U.S. Federal Agency Use of Linear Non-Threshold Assumption for Environment and Health Regulations, Reflective of the Precautionary Principle

(A Few Excerpted Writings)

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Laws of Fear: Beyond the Precautionary Principle

By Cass R. Sunstein

"**If we lack clear evidence, it might seem 'precautionary' to assume that…[low-level toxic agents, including carcinogens…cause adverse effects], and hence to assume, in the face of uncertainty, that the dose-response curve is linear and without safe thresholds**. In the United States, this is the default assumption of the Environmental Protection Agency. But is this approach unambiguously precautionary? Considerable evidence suggests that many toxic agents that are harmful at high levels are actually beneficial at low levels. **Thus, 'hormesis' is a dose-response relationship in which low doses stimulate desirable effects and high doses inhibit them**. When hormesis is involved, government use of a linear-dose-response curve, assuming no safe thresholds, will actually cause mortality and morbidity effects. Which default approach to the dose-response curve is precautionary? To raise this question is not to take any stand on whether some, any, or all toxic agents are beneficial or instead harmful at very low doses. It is only to say that the simultaneous possibility of benefits at low levels makes the **Precautionary Principle** paralyzing. **The principle requires use of a linear, non-threshold model**; but it simultaneously condemns use of that very model. For this and other reasons, unreflective use of the Precautionary Principle, it has been argued, threatens to increase rather than decrease the risks associated with food.
(pp. 30-31)

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Hormesis in precautionary regulatory culture: models preferences and the advancement of science

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"Hormesis and the choice of default models

The predicament of scientific evolution in precautionary culture –as discussed above- is well illustrated in the EPA quote at the beginning of our article. On the one hand it is recognised that adaptive responses could well be a reality and scientific progress will undoubtedly elucidate this issue more fully; **on the other hand current and future knowledge on hormesis is ignored as an assumed principle of safety and will therefore not be part of the EPA risk assessment methodology**. This EPA position is in a similar fashion reflected by Page:49

> 'When a regulator makes a decision under uncertainty, there are two possible types of error. The regulator can overregulate a risk [false positive, author] that turns out to be insignificant or the regulator can underregulate a risk that turns out to be significant. If the regulator erroneously underregulates [false negative, author], the burden of this mistake falls on those individuals who are injured or killed, and their families. If a regulator erroneously overregulates, the burden of this mistake falls on the regulated industry, which will pay for regulation that is not needed. This result, however, is fairer than setting the burden of uncertainty about a risk on potential victims.'

This position is classical asymmetric and typical for precautionary culture: it assumes what actually should be proven, namely, that the health effects of an assumptive over-regulatory approach would be superior to the alternative. **The concomitant assumption is that there are no health detriments from proposed overregulation.** Page presents a choice between health and money or even health with no loss whatsoever, as a peripheral presumption is that industry will find a better and a cheaper as well as safe way. Something (health) is gained with nothing lost (no adverse health effects from overregulations).50

The position proposed by Page would, in the case of the EPA, make sense only when (1) overregulation in terms of public and environmental health would indeed be superior to under-regulation, and (2) that in the face of uncertainty ignoring hormesis is the 'safe' option.51 **Both stances are to be found in the EPA risk assessment document, where issue (1) is addressed under the term 'conservatism', and issue (2) –the main topic of this paper- portrays the precautionary *deus ex machine* inference of guidance.** These two topics are very much related. As the EPA states (p. 11 – 12):

> 'Because of data gaps, as well as uncertainty and variability in the available data, risk cannot be known or calculated with absolute certainty. Further, as Hill (1965) noted, a lack of certainty or perfect evidence 'does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.' Therefore, consistent with its mission, EPA risk assessments tend towards protecting public and

environmental health by preferring an approach that does not underestimate risk in the face of uncertainty and variability. In other words, EPA seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated. However, because there are many views on what 'adequate' protection is, some may consider the risk assessment that supports a particular protection level to be 'too conservative' (i.e., it overestimates risk), while others may feel it is 'not conservative enough' (i.e., it underestimates risk). This issue regarding the appropriate degree of 'conservatism' in EPA's risk assessments has been a concern from the inception of the formal risk assessment process and has been a major part of the discussion and comments surrounding risk assessment.'

