)
2. The dose-response assessment describes the relationship between the level of exposure and the response of the exposed animals (or humans).
3. Exposure assessment aims to determine the likelihood and the extent of exposure to humans or animals.
4. Finally, in risk characterization, information gathered in steps 1 to 3 is used to assess whether actual levels of exposure are likely to cause harm. If actual exposures exceed the levels known to cause adverse effects in the laboratory, then the chemical is considered to be “of concern”. The appropriate “margin of safety” is determined on a case-by-case basis.

Risk assessment (RA) represents a well established and commonly used method to estimate health or environmental risks from chemical uses. But it is important to note that RA falls short of giving all answers that are necessary to reduce risks from chemicals. This means that risk assessment has several important limitations when it is used as a basis for policy making. Let's have a look at some of these limitations:

Performing a proper RA requires extensive and detailed knowledge about both exposures and effects. This type of knowledge is very seldom readily available. We then depend either or both of the following:

- I **Finding out what possible damage has already occurred from the use of a chemical – i.e. looking at “real life” data.**
- II **Conducting laboratory tests to check if the chemical will cause an effect, and how much of the chemical is needed to for the effect to appear.**

#### \* USING “REAL LIFE DATA” TO CALCULATE RISKS

Harmful effects of chemicals can be estimated by gathering information about humans that have been exposed to a certain chemical, a scientific method called epidemiology. The advantage of using “real life data” in risk assessment is that the size and nature of exposure are directly relevant to the assessment of human risk.<sup>13</sup> Therefore, epidemiology provides important contributions to a health risk assessment and such data are usually given much weight in the risk assessment process.

But there is grave disadvantage: epidemiological data become available only after humans have been exposed and often injured due to chemicals. And as real life situations also include a multitude of other influences beside of the chemical that is studied (for instance a myriad of other exposures, genetic aspects, human behaviour and life-style factors!), it remains difficult to establish a link between the exposure to a single chemical and its effects. As a consequence, even very large risks can remain undetected in epidemiology.

#### \* USING ANIMAL TEST DATA FOR HUMAN EFFECTS

Because of these and other problems to carry out epidemiology studies, workable “real life” human data are only likely for a very limited number of substances. Instead, we are most often forced to use data from animal experiments.

It is widely accepted that effects seen in animal studies are relevant to assess the risk to humans.<sup>14</sup> This assumption is scientifically valid since extensive experience shows

that substances known to cause diseases in humans also, in the vast majority of cases, cause similar diseases in experimental animals. Furthermore, commonly used laboratory animals are similar, in biochemical and physiological respects, to humans and many other animal species. But in some cases there may be significant differences between, for instance, how a mouse and a human being react to a specific chemical.

#### \* **DANGER OF NOT DETECTING AN INCREASED RISK**

The chance that a scientific study will detect a harmful effect depends on numerous factors, such as the scale of the risk. If a chemical increases the risk of an illness with only a fraction of a percent, the consequence can still be very significant if the exposure is widespread. For instance, if one million people get exposed to a chemical, e.g. through a consumer product, and the increased risk from the exposure gives rise to cancer in one out of 10 000 (0,01 %), the consequence would be 100 new cancer incidents.

Yet, animal studies and epidemiology generally fail to detect such a risk. As a rough rule, for an effect to be discovered in animal studies the added risk must be larger than 10 percent. In addition, many epidemiology studies also fail to detect excess risks much higher than 10 percent.

An example from epidemiology is a study on human cancer risk from acrylamide exposure via food.<sup>15</sup> This study included 987 humans with cancer, and about half as many healthy controls. The study found no link between exposure and incidences of four types of cancer. But a succeeding analysis of the study by other researchers showed that to enable detection of an effect at the size expected would have required a study of 470 000 humans with cancer and 235 000 healthy controls.<sup>16</sup>

In comparison, the maximum number of animals in standardized tests is one hundred per group. To enable detection of adverse effects in such small groups it is common practice to increase the dose levels. Therefore, toxicity data is in many cases obtained from exposures that are higher than what is directly relevant to humans. Unfortunately this practice gives rise to new problems. Effects at high doses can be disproportionate, and also qualitatively different, from effects seen at low dose exposure. In risk assessment higher weight is usually assigned to effects seen at doses close to the exposure levels relevant to humans, but it is generally assumed that effects seen also at higher doses are relevant to risk assessment in the absence of evidence to the contrary.

