

Critical Reflections on Conservatism in Nuclear Safety Regulation

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1. Introduction

A recent report published by the Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) says that a fundamental principle for safety regulators is the practice of conservative decision making [1]. Nuclear regulators frequently face challenging issues surrounded by uncertainties or lack of data and information. No matter what efforts will be made to collect the available information and to assess the issues, nobody can clear all the uncertainties and make absolutely certain decision. More often than not, the regulators have to make a decision in light of continuing uncertainties and limited information. It is at this point that the principle of conservatism should play a role. However the principle comes in many diverse forms such as default conservatism, precautionary principle, defense in depth and realistic conservatism. These different forms of conservatism have different roles and meanings that will take a decision maker to drastically different results.

This paper reviews different forms of conservatism in critical way, presents analytical framework for decision-making under uncertainty and suggests future research works needed.

2. Reviews and Discussions

2.1 Default Conservatism

Default conservatism is related to cancer risk assessment of carcinogenic materials for which Environment Protection Agency (EPA) of the US is responsible. Defaults had their origin in the early 1970s. In proceedings involving pesticides, EPA lawyers offered a witness from the National Cancer Institute who proposed cancer principles as criteria for evaluation of carcinogenic risk from the pesticides. The 7 cancer principles were offered by the EPA as "facts" that should be officially noticed as a basis for regulatory decision. After long standing disputes about the "facts", EPA published Cancer Guidelines in 1986 where some important defaults were included. Some of them are:

- Laboratory animals are a surrogate for humans in assessing cancer risks,
- Intake of one molecule of a chemical has an associated probability for cancer induction,
- Chemical intake is integrated over time, irrespective of intake rate and duration, etc.

It has been criticized that defaults are generic principles treated as "facts" chosen as a matter of

political resolution and not based on scientific results. Proponents of defaults say that it should be understood to mean a choice that avoids underestimating risks, that is a form of conservatism [2].

In 1994, the report of the National Academy of Sciences, *Science and Judgment in Risk Assessment* pointed out that EPA rests heavily on defaults and made two major recommendations as a condition of their continuing use of defaults [3]:

- EPA should identify and state the scientific and policy basis for each default and criteria for departure from defaults.
- EPA should adopt iterative approach to risk assessment to reduce reliance on defaults that will result in being free from defaults.

2.2 Precautionary Principle

The simplest interpretation of the precautionary principle is that "it is better to be safe than sorry". The European Union has taken a leading role in promoting the precautionary principle as a basis for making decisions on environmental policy. Although an explicit definition or specific guidance of the principle has not been made, the European Commission has presented the general idea that regulatory action should be taken even when harm cannot be established and indeed even when it is highly speculative [4]. A strong version of the principle is shown in the Wingspread Declaration made by environmentalists in 1998, which states: When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.

The following reasons were provided why the application of this principle would not make a better decision making.

First, it does not address a complex setting with regard to risk management. Reducing risks in one policy domain could increase risks in another, especially when resources are scarce.

Second, it could prevent technological innovations that has supported rising living standards. No innovator may challenge a new technology unless he can show an evidence of no harmful effect, including full consideration of long-term effects.

Third, precautionary measures can produce more significant risk. For example, the USA has learned that when FDA regulation of new drugs became too stringent, it caused harmful delays in the introduction of effective therapies into medicine.

Fourth, it can be used as potential disguise for protectionism. It is important to recognize that trade barriers will lead to more risky world. Critical medicine and vaccine, for example, should be traded in free market, which ensures optimized way of production, distribution and consumption.

Fifth, it is not a new concept if its purpose is only to remind us that sensible precautions are an important feature of wise decision making. There are well established approaches to precaution and uncertainty in both decision theory and economics. Option value or value-of-information analysis gives way to quantify its effects on final decision. Neither of them requires a universal new principle.

