Substantial equivalence

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Substantial equivalence is a concept, developed by OECD in 1991, that maintains that a novel food (for example, genetically modified foods) should be considered the same as and as safe as a conventional food if it demonstrates the same characteristics and composition as the conventional food. Substantial equivalence is important from a regulatory point of view. If a novel food is substantially equivalent to its conventional counterpart, then it could be covered by the same regulatory framework as a conventional food.[1]

The concept is used to determine whether a new food shares similar health and nutritional characteristics with an existing, familiar food with an established history of safe use.

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Definition and Controversy

To facilitate rapid approval for genetically modified foods the "substantial equivalence" concept was proposed by the Food and Agriculture Organization (FAO) and World Health Organization in the early 1990s. The stringent testing normally required for new food products can cost millions of dollars and take years of testing before a product gains approval for marketing. Such demands and delays would have made genetically modified foods unprofitable for private companies, substantial equivalence can allow products to get to market within months of their development.

Reasoning about **substantial equivalence** is widely used by national and international agencies - including the Canadian Food Inspection Agency, Japan's Ministry of Health and Welfare and the U.S. Food and Drug Administration, the United Nation's Food and Agriculture Organization, the World Health Organization and the Organisation for Economic Cooperation and Development (hereafter OECD).[2] It has been argued that by invoking the doctrine of substantial equivalence the GMO industry has avoided safety testing, and that forthcoming novel food production technologies may follow this example.[3]

Some other new biochemical concepts that are important for understanding the **substantial equivalence** of a novel food or crop to an existing food or crop are **metabolic profiling** and **protein profiling**. These concepts refer, respectively, to the complete measured biochemical spectrum (total fingerprint) of compounds (metabolites) or of proteins present in a food or crop. Substantially equivalent foods have the same metabolic and protein profiles, or more precisely, **biochemical profiles** of a new food are deemed to be substantially equivalent to an existing food if they fall within the **range of natural variation** already exhibited by **biochemical profiles** of existing foods or crops.

Over the history of its usage the term **substantial equivalence** has been interpreted differently by the various participants in the debate about GM food safety.

The current state of the concept is clarified in several recent food science articles.[2][4][5][6]

> International consensus has been reached on the principles regarding evaluation of the food safety of genetically modified plants. The concept of substantial equivalence has been developed as part of a safety evaluation framework, based on the idea that existing foods can serve as a basis for comparing the properties of genetically modified foods with the appropriate counterpart. Application of the concept is not a safety assessment per se, but helps to identify similarities and differences between the existing food and the new product, which are then subject to further toxicological investigation. Substantial equivalence is a starting point in the safety evaluation, rather than an endpoint of the assessment. (Kuiper and others, 2001)

The utility of the **substantial equivalence** concept is illustrated by the way certain food products - such as processed and purified food components like soybean oil, starch or crystalline sugar - may be considered substantially equivalent even though the varieties from which they were obtained are different.

As a notion **substantial equivalence** was first articulated by the OECD, which hosted discussions that led to a key publication '*Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*' (OECD, 1993)[1] (http://www.oecd.org/dataoecd/57/3/1946129.pdf) .

The concept has been criticised, for instance in 1999 by Erik Millstone (University of Sussex) Eric Brunner (UC London) and Sue Mayer (GeneWatch UK)[7] who argued that the concept was pseudo-scientific, and that:

> [T]he biotechnology companies wanted government regulators to help persuade consumers that their products were safe, yet they also wanted the regulatory hurdles to be set as low as possible. Governments wanted an approach to the regulation of GM foods that could be agreed internationally, and that would not inhibit the development of their domestic biotechnology companies.

But **substantial equivalence** recognises the fact that existing foods often contain toxic components (usually called antinutrients) and are still able to be consumed safely - in practice there is some tolerable chemical risk taken with all foods, so a comparative method for assessing safety needs to be adopted. For instance, potatoes and tomatoes can contain toxic levels of respectively, solanine and alpha-tomatine alkaloids.[6][8]

It also recognised the well supported scientific argument that:

> While rDNA techniques may result in the production of organisms expressing a combination of traits that are not observed in nature, genetic changes from rDNA [recombinant DNA] techniques will often have inherently greater predictability compared to traditional techniques, because of the greater precision that the rDNA technique affords; (and) it is expected that any risks associated with applications of rDNA organisms may be assessed in generally the same way as those associated with non-rDNA organisms.

which was first voiced in 1986 by the OECD Recombinant DNA Safety Considerations. Paris: OECD, 1986, cited by Miller (1999) , and has subsequently re-affirmed in numerous scientific deliberations,[9] and by comprehensive chemical comparisons of recombinant DNA derived crops and their conventional crop counterparts discussed below.

It is for this reason legislators treat a new food by comparison with its nearest existing known counterpart, taking into account natural ranges for variation in metabolic and proteins profiles, and particularly profiles of anti-nutrients. If a GM food was found to be **substantially equivalent** to its nearest existing counterpart by careful compositional analysis ('profiling' or 'fingerprinting') of the full set of chemical compounds in the food, it can be argued that it is at least as safe as that conventional counterpart.