## \* NON-ANIMAL TESTS – A SOLUTION?

Non-animal test models usually comprise organ- or cell cultures (mammalian, bacteria, or yeast cells are commonly used) that are exposed to the (potentially) toxic chemical under laboratory conditions. One advantage of using organ- or cell cultures is of course that animals are not needed – beneficial not least from an ethical point of view. Another advantage is the reduction of costs (which also means that more chemicals can be tested). Furthermore, they are powerful tools in providing detailed information about biological mechanisms of toxicity, for instance whether a chemical molecule can cross the cell membrane, or whether it will interact with structures on the cell surface or within the cell (such as bind to a receptor or interact with other large molecules like proteins or DNA).

However, cells in a test-tube constitutes only a vague replica of an intact body, with its many organs and processes (metabolism and organ repair mechanisms) interacting in a complex fashion. Non-animal models provide insights about how a chemical molecule can interact with biological material, but it can not answer the question of what (if any) adverse effect will manifest in an intact animal. Non-animal models can therefore not replace animal testing, but must supplement it.

This is also reflected in the regulatory system. Data from cell cultures are currently not sufficient for performing a hazard assessment according to the European classification and labelling directive.<sup>17</sup>

## Problems interpreting data

For ethical and other reasons we do not perform large scale environmental experiments and toxicity experiments on humans. Laboratory experiments on animals, bacteria, etc are used as substitutes. Effects seen in animals under laboratory conditions are translated to human health risk or to risks to the entire ecosystem. But there are, as we have seen, important limitations. Even for the most well-examined substances significant uncertainty remains about their effects on human health or in the environment.

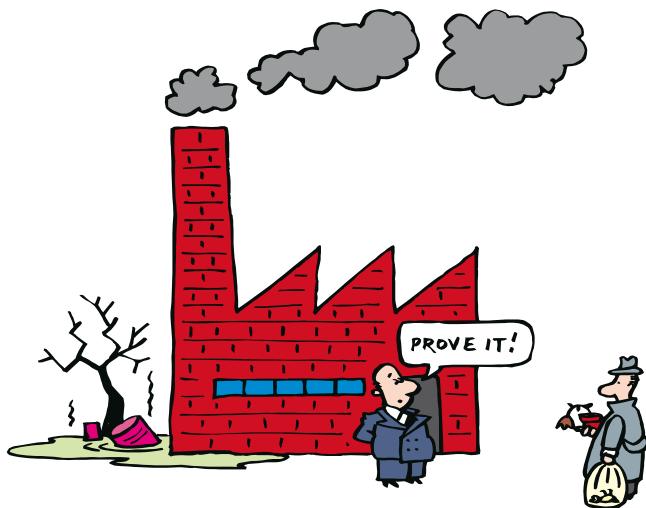
But also in cases where we have “sufficient” information, scientific controversies often occur around how to interpret the information. Let us use trichloroethylene (TCE) as an example. TCE is a widely used industrial solvent. We know a good deal about its toxicity compared with most industrial chemicals. At least fourteen long-term experiments have investigated TCE’s ability to cause cancer in animals. There have also been at least eight high quality epidemiological studies on the substance looking at humans effects. A number of these studies have suggested that TCE can cause cancer,

especially in the liver and kidney. But risk assessors continue to disagree about the level of risk that the chemical poses. Thirty different risk assessments have been conducted for TCE, but they have not produced a consensus on the relationship between TCE exposure and cancer.<sup>18</sup>

The differences between the TCE risk assessors included what types of data and how much data are needed to consider an effect proven, and the assumptions made regarding the nature and extent of human exposures.