2.3 Defense in Depth

The history of nuclear reactor safety may provide insights regarding the value of caution and risk assessment. Before the publication of the Reactor Safety Study (WASH-1400) of 1975, probabilities of accidents were not quantified and the consequences of core damage accident were thought to be disastrous. Precautionary attitude prevailed and this led to conservative design, operation limits and large safety margins. Defense-in-Depth approach was adopted and has been used and continues to be an element of the safety philosophy. As risk assessments on nuclear power plants are conducted and knowledge and experience accumulate, it becomes to know that precautionary measures were not always taken in right places. While some important risk contributors were missed, in some instances, unnecessary regulatory burden was imposed in terms of defense in depth. In the early attempts of the US Nuclear Regulatory Commission (NRC)'s moving to risk-informed regulation, 'defense in depth' was used to avoid making changes in regulations or regulatory practices that seemed appropriate in the light of results of quantitative risk analyses [5].

The NRC had concerns that arbitrary appeals to defense in depth could inhibit the effective use of risk information in the regulatory process. In order to give resolution to this situation, ACRS (Advisory Committee on Reactor Safety) presented two views on defense in depth (structural versus rational view) and suggest as a pragmatic approach that defense in depth (structural approach) is applied at a high level and risk assessment (rational approach) is implemented at lower levels.

2.4 Realistic Conservatism

In his speech at Regulatory Information Conference of 2003, NRC Chairman Nils Diaz described his thoughts on realistic conservatism: "conservatism" in the sense of preserving adequate safety margins and "realistic" in the sense of being anchored in the real world of physics and experience. He argued that "NRC's objective should be to regulate in a manner that corresponds to the actual risk presented, and that must be realistically conservative. Under-regulation puts the

public safety at risk; over-regulation diminishes the value to society of the regulatory activity. It could be counter-productive to safety by diverting resources from the important safety issues."

This notion is closely related to careful consideration of benefit and cost of regulation. However, it still does not answer the question of how much realism or how much conservatism is appropriate.

3. Avoiding vs. Analyzing Uncertainty

Uncertainty is a feature of the most often and basic decision problem. When faced with uncertain decision setting, people choose their own best alternative based on his/her risk attitude, namely risk-neutral, risk-aversion and risk-taking attitude. Then, which attitude must be adopted in the case of governmental decision on public projects, regulatory action and so on? Let's take an imaginary example in nuclear safety: "There are two alternative safety actions. While action X results in achievement of $10E-4$ CDF in certainty, action Y results in uncertain situation of 90.91% chance of achieving $10E-5$ CDF and 9.09% chance of $10E-3$ CDF. Which one should regulator choose?" Is it a conservative decision to choose X, a certain outcome not Y, uncertain but safer outcome in terms of probabilistic expectation? Conservatism is not to avoid uncertainty but to have attitude of analyzing it with sufficient consideration to the cause of uncertainty and full attention of the effects. We can depend on decision theory and several methods used in economics to deal with uncertainty.

4. Conclusion

When faced with uncertainty, regulators should not only adopt conservatism but also take cautious attitude not to abuse it. As more operating experience and improved safety analysis methods give us a deeper understanding of nuclear safety, safety margins, and their uncertainties, it may be possible to reduce overly conservative margins or to add margins where needed. Conservatism is not to avoid uncertainty but to confront it in a cost-benefit way. It should be recalled that more risks can arise from conservative inaction than from cost-benefit action.

REFERENCES

- [1] OECD/NEA, Nuclear Regulatory Decision Making, 2005.
- [2] R. C. Barnard, Risk Assessment: The Default Conservatism Controversy, Regulatory Toxicology and Pharmacology, Vol.21, p.431, 1995.
- [3] NRC/NAS, Science and Judgment in Risk Assessment, National Academy Press, Washington DC, 1994.
- [4] European Commission, Communication from the Commission on the Precautionary Principle, Brussels: The commission of the European Communities, 2000.
- [5] ACRS, Letter to Chairman, The Role Of Defense In Depth In A Risk-Informed Regulatory System, May 19 1999.