Comment on *Risk versus Hazard – How to Regulate in the 21st Century*

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Introduction

The debate as to whether chemicals should be regulated according to hazard or risk is once again under the spotlight, this time commented by Ragnar Lofstedt, PhD, Professor and Director of the Kings Centre for Risk Management at Kings College in London. He takes the reader through the history of risk assessment and chemical control, presents two interesting current case studies and sheds light on the influence of politics on the implementation of regulation.

Professor Lofstedt's assumption that two different methods of assessment exist is not a complete statement. In fact this is a confusing way to describe the scientific and political processes involved in regulation. It is not a choice between two methods, but rather a balance between political ambition and scientific facts within one method. Examples can be found where science has been more influential than policy on the actual regulatory decision, and vice versa.

Underpinning the discussion in this article on risk vs hazard is a claim that hazard assessment is not based on science, in a context where the scientific basis for risk assessment is taken for granted. This is an unfortunate statement which is not in line with the current work on assessment in chemical control.

A loaded question

"How am I to get in?" asked Alice again, in a louder tone. *"Are* you to get in at all?" said the Footman. "That's the first question, you know."

Borrowing this quote from Lewis Carroll's book *Alice's Adventures in Wonderland*, I would like to draw a paralell with the debate on risk vs hazard. When the question "Regulate on the basis of hazard or risk?" – is spelled out the way Professor Lofstedt does in his article, the first question is:

– "Are there two different methods to choose between?"

As I see it, after almost a decade in chemical regulation, there is no such choice. The regulatory processes I have been involved in were all based on risk assessments where the hazard was the trigger or the starting point of the process. The list of chemicals which have been subjected to risk assessment of this kind is long: DEHP, HBCDD, TBBPA, Pb, Cd, Hg, PFOA, PFOS, MCCP, DekaBDE, NFE, BPA and others.

In addition to my experience that the implementation of chemical regulation is always based on one method, namely risk assessment founded on scientific hazard data, risk assessment is often allowed to take up a lot of resources and time. The risk assessment process on DEHP was ongoing at the time when I started my period as Director-General at the Swedish Chemicals Agency KEMI in 2001. When I left nine years later it was still an open process. If the Reach Regulation had not come into force, my guess would be that the process would still be running today. Fortunately, the taxpayers of Europe will be happy to learn that a decision was taken earlier this year that put an end to this costly process. It would also be interesting to see how much more new scientific data was produced during this fifteen-year-long risk assessment. No wonder that , introducing the White Paper on the Reach Regulation one of Commissioner Margot Wallström's arguments, was that the existing regulation did not work. It had succeeded in regulating 10 chemicals in 11 years, or was it the other way around? DEHP alone took more than 15 years.

Why this debate on risk vs hazard?

One of the main reasons for this lengthy debate is the fact that we have had a slack and easygoing regulation in force during a period when a hundred thousand new chemicals arrived on the market, with little or no knowledge of the risks and hazards of expo-

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sure. This has created a political headache now that the flow of scientific studies has slowly put the jigsaw puzzle together, revealing that we are all heavily exposed to hazardous chemicals in our daily life.

Professor Lofstedt describes Sweden as a country with a strong position on phasing out chemicals, saying that it can afford to do so as there is no chemical industry there. His definition of "chemical industry" may of course be queried.

Last year the Swedish Chemicals Agency published a report (KEMI Report 2/2010) "The Chemical industry from an economic perspective". The report describes how the chemical industry has expanded rapidly throughout the 20th century and is today a major industry in Sweden. The economic turnover and profitability of the Swedish chemical industry have developed rapidly in recent years. The chemical industry is the fifth largest industrial sector in Sweden and contributes just over 12 % of economic turnover in Swedish industry.

Most of the activity takes place in companies that form part of international groups. Profitability is high, particularly in the pharmaceutical industry. There are, however, large differences between various subindustries and companies.

The number of substances that are produced or imported into Sweden has increased, and so has the total volume (although to a lesser extent). The situation for chemical products sold in Sweden is that the number of products has increased.

Another perspective on the author's statement that Sweden can afford to phase out hazardous chemicals because there is no chemical industry in the country is the size of the costs for the demands that have been placed on the chemical industry up until now. Based on data from the Swedish Agency for Economic and Regional Growth and consulting the Statistics Sweden, it has been calculated that the costs of chemical control regulation came to about 0.2 % of the turnover of the chemical industry.