## Who has the burden of proof?–

The current laws put almost all burden of proof on authorities and individuals when it comes to demonstrating harm from chemicals. With the exception of a few groups, such as pharmaceuticals, pesticides and food additives, manufacturers have the right to continue to produce and market chemicals without investigating risks or finding alternatives. As we shall see, it is a very costly and time consuming task to research health and environmental effects of chemicals. And since society has only capability to carry out risk assessments for a tiny portion of all chemicals in use, the production and sales of thousands of substances continue without market or legal consequences. Even in cases where a substance is strongly suspected of causing harm, investigations normally continue for many years, often without any preventative action. Only when the link between the substance and effect has been scientifically established, can measures usually be enforced against the use.



# Lessons to be learned

There are many lessons to be learned from past decades of chemical management. Animal data and epidemiology are important sources of information to risk assessment. But the data on which we base risk assessments will always be subject to scientific uncertainty due to practical reasons (we cannot perform animal studies using billions of mice, and we cannot perform large scale experiments on humans). Any extrapolation of data may under- or overestimate actual risks.

It is also clear that increasing the number of laboratory tests won't solve the problem. Under the existing substances regulation, the burden is on government agencies to perform risk analyses of chemicals currently on the market to determine whether they are harming people and the environment. This occurs through risk assessment, which is often hampered by incomplete data. As a result, very few chemicals have been assessed fully for the risks they may pose.

Since 1994, the European Commission has drawn up lists of 141 priority chemicals to be assessed first for human health and environmental effects, from among the tens of thousands of chemicals that have not been adequately tested or assessed. As of 2005, the risk assessment and recommendation process has been completed for just 28 of these chemicals!<sup>19</sup> In other words, of around 70,000 chemicals that need to be assessed, risk analyses have been completed at a rate of fewer than three per year. At this rate, it would take more than 20,000 years to complete the process for the chemicals currently on the market!



While the nuances of the risk assessments are debated, chemicals are treated as though they were safe. At this rate, millions of people can be – and are – exposed to harmful chemicals over a period of years or decades, while the studies are being completed.

The central questions are therefore: How much evidence do we need in order to classify a chemical or an exposure as harmful? In particular, how much evidence do we need to warn people that a chemical might be dangerous to their health? How much do we need to know to limit exposures? And how much data – and what type of results – are needed to ban the use of a chemical? These are policy questions rather than scientific questions, i.e. they cannot readily be solved by just another toxicity study. They concern where to put the burden of proof, and what degree of caution is desired. There is no consensus about what constitutes an appropriate answer to them.<sup>20</sup>

## *How much evidence do we need to warn people that a chemical might be dangerous to their health?*

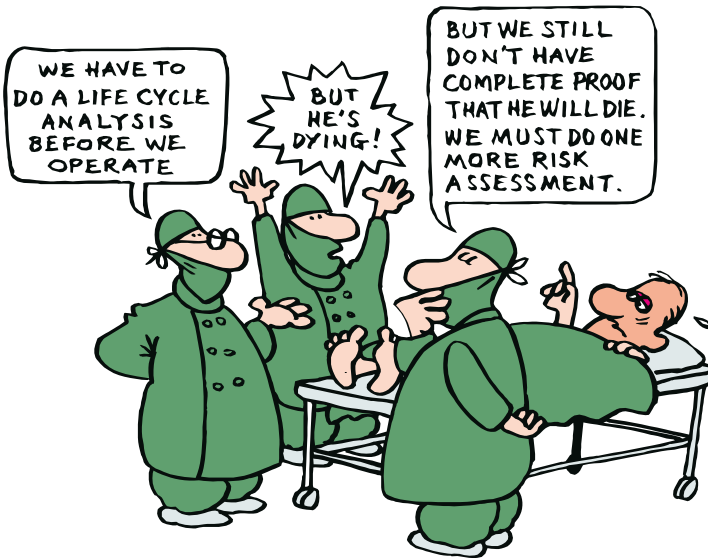
### **Health and economic costs of inaction**

