

How Chemicals Are Regulated in the European Union: A Commentary

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Introduction

Professor Ragnar Lofstedt has written a very interesting and thought provoking paper “Risk versus Hazard Assessment – How to Regulate in the 21st Century”. The paper reflects upon the advantages and disadvantages of using risk assessments compared to hazard assessments of chemical compounds. It investigates the debate that has been going on in recent years in Europe between regulators, politicians, NGOs and industry on the subject.

This commentary will discuss some of the assumptions that the analysis rests on as well as some of the conclusions that are presented in the paper.

First, the commentary will discuss the definition and critique of the “risk assessment” approach that Lofstedt presents. The commentary here concludes that Lofstedt’s analysis of risk assessment does not take sufficiently into account the fact that risks can not always be calculated in an exact way because uncertainty rather than certainty is the condition when analysing chemicals.

Secondly, the commentary addresses Lofstedt’s view on democracy and regulation. The commentary here questions Lofstedt’s assumption that divergent interests and views are a problem for the EU regulation. Divergent interest should rather be seen as a key feature of democracy.

Thirdly, the commentary discusses the assumptions that Lofstedt makes about the incentives and interests that politicians and businesses have for influencing the European regulation. Here the commentary concludes that Lofstedt’s sceptic view on politicians’ motives is somewhat contradictory to his positive view on the industry’s motives.

Finally, the commentary will sum up and conclude on the points presented.

Risk assessments, the condition of uncertainty and the precautionary principle

Lofstedt gives a good overview over the key features as well as the upsides and downsides to risk assessments and hazard assessments. However, his paper can be criticized for not taking the condition of uncertainty into account when analysing risk assessments.

Lofstedt describes risk assessment as based on the probability that a chemical substance will cause harm to humans or the environment when it is used. Hazard assessments, on the other hand, focus on the properties of a chemical. The question of this assessment is whether the chemical has the potential to cause an adverse or harmful effect.

According to Lofstedt, hazard assessments suffer from the fact that they are not as scientific as risk assessments (pp. 153–154). Hazard assessments can therefore be criticized for being unscientific because they only take into account the properties of a given chemical and not the actual risk that it poses to humans and the environment. On the other hand, risk assessments – which according to Lofstedt are more scientific than hazard assessments – also have their downsides. Among other things they are more expensive and take longer time to implement than hazard assessments (p. 154).

Lofstedt states clearly that the basis of a risk assessment is the probability (p. 149) that a substance will cause harm. However, he does not engage with the crucial criticism that the probability is not always known. This is fundamental because knowing the probability is the basis for any risk analysis.

Lofstedt does not take sufficiently into account that the main problem with risk assessments is the fact that in many cases the risks are not known. Often reality is so complex – or the substances assessed are so new – that uncertainty is the general condition. But risk assessments are based on the condition of certainty. It is assumed that the risk can be calcu-

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lated in an exact way. Regretfully, this is far from always being the case.

The precautionary principle – which is incorporated in much of the ENVI-legislation today – builds on this very acknowledgement that uncertainty is the general condition. Therefore – the principle says – decision-makers should act even before we have scientific certainty in order to prevent harm to humans and the environment. Under the condition of uncertainty it is not possible to assign probabilities to different outcomes/scenarios. Thus risk assessments in many cases give false promises concerning our ability to calculate and control the risk.

This is often the case in the field of chemical (environmental) legislation where one must take into account such well known phenomena as cocktail effects and bioaccumulative long-term effects.

Cocktail effects are the result of the mix of many different substances in one product. The risk assessments, however, are only conducted on one substance at the time and do not take cocktail effects into consideration. Hence, all the probabilities are not in any way known.

Bioaccumulative long-term effects are far from always being taken into consideration in the risk assessment either. Bioaccumulation is the process where the concentration of a chemical in a biological organism increases over time compared to the surrounding environment. The risk assessments, however, often only take short-term effects into consideration. Especially in the field of chemical legislation it is the long-term effects that can have very severe consequences. A good example is, in fact, Deca-BDE which is toxic on the long term and bioaccumulative. It has earlier been claimed that Deca-BDE was not bioaccumulative but now it appears to be so.

Risk assessments thus have a number of inbuilt flaws that should be taken into consideration in a discussion of risk vs. hazard assessments.

Divergent viewpoints and the condition of democracy

Lofstedt analyses the dilemmas that come from divergent interests in different parts of the political system. According to Lofstedt, this leads to problematic regulation. This assumption can be questioned, as divergent interests are and always will be a basic condition of democracy.

A main argument in Lofstedt's paper is that divergent views are a challenge/weakness for EU legislation. Lofstedt stresses, for instance, that not everyone supports the ban of Deca-BDE and BPA. He also argues that the divergence in interests and motives from different players leads to problematic regulation: *"UK authorities, for example, worry about fires while Swedish policy makers are concerned by man-made chemicals. What are the reasons for these differentiating cultural views on regulations, and what are the consequences of them? Is more dialogue between regulators and policy makers needed?"* (p. 161)

The assumption that lies beneath this argument can be questioned. Arguing that it is a problem or a weakness for a political system that not everyone agrees about the same policy or regulation is close to putting a question mark up behind the very concept of democracy.

