Part II. Innovation in today's food sector

After the historical retrospective on the exemption to patentability of food in part I, part II describes the present-day food sector with its most important technological developments and its fields of innovation. The impact of biotechnology on the food sector is of special interest in part II.

The food sector is the largest manufacturing sector in the EU. Its annual production amounts to €626 billion, accounting for 13% of the total manufacturing sector. It is larger than the automobile, chemical, machinery and equipment sectors. Four main fields dominate the food sector: beverages, various products including bakery, chocolate, and confectionery products, and finally meat and dairy. Total food exports to developing countries in 2002 amounted to €46 billion. Seven percent of European food production in 2002 was exported to developing countries. The food sector covers a market of 450 million consumers in the enlarged EU. Food remains amongst the most important consumption items. Together, food and non-alcoholic beverages accounted for an average of 12.8% of total household expenditures in 2000. The European food sector processes 70% of all European agricultural products.[280]

The European food sector is experiencing a rapid structural change. This change is mainly caused by the emergence of huge retail companies and the concentration in the food sector. Key consumer trends include a slow population growth and a rising demand for convenience food. Furthermore, better educated consumers have begun to confront the food sector with concerns about health, nutrition, food safety and the environment.[281]

Innovation is the key instrument for the food sector, as consumers favor new food.[282] Saturation in domestic markets of developed countries and growing competition in export markets makes innovation a crucial tool for the food sector. Moreover, added value and convenience are the driving forces for the development of new food.[283]

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280 Confederation of the Food and Drink Industries in the EU (CIAA), Data and Trends of the EU Food and Drink Industry, Brussels 2003, 5.

281 *Hughes,* Building Partnerships and Alliances in the European Food Industry, in: *Galizzi&Venturini* (eds.), Economics of Innovation: the Case of Food Industry, Heidelberg 1996, 101.

282 *Naderi,* Erfolgreiche und erfolglose Produktinnovationen in der Ernährungsindustrie, Lizensiatsarbeit, Universität Bern 1998, available at www.iop.unibe.ch/Forschung/lizarbeiten.htm.

283 „(...) product development in the food industry strives to provide novel or improved food products with high added-value compared to the raw materials that are used to produce them.“ *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

The production of processed food is based on agricultural raw materials, which are mainly seasonally produced. This seasonal production must be converted into a continuous process in order to secure a constant delivery of processed food to the consumer market. The production of processed food typically comprises the steps of processing, conservation, and packaging.

The starting point for the production of processed food are agricultural raw materials. The characteristics of agricultural raw materials impose specific difficulties on the production of processed food. Agricultural raw materials, unlike other raw materials, are characterized by seasonal production, fluctuating quality, and limited shelf life.[284] These specific features of the production of agricultural raw materials influence innovation in the food sector to a great extent. The specificities of consumer demand and of the production of agricultural raw materials are reflected in the innovation process of the food sector. The most recent innovations, first and foremost regarding biotechnology[285], are explained in the following. Innovation in the production of agricultural materials, comprising the production of plant-derived agricultural raw materials and of animal-derived agricultural raw materials, has been remarkably influenced by biotechnology in recent years. Innovation in the processing of agricultural raw materials has also been changed by biotechnology, paving the way for new food creations.

A. Innovation related to the production of agricultural raw materials

Innovation related to the production of agricultural raw materials has been influenced to a large extent by the implementation of biotechnology. Biotechnology applies to plant production as well as to animal production and opens up completely new fields for agricultural production.

284 *Strecker et al.,* Marketing in der Agrar- und Ernährungswirtschaft, 3rd ed., Frankfurt am Main 1996, 23, 24.

285 „The integration of (new) food functionalities into product formulation in many cases requires research-intensive biotechnological innovation strategies.“ *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

I. Innovation related to the production of plant-derived agricultural raw materials

Innovation related to the production of plant-derived agricultural raw materials has been revolutionized by the implementation of biotechnology. Biotechnology related to the production of plant-derived agricultural raw materials generally aims to enhance a range of traits in plants. Table 9 gives an overview of the categories of such traits. Plant biotechnology used in the production of plant-derived agricultural raw materials focuses mainly on agronomical traits, traits related to the production of processed food, and health-related traits.