To postpone action against a substance that causes harm does not only lead to human suffering, illness and even death. It also creates large economic costs. The costs of treating environmentally-induced illnesses deplete the resources of individual families and can strain the capacity of government agencies that provide health and social services. And when fetal, infant, or childhood exposure to toxic chemicals impairs the ability of children to learn and develop normally, the long-term costs to an economy can be very significant.

The health and environmental benefits of safer chemicals management have also economic implications. For example, major economic savings are expected from the European Union's proposed new chemicals policy, REACH. A recent study estimated that REACH could produce economic gains worth up to €4.8 billion annually by 2017, and up to €95 billion over the following 25 years. In contrast, the total cost of implementing REACH is estimated at no more than €5 billion spread over eleven to fifteen years.<sup>21</sup>

The dilemma we confront in the field of chemical exposure can be described as follows:

Imagine that you are a medical doctor responsible for the health of a patient in severe crisis. Standing in front of the severely ill patient, would you just wait for a thorough examination that could take place during the coming week, or would you quickly act with precautionary measures until you have that information you need? Try to take best possible measures to reduce the risks while there is uncertainty?



# Finding solutions

How can we develop a system that effectively protects human health and the environment?

We need to develop the procedures for risk assessment to meet the need for handling scientific uncertainty. The decision makers in the field of public health need to be aware of the level of evidence<sup>22</sup> in order to determine the degree of precaution needed. Generally speaking, risk assessors should provide decision-makers with the information they need to make their decisions according to the precautionary criteria they have chosen.

We need to generate more knowledge about the industrial chemicals in commercial use. The proposed new REACH system in Europe aims at substantially increasing the knowledge on which chemicals risk management is based.<sup>23</sup> Clearly the enormous knowledge gap that we are facing cannot be filled in one step. Since it will take long time to fill it, it is essential to collect the most important data for the most important chemicals first. In other words, priority setting for data acquisition is of major strategic importance. Furthermore incentives should be created so that data beyond what is required by the legislation is also generated. Companies that produce and sell chemicals should be required to show that their products meet reasonable safety standards before selling them.

We need to simplify the regulatory process to ensure that scientific data can effectively lead to actions that reduce risk when such measures are considered necessary.

*"Given our understanding of the way chemicals interact with the environment, we are running a gigantic experiment with humans and all other things living."*

*– Sir Tom Blundell, Chairman, UK Royal Commission (June 2003)*

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Industrial chemicals assist our daily life in countless ways, and the use of them has therefore grown dramatically over the last sixty years. Unfortunately, they also present environmental challenges. Some of these chemicals last in nature for a long time and can build up in humans and wildlife. As a consequence, they potentially pose a significant threat to both health and ecosystems.

Despite the impressive scientific capacity in the world, the knowledge about the tens of thousands of industrial chemicals in commerce is still very limited. In most cases we lack even basic information about the hazards and risks, and no comprehensive system is in place to ensure protection from harm. At the same time, unexpected health and environmental effects are frequently reported.

What we need is a science-based system for chemicals control that efficiently identifies chemicals of concern, and also enables us to take prompt action to reduce these risks. A key in a new strategy is the precautionary principle, which urges us to take early actions to prevent harmful effects even when relations between cause and effect are not fully scientifically proven.

*Produced in cooperation between the Swedish research programme NewS (A New Strategy for Risk Assessment and management of chemicals) and the International Chemical Secretariat.*

*NewS consists of eleven research projects that propose a new strategy for coping with potential unwanted adverse effects to human health and to the environment from exposure to chemical substances. Science-based precaution is a key term in the new strategy, and so is simplified risk assessment.*

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A new strategy for risk  
assessment and management  
of chemicals

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