One could also ask: if everyone always agreed on the same policy why would we need democracy in the first place? Democracy is based on the idea that incorporating different viewpoints and ideas in the policies conducted is actually an advantage rather than a downside.

It is a necessity that the EU legislation reconciles different interests and viewpoints. The alternative would be to listen only to some stakeholders and ignore the rest. This would neither be a desired nor a realistic solution. But, given the fact that not everyone agrees, the majority has to take a decision. That is the way democratic systems work, and therefore it cannot be described as a downside that "only" a majority supports a given policy, as it was the case with the ban of the brominated flame retardant Deca-BDE and Bisphenol A (BPA).

Interests of politicians and business

Lofstedt makes various questionable assumptions (explicit or implicit) about the motives of different actors operating in the political system. First, Lofstedt assumes that the politicians supporting hazard assessment in his case studies are doing so for somewhat populist reasons. But where is the evidence for substantiating such a claim? Secondly, he seems to have perhaps a little too much faith in the good and altruistic intentions of the industry.

Lofstedt concludes that "Scandinavian" politicians from both the left and the extreme right are in fa-

vour of banning certain chemical substances (hazard assessment) because of populist reasons as they are trying to win domestic audiences (p. 161). Lofstedt uses his case studies of the regulation of BPA and Deca-BDE to show this.

Lofstedt points to the fact that investigations have shown that the risks involved with these substances are not high (pp. 156, 159). He thereafter blames the “Scandinavian flavour” (p. 160) for the ban of Deca-BDE and BPA. He points out that Danish and Swedish politicians went for a ban because of what can be described as vote maximizing motives:

“... the Swedish socialist MEP, Asa Westlund, argued as part of her re-election campaign that she was helping the Swedes from being inundated by dangerous chemicals by her political efforts in the European Parliament ...” (p. 161)

This postulate is, however, never supported by any evidence. The logic seems to be that every time a politician draws attention to a policy or a point of view in his or her election campaign, then he or she does it out of populist reasons. This is clearly not always the case. In the cases analysed by Lofstedt it could be that the politicians agreed with the logic behind the precautionary principle for the reasons pointed out in part 1 of this commentary. This explanation is not taken into account. Instead, the politicians who support a ban of the substances are described as trying to “gain domestic ‘green’ credentials” (p. 162), or to “win green credit” (p. 161).

The “populist” argument is not being used when talking about the actors who support a risk assessment approach. Rather, it seems that anyone who agrees with Lofstedt and believes that the risk-assessment-approach is to be preferred (eg. the industry, see below) does so out of rational and scientific reasons. And everyone who supports a hazard assessment-approach and thereby disagrees with Lofstedt is, on the other hand, motivated by populist intentions trying to maximize votes. This way of arguing is more of a political point of view than it is a scientific argument.

It seems self-contradictory one the one hand to have such a sceptic view on politicians’ motives and on the other hand to regret that the industry’s point of view is being disregarded as what “low trust bodies”.

“... policies and scientific arguments put forward by “low-trust” bodies, such as the chemical industry and

its consultants, even though they may be based on stronger scientific evidence than those made by the Scandinavian regulators, are increasingly being questioned by stakeholders, academics and other bodies...” (pp. 161–162).

But it is nevertheless a fact that industry does have a huge economic interest in the EU legislation on chemicals. This should not be ignored. Therefore, it is also of crucial interest to the industry which kind of method (risk assessment or hazard assessment) is used to assess chemicals.

When Adam Smith wrote “The Wealth of Nations” in 1776 he knew that the rational self interest of businesses was the very driver of economic development. Later – in the last century – Milton Friedman told us that “the business of business is business”. Lofstedt’s paper does not take these viewpoints into due account. Rather, Lofstedt is close to arguing that business’ main goal is not making good business but, rather, enlightening the general public about the laws of chemistry. This, however, is highly doubtful.

Conclusion

This commentary has tried to highlight three problems linked to the assumptions that Lofstedt bases his paper on.

First of all, Lofstedt does not take sufficiently into account the condition of uncertainty when analysing the upsides and downsides of risk assessment. We cannot always know how big the risk of a given scenario is, and therefore decision-makers must sometimes act in accordance with the precautionary principle, that is before science make its conclusions.

Secondly, Lofstedt points out that it entails a weakness for the EU legislation that it is influenced by divergent interests and viewpoints. It is, however, hard to imagine a democratic political system that does not take divergent interests and viewpoints into account. Therefore this argument seems problematic.

Thirdly, the paper, on the one hand, describes politicians who favour hazard assessments as populists. On the other hand, it analyses the industry without taking into account the economic interests it has in the chemical legislation. The very sceptic view on the politicians’ motives does not correspond with the very positive/uncritical view on the industry.