The EPA document clearly chooses not to underestimate risk in order to –as they put it- protect public and environmental health. **Over-regulation is therefore clearly favoured over under-regulation, although different views exist on what these terms exactly mean. Incorporating hormesis is -as it shows- regarded by the EPA as potentially resulting in an underestimation of risk. This is however postulated without proper scientific evidence; the path towards safe regulation is inferred a priori and results in the choice of default toxicological models, namely the linear threshold (LT) and nonthreshold (LNT) models. In terms of the over-regulatory bias, the choice to ignore hormesis seems logical and very much in line with precautionary culture.52 However, as risks and costs are on all sides of the societal and regulatory equations, *the choice of threshold and nonlinear default models as a precautionary basis of regulation in the face of uncertainty and ignorance* is the result of the *deus ex machina* inference of guidance. Parenthetically, it is ironic that the EPA chooses to quote on the disregard of knowledge, while ousting the concept and the knowledge of hormesis from its risk assessment procedures without a proper rational**.

Thus it is all the more interesting to review the principal position of the EPA to ignore the biphasic response. In the Belle Newsletter of March 2004, Griffiths –in his response to Hammitt- gives some insight in the (public) reluctance towards hormesis, which is in line with what we have put forward on precautionary culture:53

'On the surface, the results of determining that a substance displays hormesis seem relatively uncontroversial. If the hormetic exposure-response curve is steeper than the linear curve, then the marginal benefits of reducing exposure are greater than under the linear model, and the optimal regulatory level is more strict. If the hormetic curve is flatter, then the detrimental effect of a substance is substantially less than that implied by the linear curve. In other words, hormesis appears to imply stricter regulation or less harm. **Most government economists, though, know that regulatory decisions are (and should be) made including factors other than the economically optimal level. One of these factors is public concern, and there seems to be some public reluctance to assuming hormesis.**

There are a number of possible reasons for this public concern. One possibility is that determining a substance to be hormetic will always imply

a lower level of risk for any given exposure. One might argue that precaution dictates that we default to a model that produces the highest level of risk. Assuming a linear model when hormesis is valid, however, raises Portney's (1992) 'happyville' problem, where the government must decide whether to regulate a chemical that is of public concern but, in fact (according to risk assessors), poses no real risk. The benefits of regulation in such a situation are unclear. **Another possible concern is that assuming hormesis will weaken regulatory standards. As pointed out above, this is not necessarily true.** The optimal level could be more strict under hormesis if the slope of the hormetic curve is steeper than the linear curve. … **The real concern is where the optimal regulatory level under hormesis is less strict than the liner no-threshold model, the region where the hormesis curve is relatively flat.'**

We therefore need to take a closer look at the hormesis issue incrementally from the molecular up to the epidemiological, in which fundamental toxicological, economic and public health issues are interconnected. In our view this would contribute considerably to a more rational approach of chemicals regulation, which shows to have an over-regulatory track record.54"
(pp. 7-8)

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Interpreting the Precautionary Principle

Edited By Timothy O'Riordan and James Cameron

…***Evidentiary Approaches to the Precautionary Principle***

"*Use of conservative evidentiary presumptions*

US environmental law is also precautionary in using conservative evidentiary presumptions that tend to overestimate risk. **Examples of conservative assumptions include linear, no-threshold dose response curves and extrapolating from substances whose risks are known to related substances whose risks are unknown**. In some cases, a statute itself establishes an evidentiary presumption. For example, under the Delaney Amendment, if a food additive causes cancer in animals, this creates an irrebuttable presumption that the additive is unsafe (21 U.S.C. Sec. 348(c)(3)(A). Other evidentiary presumptions have been created by regulation. **OSHA regulations, for example, mandate the use of no-threshold dose-response curves for carcinogenic**

substances (close to a 'worst case' model) and permits inferences of carcinogenic hazard from one or more positive animal tests (29 C.F.R. Sec. 1990.143).

The use of conservative evidentiary presumptions, even in the absence of statutory authorization, has been sanctioned by the US Supreme Court. As it concluded in the Benzene case, **"[S]o long as [assumptions] are supported by a body of reputable scientific thought**, [agencies are] free to use conservative assumptions in interpreting data…risking error on the side of overprotection rather underprotection" (*Industrial Union Dept., AFL-CIO*, 448 U.S. at 656). Relying on this decision, **the DC Circuit Court of Appeals in *Public Citizen Health Research Group v. Tyson* upheld OSHA's use of animal studies to predict human health effects and of a no-threshold, linear dose-response curve**.