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SCIENC, NEW FOODS AND PUBLIC POLICY
Using the Concept of Substantial Equivalence

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In an article appearing in *Nature*, Millstone *et al*. argue that the concept of substantial equivalence used to assess the safety of genetically-modified (GM) foods is "a psuedo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests."[2]

The history of the application of this concept reveals three important features that are not consistent with the assessment of Millstone *et al*. First, it provides a scientific basis for safety assessment of both convention and GM foods. Second, it offers the flexibility needed to accommodate emerging scientific findings and to develop a more robust regulatory framework based on familarity. Third, it represents a practicable elaboration of the precationary approach.

The concept of substantial equivalence holds that existing foods provide the basis against which to assess the safety of GM foods. The Organisation for Economic Cooperation and Development (OECD) has stated that "if the new or modified food or food component is determined to be sustantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant."[3]

The normal practice is public policy and regulation is to seek to apply existing principles and practices to a new situation unless it can be demonstrated right away that there are better alternatives. But the use of existing principles if often treated as starting point. What is critical is the ability of the regulatory system to accommodate new knowledge, revise the principles and abandon them where necessary.

The concept of substantial equivalence is used in the medical field to establish that a new devise performs essentially the same functions as the one that it is replacing. In fact, this

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[2] . Millstone, E. et al. (1999), "Beyond Substantial Equivalence," *Nature*, Vol. 401, pp. 525-526.

[3] . OECD (1993), *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*. Organization for Economic Cooperation and Development, Paris.

is a tool for regulators, not a scientific doctrine. The establishment of substantial equivalence is a regulatory function that is based on extensive science and technical work whose results are provided to the regulators by industry.

The concept was first articulated in the OECD in the early 1990s on the basic consensus positions developed in the mid-1980s about the risks of genetic modification. In the early 199s the concept was adopted as a basis for harmonization of international and national practices by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).[4] It has since then been elaborated and integrated in the national laws and practices of many countries around the world.[5] The first GM food approved for commercialization using this concept was the Flavr Savr tomato released by Calgene in 1992.

This view has often been represented and used to argue that the concept of substantial equivalence allows for the introduction of foods without adequate testing and therefore endangering human health. In addition, critics have argued that the concept lacks scientific validity and inhibits safety research.

The substatial equivalence concept is not a substitute for safety assessment neither is it a tool for confirming that a particular food or compound is safe. It is an analytical framework that allows regulators to assess the safety of a new product in relation to an existing one. This process requires comparative data on molecular, nutritional, biochemical, toxicological and immunological charateristics.

Where such substantial equivalence cannot be demonstrated, more analytical work and testing is required to establish the safety of a new product. The concept therefore provides a basis for promoting research, rather than inhibiting it.

This point is demonstrated by recent work that covers ecological issues as well as assessment criteria for foods where substantial equivalence cannot be demonstrated.[6] Indeed, regulators are now requiring detailed information for secondary effects of genetic modification on the biochemistry and physiology as well as secondary metabolism of GM crops.

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[4] . WHO (1991), *Strategies for Assessing the Safety of Foods Produced by Biotechnology*. World Health Organisation, Geneva.

[5] . WHO (1995), *Application of the Principle of Substantial Equivalence to the Safety Evaluation of Foods or Food Components Derived from Modern Biotechnology*. World Health Organisation, Geneva; FAO (1996), *Biotechnology and Food Safety*. Food and Agriculture Organisation, Rome; McIntyre, K.E. (1998), "Regulating genetically modified foods in Canada," *Chemtech*, Vol. 28, pp. 43-46; Heath Canada (1994), *Guidelines for the Safe Assessment of Novel Foods*. Health Canada, Ottawa; Nordic Working Group on Food Toxicology and Risk Assessment (1991), *Food and New Biotechnology: Novelty, Safety and Control Aspects of Food Made by New Biotechnology*. Nordic Council, Copenhagen; United States Food and Drug Administration (1992), *Statement of Policy: Food Derived from New Plant Varieties*. Notice. Federal Register 57: 104 22984-23005; European Economic Community (1995), *Risk Evaluation of Genetically Modified Microorganisms in Relations to Human Health*. Microbial Ecology in Health and Disease, Vol. 8, Supplement 1, London.

[6] . OECD (1999), *Report of the OECD Workshop on the Toxocological and Nutritional Testing of Novel Foods*. Organization for Economic Cooperation and Development, Paris.

Critics of this concept have suggested that alternative approaches, especially those based on the precautionary approach be adopted for dealing with GM foods. The assumption in these calls is that the approach does not provide the safeguards needed in dealing with potential risks of GM foods.

Applying a substantial equivalence approach would favour the early approval of those GM foods that show the greatest similarities with conventional ones. This approach would reduce the risks associated with substantially different foods as their approval would have to await more safety studies. This incremental strategy that is inherent in the substantial equivalence approach provides a practible basis for implement the precautionary approach.

An appeal to sound science in safety assessment does not represent certainty, a goal that cannot be reached. What the substantial equivalence approach has shown is that biological processes demand more scientific research than had previously been thought. The lack if information in vast areas, including on conventional crops, is a case for more research and safety assessment, not the repudiation of the comparative tools that make it possible to start this process.