Table 9:
Applications of biotechnology in the production of plant-derived agricultural raw materials.[286]

Area	Tool
Agronomical traits[287]	Plant breeding - Trait expression - Selective breeding technologies via molecular markers - Fertility control Pest control - Disease resistance - Insect resistance - Herbicide tolerance Yield enhancement - Biomass production - Crop yield - Abiotic stress tolerance, salt, drought - Plant nutrition and water use
Traits related to the production of processed food	Food Composition - Amino acids, carbohydrates and fatty acids - Phytochemicals, e.g. anti-oxidants, isoflavones Production of processed food - Food quality, improved shelf life, reduced allergenicity/mycotoxins - Plants producing food enzymes, e.g. lactase, lipase - Enzymes for improved food production and consistency with reduced waste, e.g. phytase, cellulase
Health-related traits	- Nutrients, e.g. iron, vitamins - Amino acids, carbohydrates and fatty acids - Phytochemicals, e.g. isoflavones, antioxidants - Nutraceuticals - Production of pharmaceuticals, active molecules in plants

286 *McElroy*, Sustaining Agbiotechnology through Lean Times, 21 Nature Biotechnology 996, (2003). See also *Chua&Tingey*, Plant Biotechnology: Looking Forward to the Next Ten Years, 17 Current Opinion in Biotechnology 103 (2006). For an overview over the application of biotechnology to the staple food crop wheat see *Bhalla*, Genetic Engineering of Wheat – Current Challenges and Opportunities, 24 Trends in Biotechnology 305 (2006).

287 For more information see *Castle et al.*, Agricultural Input Traits: Past, Present and Future, 17 Current Opinion in Biotechnology 105 (2006).

The majority of genetically modified crops are modified with respect to agronomically valuable traits. Such traits include genes for yield increase and pest control.[288] The main emphasis in pest control has been laid on the development of two traits. First, a bacterial gene from *Bacillus thuringiensis* encoding a protein resisting corn borer has been identified.[289] This gene has been introduced in plant species like corn. The so-called Bt-corn is resistant to the corn borer. Bt-corn consequently does not require any application of insecticides against corn borer. Secondly, genes encoding for proteins that deactivate herbicides have been introduced to plant species, making them resistant to herbicides, e.g. glyphosate. Glyphosate is effective at low concentrations. Moreover, glyphosate is not toxic to humans or other mammals and is rapidly degraded by soil microorganisms. Tolerance to glyphosate has been introduced into soy, maize, oilseed rape and sugar beet.

These transgenic plants generate direct economic benefits for farmers by lowering the financial and environmental costs of food production. Consumers profit indirectly from cheaper agricultural raw materials reducing the price of processed food. Since their first commercial introduction, genetically modified plants with agronomical traits have been rapidly adopted in a number of important agricultural markets.[290] Moreover the "American experience from almost a decade-long use of biotechnology-derived crops indicate that these crops have revolutionized crop production and provided vast hope to growers by helping to meet one of the key goals of production agriculture: improving yields with the use of minimal inputs."[291]

Agronomical traits also comprise traits for sustainable food production, e.g. sustainable use of water. The pollution of water can be reduced by using herbicide-resistant plants. These plants generally need only one application of the respective herbicide. Insect-resistant plants generally need no plant protection agents against that insect at all. Finally, plant breeding generates plants being more tolerant of drought and salt. Consequently plant biotechnology has the potential to make an important contribution towards sustainable food production.[292] Traits related to the production of processed food aim at the improvement of the composition of food and feed for better food-production applications.[293] The improvement of plant varieties is currently focused on the supply of high-quality raw materials and the improvement of processability.

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288 E.g. RoundupReady® corn for tolerance to glyphosate-containing herbicides or Bollgard *Bacillus thuringiensis* cotton for lepdiopteran insect control by Monsanto, St. Louis, MO.

289 For the environmental impacts see *Romeis* who measured no direct negative influence on control organisms and concludes that Bt-crops contribute to integrated pest management, *Romeis et al.*, Transgenic Crops Expressing Bacillus Thuringiensis Toxins and Biological Control, 24 Nature Biotechnology 63 (2006).

290 *James,* Global Status of Commercialized Transgenic Crops, 2002, ISAAA Briefs No. 27.

291 *Sankula et al.*, Biotechnology Derived Crops Planted in 2004 – Impacts on US Agriculture, National Center for Food and Agricultural Policy (2006), 100, available at www.ncfap.org.

292 *Bennett,* The Foundation of Food Security, 2003 (2) Syngenta Lectures 4.

293 *McElroy,* Sustaining Agbiotechnology Through Lean Times, 21 Nature Biotechnology 996, 998, table 2 (2003).

Traits related to the production of processed food comprise genes for economically valuable oils, proteins and starches. Modified fatty acid composition, e.g. genetically modified soybean plants yielding oil low in polyunsaturated fats, and altered carbon-partitioning for novel starch production in potatoes, are examples of this.[294]

The first generation of genetically modified plants with traits relevant for the production of processed food was commercialized in the 1990s. The FlavrSavr® tomato by Calgene was genetically modified to delay fruit softening for longer maturation and improved flavor. Polygalacturonase breaks down the pectin that holds cell walls together causing the softening of fruits. The introduction of an polygalacturonase antisense gene into the tomato plant neutralized the gene encoding polygalacturonase. Such genetically modified fruits showed a longer shelf-life than the wild type.