The statement in Professor Lofstedt's article that it is easy for a country to take strong anti-chemical positions as there are no economic consequences for its domestic market can be discussed further.

Member State babies and political influence

Professor Lofstedt paints an entertaining picture of the cultural and national differences in priorities within Europe. In the days when the Swedish government was negotiating to become a member of the European Union, one of the delegates sighed heavily when he found himself arguing for the activities that our country did not want to give up. Among these were "bestial" hunting methods, the taking of snuff and other quite unbecoming customs.

In the same context we are given a number of other examples of the differences in worries and concerns. The example of dioxins in Baltic fish has caused a lot of confusion. I used to meet it often as an opening remark in meetings with Commission representatives when we were about to discuss regulation of chemicals.

In our part of the world we have placed legislation, such as regulations on chemicals, in the hands of politicians. We elect them. And as we like to keep and defend our democratic society, I believe we have to accept the fact that our politicians may, can and indeed do have an influence on the decision-making concerning regulations. So the fact that decisions based on a risk assessment may allow room for political influence seems to be quite in order. I do not see any reason why this part of our society should be drawn into a political vacuum.

Lobbying would never have been invented if there had been no political influence on the making of decisions. Presenting possible or probable consequences to politicians before a decision is made is, in my experience, a most valuable activity. A lot of mistakes have been avoided due to lobbying. Thanks to lobbying, politicians are better informed at the moment when they have to vote in the chamber.

But the idea expressed by Professor Lofstedt in the case studies that non-commercial organisations actually outweigh the chemical industry in their campaigns seems rather unrealistic to me. He explains that the bans on Deca-BDE and BPA were to some extent optional due to the campaigns of the International Chemical Secretariat. One can wonder when these bans would have been effected if there had been no lobbying from industry.

A quick examination of the differences in size of the campaign budgets of ChemSec and Cefic leads me to doubt that argument.

Stigmatisation of products

The problematic scenario with the stigmatisation of products is set out by Professor Lofstedt in consider-

able detail. This is an area that would benefit from more reflection. More than once I have seen CEOs in the chemical industry bringup this issue. I have met honest frustration and confusion. They focus on risk management. They are sincerely engaged in minimizing risk, and are confused by the fact that chemicals and the chemical industry are often mistrusted.

Having spent quite a few years in the food industry, I am tempted to compare both of them. In the 1980s, there were several major food scams. Professor Lofstedt cites the experience of BSE in meat production, giving himself as an example. Before the BSE scare other types of problems or scandals also occurred. But in those days the arguments within the food industry usually ended with statements to the effect that consumers had overreacted or were badly or misinformed.

In my experience this conclusion is seldom very productive. It creates a situation where dialogue is cut off. Where both sides confirm within the group that the other side is off the track. I get flashbacks when talking to chemical industry CEOs today. The arguments today are the same as those in the food industry before BSE.

The difference BSE made was to force the food industry to listen and to show more respect to consumers. They were no longer just misinformed and misled. From that time on they were entitled to ask questions, to get relevant information and to be properly informed about hazards and risks.

Information on chemicals

On all food products the regulation is that all ingredients must be listed on the package, except for ingredients in minute quantities. I know that not all consumers read this information, but if that were an argument to withdraw the regulation, most consumers would react. The list of ingredients presents vital information to consumers with allergies and to those who are on special diets. But for many more consumers this listing stands for transparency and openness.

The same concept could be applied to listing chemicals in articles. This would present a lot of difficulties. But those difficulties have already been dealt with in the regulation for food labelling. A large number of chemicals could be listed in one article, but they could be named as compounds, just as in the food labelling regulation. The names of the chemicals are long, hard to read and understand, in the same way as food additives. Therefore a system has been worked out with E-numbers. A full catalogue is available where anybody who is interested can learn more about these ingredients.

If the chemical industry is worried about the stigmatisation of products, it might be better for them if they discouraged members of the public from informing themselves. I believe this piece advice from Professor Lofstedt is extremely dubious.

Instead, it would be better to try for more openness. If the experience in the chemical industry today is that public mistrusts it, it will not be successful in campaigning further with authority and a sense of guidance. Indeed, with the current world-wide development of social media where authorities are openly and briskly criticised, it is bound to fail.

Chemicals are vital to our beloved lifestyle. My iPod, my laptop and my car are very dear to me. I could not enjoy any of that if it was not for the chemical industry. There is lot of consumer ground for creating loyalty. But that process is hindered by a common feeling that industry is "covering up". Open up instead!