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Commentary: The substitution principle in chemical regulation: a constructive critique by Ragnar Löfstedt

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Introduction

Ragnar Löfstedt, in his article about the consequences of the substitution principle in chemical regulation, adopts a critical perspective, but the question is whether it is critical enough. Löfstedt outlines the history, definitions, and pros and cons, as well as contemporary implementations of the principle, particularly in Europe, and presents three cases—the phasing out of lead solders in electronics; the transition from bleached to chlorine-free pulp; and the ban on bisphenol A (BPA) in baby bottles—showing that the substitution principle has not always has the regulator's intended effect. He argues that one of the main challenges of the substitution principle is that thus far it has been based on hazard categorizations (the potential for something to cause harm) rather than risk assessments (the combination of the likelihood of causing harm and the severity of any harm done), and he expresses concern at the consequences, for example, of the BPA case, where a substance was banned without the alternative substances being properly investigated—the result being fewer evidence-based decisions. Löfstedt gives a number of recommendations aimed at developing evidence-based substitution—substitution should be based on risk assessment; risk–risk trade-offs should be included in risk management decisions; a research programme should be initiated; and policymakers should better educated concerning what can be achieved by substitution in order to avoid being influenced by the media and public opinion—and he concludes by arguing that the substitution principle is an under-researched and imprecise regulatory tool, which, much like the precautionary principle, the wider academic community ought to investigate and scrutinize further.

While unable to do full justice to Löfstedt's article here, I have chosen to concentrate on the two critical issues I find particularly interesting. The first is his discussion of whether the

substitution principle should be based on hazard categorizations or risk assessments, and how this relates to the role of knowledge in contemporary society. The latter point leads me to the second, closely related, issue: the potential controversy between actors involved in the regulation process, and the consequences it can have for risk management and the regulation of chemicals. However, first of all, I would like to stress that Löfstedt's contribution is very important, for it sheds light on a highly topical and significant, yet not much explored, field of risk policy. Annie Lööf, leader of the Centre Party in Sweden, referred in a speech on 6 July 2013 to the ban on BPA in baby bottles, saying, 'This will not do. One of the top priorities of environmental politics in the future will be to ensure that the chemicals we use do not harm people or the environment. We need a non-toxic life' (translation by the author); proof, if proof were needed, of how high on the political agenda chemical hazards are in one of the European countries most active on the issue.

Hazard-based or risk-based substitution—a matter of controversy?

Löfstedt points out that the substitution principle is often based on hazard categorization, which can lead to risk–risk trade-offs, where one hazard is replaced by an equally serious, or worse, hazard, resulting in unintended socio-economic costs. Under such circumstances it would be far better if substitution were based on risk assessments. Generally speaking, much emphasis is put on the distinction between a hazard and a risk in chemicals regulation (Hansson et al. 2011; Molander and Rudén 2012), and I would agree with Löfstedt: risk assessment is important, not least to avoid risk–risk trade-offs. However, risk assessment is sometimes just as problematic as hazard categorization. First of all, a risk assessment depends on available data, which means historical or experimental data. The collection of existing data can be time-consuming, and if data are limited, contradictory, or simply unavailable, the risk assessment is difficult or even impossible to conduct. Furthermore, where such problems exist, the process of doing a risk assessment will be a lengthy one, as will the substitution process itself—something Löfstedt also stresses as a drawback of the substitution principle.

Furthermore, in accordance with Löfstedt's suggestion of the need for more research in this area, the perspective needs to be broadened to include consideration not only of the kind of evidence that would be produced in the course of substitution, but also how evidence and knowledge are gathered and used by different actors in the regulation process. Like evidence,

knowledge of hazards and risks is fluid both spatially and temporally, as it depends on the particular people, times, and contexts in which it is produced. Over time, knowledge can be to varying degrees reliable, accepted, and challenged. DDT is a classic example. A product whose inventor was awarded the Nobel Prize in 1948, some twenty years later it was banned when new knowledge of its harmful properties was made public. The upshot is that knowledge, as well as evidence, can be essentially objective, but never entirely objective (see Chalmers 1990). This is particularly true of the knowledge of hazards and risks, since it involves human and natural systems with complex interactions, not to mention large and rapid variations as a result of developments such as new processes and materials. Knowledge of hazards and risks can also be contentious, because it is often produced in a context of controversial social and environmental values and competing economic and political interests. Therefore, politics and policy can never be entirely based on scientific evidence, and even if policymakers claim to do so, it will always be filtered through values and ideology. Again, obviously, the best available knowledge should be used to make decisions, but that does not mean that decisions should only be made on the basis of scientific evidence—there is always a measure of ideology in decision-making, and, as Löfstedt also points out, far better that it is transparent than it is disguised, dressed up as scientific evidence.

As already mentioned, chemical regulation is an area of potential controversy since major health, environmental, political, and economic interests are at stake. It is interesting to note that, whereas public authorities and environmental NGOs tend to favour hazard-based decisions, the chemical industry tends to argue that decisions should be based on risk (this is a general tendency—there are exceptions of course). In other words, the question of whether chemical regulation should be based on hazard categorization or risk assessment is not only a matter of definition and practical procedures; it is also a matter of conflicting interests. This is also the case when it comes to the supposed target of the categorization or assessment, as Hansson et al. (2011) point out: environmental NGOs and policy-makers are inclined to focus on the existing substance or product; industry representatives on the process of substitution and the substance or product to be substituted. Hence, the substitution principle is influenced by underlying conflicts between the different interests and points of view, which, if they fit with the media logic of the day, will also make the news. Given the experiences from another controversial regulatory area, gene and biotechnology, we can learn that regulation is

important not only for its practical consequences, but also for calming ongoing controversies, not least in the media (Fjæstad et al. 2001; Olofsson 2002). Hence, is important to uncover and analyse underlying controversies, the better to understand what is at stake, and who is involved and in what way, before promoting a particular way of going about a substitution, whether based on hazard categorization or risk assessment.

Conclusion

To conclude, I would agree that substitution should be based on the best possible available evidence, but whether that is achieved through hazard categorization or risk assessments is secondary and will vary according to the available data and a number of other circumstances (cf. Hansson et al. 2011). Since chemical regulation, and thus also the substitution principle, is bound to be controversial given the size of the interests at stake, it will draw media attention, and most likely be subject to political opportunism and lobbying both from industry and from the health and environmental NGOs. The real challenge is to find ways, despite this, to operate the substitution principle in an effective and sustainable way. If we are to reach such a goal, more research will be needed, particularly on the social, political, and economic aspects of the regulatory process.

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