For instance, the US FDA effectively uses **substantial equivalence** as part of their policy:

> The FDA's policy defines certain safety-related characteristics of new foods that, if present, require greater scrutiny by the agency. These include the presence of a substance that is completely new to the food supply, an allergen presented in an unusual or unexpected way (for example, a peanut protein transferred to a potato), changes in the levels of major dietary nutrients, and increased levels of toxins normally found in foods. Additional tests are performed when suggested by the product's composition, characteristics or history of use. For example, potatoes are generally tested for the glycoalkaloid solanine, because this natural toxin has been detected at harmful levels in some new potato varieties that were developed with conventional genetic techniques.[9]

A biotechnology company could establish **substantial equivalence** by comparing food **biochemical profiles** such as protein, carbohydrate, fatty acid levels, nutrients, antinutients and other plant metabolites between the novel food and its traditional counterpart.

Critics have argued that there were no clear and universal guidelines stipulating what to test and how similar the items in question should be. For example, Roundup Ready Soybeans contained a new previously unknown enzyme, *5-enolpyruvyl shikimate-3-phosphate synthetase*. The manufacturer argued that as cooking deactivates the enzyme and people do not eat uncooked Soybeans its presence was irrelevant. Although this argument ignored that the still functional enzyme could be consumed with the meat if the Soybeans were fed to cattle, it was approved by the FDA without testing. Erik Millstone *et al*.[7] state:

> The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its 'substance' ceases to be acceptably 'equivalent' is not defined anywhere, nor has an exact definition been agreed by legislators. It is exactly this vagueness which makes the concept useful to industry but unacceptable to the consumer.

But the response of the proponents to this criticism was that they were being misrepresented:

> Substantial equivalence is not a substitute for a safety assessment. It is a guiding principle which is a useful tool for regulatory scientists engaged in safety assessments. It stresses that an assessment should show that a GM variety is as safe as its traditional counterparts. In this approach, differences may be identified for further scrutiny, which can involve nutritional, toxicological and immunological testing. The approach allows regulators to focus on the differences in a new variety and therefore on safety concerns of critical importance. Biochemical and toxicological tests are certainly not precluded. Peter Kearns (OECD) Paul Mayers (Health Canada)[10]

The quandary of what to test has been resolved by the concept of testing everything and thus determine the **biochemical profile** of the food, as recently comprehensive biochemical profiling of metabolites and proteins in food have become technically possible. These provide an empirical route for determining if a food is in fact substantially equivalent to an existing food, and this approach, also called metabolomics (for metabolite profiling) or proteomics (protein profiling) has established the equivalence of one strain of GM potato and its conventional counterparts, and also the equivalence of a new GM tomato variety to its existing counterpart.[11][12][13]

The range of **biochemical profiles** routinely seen in different conventional varieties of the same crop and under different growing condition[6][11][13] provide a natural criterion for defining what constitutes an "equivalent composition". If a new GM food falls within the natural range of existing variation it is equivalent.

Scientists from the United States National Academy of Science, the Royal Society of Canada and the Medical Research Council (UK) have however, pointed out that a genetically engineered food may not only be substantially equivalent, but effectively almost completely identical with its natural counterpart and still contain an unexpected toxic substance not tested for despite passing Substantial Equivalence requirements.[14] A leading pro-GM scientist, Dr Andrew Chesson, admitted that substantial equivalence testing is flawed and that some current safety tests could allow harmful substances to enter the human food chain.[15]

> "Substantial equivalence does not function as a scientific basis for the application of a safety standard, but rather as a decision procedure for facilitating the passage of new products, GE and non-GE, through the regulatory process"—**Royal Society of Canada**[16]

Michael R. Taylor

On the 17th July 1991, Michael R. Taylor was appointed as the FDA's Deputy Commissioner for Policy, the first person to hold this newly created post. Taylor previously worked as a lawyer for Monsanto, where he had great influence on the legalization of the genetically modified bovine growth hormone (BGH). During Taylor's tenure GM seeds were declared to be "substantially equivalent" to non-GM seeds, hence proclaiming proof of the harmlessness of GMs to be unnecessary. After his tenure at the FDA, Taylor became a vice-president of Monsanto. Critics have called for a review of his work at the FDA citing a conflict of interest.

On July 7, 2009, Mr Taylor returned to government as the "senior advisor" to the Commissioner of the US Food and Drug Administration for the Obama administration.[17]

Many commentators see Taylor as the originator of the concept of substantial equivalence.

Vandana Shiva concluded: "a very convenient tool called substantial equivalence principle was cooked up to say 'let's just treated [sic?] genetically engineered organisms like conventional crops'. Of course, they don't say that, when they want to patent these things. At that point, they say these are absolutely "novel", never existed before, not like nature, these are not natural. But when it comes to safety, they say: it's just like nature, exactly as nature made. I sometimes call this ontological schizophrenia." [18]

See also

- Risk management
- Generally recognized as safe
- Genetically modified food
- Genetically modified plant

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External links

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