Genetically modified plants with improved quality traits for feed are another field of plant biotechnology in the food sector. Such genetically modified plants have a higher content of feed additives like essential amino acids or essential fatty acids. Plants can perform complex synthesis. The carotinoide astaxanthin is a basic feed additive in the breeding of salmon. It is responsible for the characteristic reddish color of salmon. Wild salmon is provided with astaxanthin from crustaceans. Salmon farms must add astaxanthin as a feed additive. The chemical synthesis of astaxanthin requires 13 steps. Genetically modified plants expressing high levels of astaxanthin could be fed to salmon, making the addition of astaxanthin to feed unnecessary.[295]

Improved nutritional quality is another object of plant biotechnology in the food sector. A sweet potato has already been developed with greater protein quality.[296] Soybean and corn plants have been modified to improve their oil, protein, and carbohydrate content.[297] A rice strain has been genetically modified in order to express additional vitamin A, the so-called GoldenRice®.[298] Vitamin A deficiency causes blindness and affects up to 250 million children worldwide. Thus, GoldenRice® has been called a "major advance in global nutrition."

Health-related traits in genetically modified plants relate to the yield and efficacy of neutraceuticals or pharmaceuticals derived from natural plant products. Genetically modified plants are used as biological factories for the production of complex molecules. Therapeutic molecules have been manufactured in genetically modified plants. Plants offer a flexible manufacturing scale at low capital. Hence, genetically modified plants represent alternative manufacturing systems for pharmaceuticals.[299]

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294 *Weck,* The Transgenic Plant Market: Profits from New Products and Novel Drugs, Drug&Market Development Report No. 9070 (2002).

295 Available at www.astaxanthin.org.

296 *Moffat*, Crop Engineering Goes South, 285 Science 370, 371 (1999).

297 *Mazur et al.*, Gene Discovery and Product Development for Grain Quality Traits, 285 Science 372 (1999).

298 *Ye et al.*, Engineering the Provitamin A (B-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm, 287 Science 303 (2000).

299 *Andersson&Mynahan*, The Protein Production Challenge, 5 In vivo: The Business and Medicine Report 1 (2001).

Research and implementation of biotechnology in the production of plant-derived agricultural raw materials goes along with R&D expenditures. These expenditures can only be compensated with royalties obtained from farmers for their use of seed. Seeds bring high technology in a reproductive form to farmers. Discovering and proving infringements of plant intellectual property rights is difficult, both in developed and in developing countries. Small-scale farmers and subsistence farming prevail in developing countries, making the enforcement of plant intellectual property rights even harder.[300] License agreements with farmers of patented seeds are hardly enforceable in practice.[301]

The amortization of investment costs is difficult. This unsatisfactory law enforcement has led to biological protection mechanisms based on further innovation in the food sector, the so-called GURTs. GURTs comprise hybrids and genetically modified plants with reduced reproducibility.

Hybrid[302] technology could prevent unlicensed reproduction of protected seed. This technology currently dominates in corn, rape, sugar beet and vegetables. Not only breeders take advantage of hybrid varieties, but farmers do as well. The heterosis effect in hybrid plants produces higher and more constant yields, better resistance to biotic and abiotic stress factors, and improved handling. Farmers are usually willing to pay premium prices for hybrid varieties. But hybrid technology gives breeders a *de facto* protection by discouraging farmers from using harvested seed for replanting. It is even more difficult to use hybrid germplasm for further breeding.[303]

The GURTs are another innovation related to the production of plant-derived agricultural raw materials.[304] Inventions relating to GURTs form a class of their own. GURTs do not have agronomically or physiologically useful traits as opposed to the examples of plant biotechnology described above. The idea of GURTs was to create a mechanism for intellectual property protection in the field of plant biotechnology.[305] GURTs include genetically modified plants whose seed is unable to regerminate, using the so-called terminator technology. Delta and Pine Land Corp. invented and patented[306] this technology in cooperation with the U.S. Department of Agriculture (USDA).

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300 *Otieno-Odek*, Public Domain in Patentability after the Uruguay Round: A Developing Country's Perspective with Specific Reference to Kenya, 4 Tulane J. Int'l & Comp. L. 15, 34 (1995).

301 *Ewens*, Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds, 23 Boston College International & Comparative Law Review 285, 306, (2000).

302 A hybrid is a plant obtained by crossing of two genetically different parental plants. Most often parental plants are separately bred representatives of an "inbred line", which are homozygotic by permanent inbreeding. Hybrid varieties are plant varieties, which are based on a defined combination of inbred lines.

303 *Kock, Porzig, Willnegger*, Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unter Berücksichtigung der Umsetzung der Biopatentrichtlinie, GRUR Int. 2005, 186.

304 *Aoki*, Neocolonialism, Anticommons Property, and Bio-Property in the (Not-So-Brave) New World Order of International Intellectual Property Protection, 6 Indiana. J. Global Legal Studies 11, 54 (1998).

305 In 2002, Bayer CropScience conducted field trials of transgenic rapeseed, whose seed is sterile due to the terminator technology. Greenpeace states that farmers are deprived of the possibility to sow their seed and the environment is endangered by cross-pollination. Available at www.greenpeace.de.

306 US 5,723,765 "Control of Plant Gene Expression," granted on March 3, 1998, filed on June 7, 1995.

The intention was the creation of plants that produce sterile seeds. Moreover, the exploitation of the biological self-replicating mechanisms of plants by farmers was to be restricted. As a consequence, such seeds could only be consumed or processed, but not sowed again. Since then, several comparable mechanisms have been developed. Syngenta, Pioneer Hi-Bred, Monsanto, BASF Plant Science and others have invented and patented diverse sterility mechanisms as well as other GURTs. A different approach regarding GURTs involves plants that show certain valuable traits only if special chemicals are applied. These mechanisms are called Trait-GURTs. Traits, e.g. herbicide tolerance or salt tolerance, are expressed only if specific chemicals are applied to induce the transcription of certain genes.

The global area of genetically modified plants amounted to 90 million hectares in 2005, rising by 11% from 81 million hectares in 2004.[307] This area is grown by approximately 8.5 million farmers in 21 countries. The first transgenic crops were planted in 1996. All in all, 5% of the world's agricultural area has been cultivated with genetically modified plants. The U.S., Argentina, Brazil, Canada, China, Paraguay, and India are leading with regard to the cultivation of genetically modified plants. The share of developing countries, first and foremost China, India, Argentina, Brazil, and South Africa, cultivating genetically modified plants in 2005 was more than one-third of the global acreage, equivalent to 33.9 million hectares.[308]

Most of the genetically modified plants cultivated show agronomical traits, herbicide tolerance and insect resistance. The plant species are mainly soybean, corn, rape and cotton. The global market value of genetically modified plants was estimated at U.S.$5.25 billion in 2005, rising from U.S.$ 4.7 billion in 2004. This represents 15% of the global crop protection market and 18% of the global seed market.[309]

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307 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 3.

308 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 6.

309 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 7. For a more detailed economic analysis with further references see *Brookes&Barfoot,* GM Crops: The Global Economic and Environmental Impact - The First Nine Years 1996-2004, AgBioForum, Vol. 8 (2&3) (2005), Article 15.

II. Innovation related to the production of animal-derived agricultural raw materials

Innovation related to the production of animal-derived raw materials has been largely influenced by the application of biotechnology. The traits addressed by animal biotechnology involve nutrition, breeding and health. With respect to animal nutrition, genetically modified bacteria improve animals' health and the efficiency of their feed-to-weight conversion.[310]

Traditional breeding methods supplemented by molecular breeding, e.g. marker assisted selection, have accelerated the breeding process. Reproductive biotechnology, including artificial insemination and embryo transfer, accelerates it further.[311]

Which genes should be genetically modified to improve animal productivity or health is still difficult to predict. This is due to complex interactions of genes with each other and with the environment. Changes such as the introduction of genes that are involved in the expression of growth hormones have been successful.[312]

Animal biotechnology with regard to genetically modified animals has not yet been implemented to the same extent as plant biotechnology.[313] Genetic modification of animals is still in its infancy. Consequently, genetically modified animals for the production of agricultural raw materials have yet not been marketed in the EU. Rapid advances in molecular biology and developments in reproductive biology provide new tools for further innovation. Table 10 shows fields of biotechnological research related to the production of agricultural raw materials involving animals.

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310 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 23, available at www.ilsi.org/publications/ilsifobi.pdf.

311 FAO, Electronic Forum on Biotechnology in Food and Agriculture, Conference 3: The Appropriateness, Significance and Application of Biotechnology Options in the Animal Agriculture of Developing Countries, June 12–August 25, 2000, available at www.fao.org/biotech/C3doc.htm.

312 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 24, available at www.ilsi.org/publications/ilsifobi.pdf.

313 "Production of transgenic agricultural mammals is challenging and expensive, especially because of their low reproductive rate and internal fertilization and development." AO/World Health Organisation, Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, Rom 2003, 5, available at www.who.int/foodsafety/biotech/ meetings/en/gmanimal_reportnov03_en.pdf.