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REVIEW ARTICLE

Biotechnology: issues which should be or not

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ABSTRACT
Through the advancement of technology such as biotechnology, scientists have been able to develop more precise and powerful tools to produce crops and animals with selected traits that aim to benefit farmers and consumers.There is a rich public debate about how the potential risks associated with biotechnology methods and bio-industry products should be assessed and about whether and how bioethics should influence public policy.So, This article represents a review of the results of previous works about some of the ethical issues of biotechnology,especially genetically modified plants. We study the advantages and disadvantages of biotechnology and Finally, we evaluated the role of governments in providing important rules in biotechnology.
Key words: Biotechnology, ethical issues, Genetically Modified Foods

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Introduction

Nowadays, Most of genetic improvements can be grouped under the term biotechnology, which aims to use organisms, cells and or part of cells in technical or industrial processes (3, 10, 11). Genetic engineeringis the direct manipulation of an organism's genomeusing biotechnology. New DNA may be inserted in the host genome by first isolating and copying the genetic material of interest using molecular cloning methods to generate a DNA sequence, and then inserting this construct into the host organism (14, 15, 16).Food biotechnology is a branch of food science in which modern biotechnological techniques are applied to improve food production or food itself (9, 27). Different biotechnological processes used to create and improve new food and beverage products include industrial fermentation, plant cultures, and genetic engineering (20). Food science and food biotechnology was then progressed to include the discovery of enzymes and their role in fermentation and digestion of foods. With this discovery, further technological development of enzymes emerged. Typical industrial enzymes used plant and animal extracts, but this was later substituted by microbial enzymes. An example of this would be the use of chymosin in the production of cheese; cheese was typically made using the enzyme rennet which would be extracted from the stomach lining of the cow. Scientists then started using a recombinant chymosin in order for milk clotting, resulting in cheese curds (6). Food enzyme production using microbial enzymes was the first application of Genetically modified organisms in food production. Food Biotechnology has grown to include cloning of plants and animals, as well as more development in genetically modified foods in more recent years.

In 1994, the transgenic FlavrSavr tomato was approved by the FDA for marketing in the US - the modification allowed the tomato to delay ripening after picking (24). In the early 1990s, recombinant chymosin was approved for use in several countries, replacing rennet in cheese-making (39). In the US in 1995, the following transgenic crops received marketing approval: canola with modified oil composition (Calgene), *Bacillus thuringiensis* (Bt) corn/maize (Ciba-Geigy), cotton resistant to the herbicide bromoxiynil (Calgene), Bt cotton (Monsanto), Bt potatoes (Monsanto), soybeans resistant to the herbicide glyphosate (Monsanto), virus-resistant squash (Monsanto-Asgrow), and additional delayed ripening tomatoes (DNAP, Zeneca/Peto, and Monsanto) (25). In 2000, with the creation of golden rice, scientists genetically modified food to increase its nutrient value for the first time. As of 2011, the U.S. leads a list of multiple countries in the production of GM crops, and 25 GM crops had received regulatory

approval to be grown commercially (25). As of 2013, roughly 85% of corn, 91% of soybeans, and 88% of cotton produced in the United States are genetically modified.

Advantages of Biotechnology

Disease resistance: disease resistance is the reduction of pathogen growth on in the plant that this resistance can be performed by specialists of Biotechnology (2).

chilling tolerance: chilling tolerant species are able to grow at such cold temperatures. Cold stress is a major environmental factor that limits the agricultural productivity of plants in hilly areas.Biotechnology offers new strategies that can be used to develop transgenic crop plants with improved tolerance to cold stress (40, 41). A number of genes have been isolated and characterized that are responsive to freezing stress. Many studies have suggested that cold regulated gene expression is critical in plants for both chilling tolerance and cold acclimation.

Drought tolerance/salinity tolerance: transgenic plants over expressing the vacuolar H^+-pyrophosphatase are much more resistant to high concentrations of NaCl and to water deprivation than the isogenic wild-type strains (45).

Pest resistance: Insect attack is a serious agricultural problem leading to yield losses and reduced product quality (31). Plant biologists are workingto create plants with genetically-engineered resistance tothese pests.researchers have used genetic engineering to take the bacterial genes needed to produce such as Bt toxins and introduce them into plants. If plants produce Bt toxin on their own, they can defend themselves against specific types of insects. this means farmers no longer have to use chemical insecticides to control certain insect problems (4).

Herbicide resistance: Herbicide resistance is the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type. In a plant, resistance may be naturally occurring or induced by such techniques as genetic engineering or selection of variants produced by tissue culture or mutagenesis (12).

Nutrition: Nutrition and health are inextricably linked, so the multi-factorial influences on nutrition ultimately affect health. Malnutrition is characterized by dietary inadequacy sufficient to compromise resistance to disease, and is commonly associated with complex emergencies.golden rice is a variety of *Oryza sativa* rice produced through genetic engineering to biosynthesize beta-carotene, a precursor of Vitamin A, in the edible parts of rice. the research was conducted with the goal of producing a fortified food to be grown and consumed in areas with a shortage of dietary vitamin A, a deficiency which is estimated to kill 670,000 children under the age of 5 each year (35).

Pharmaceuticals: Medicines and vaccines often are costly to produce and sometimes require special storage conditions (13). Researchers are working to develop ediblevaccines in tomatoes and potatoes. these vaccineswill be much easier to ship, store and administer than traditional injectable vaccines (37).

Phytoremediation: Phytoremediation describes the treatment of environmental problems (bioremediation) through the use of plants that mitigate the environmental problem without the need to excavate the contaminant material and dispose of it elsewhere. Phytoremediation consists of mitigating pollutant concentrations in contaminated soils, water, or air, with plants able to contain, degrade, or eliminate metals, pesticides, solvents, explosive, crude oil and its derivatives, and various other contaminants from the media that contain them (1).

Criticismagainst GM FOODS and biotechnology

Nowadays, Environmental activists, religious organizations and government officials have all raised concerns about GM foods. It seems that everyone has a strong opinion about GM foods. most criticisms against biotechnology include environmental hazards, human health risks, and economic concerns.

Environmental Hazards

In 1999, Hileman showing that pollen from Bt corn caused high mortality rates in monarchbutterfly caterpillars. monarch caterpillars consume milkweed plants, not corn, butthe fear is that if pollen from Bt corn is blown by the wind onto milkweed plants inneighboring fields, the caterpillars could eat the pollen and perish. although the naturestudy was not conducted under natural field conditions, the results seemed tosupport this viewpoint. unfortunately, Bt toxins kill many species of insect larvaeindiscriminately; it is not possible to design a Bt toxin that would only kill cropdamagingpests and remain harmless to all other insects (8).

Gene transfer to non-target species

Another concern is that crop plants engineered forherbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicideresistance genes such as EPSPS from bacteria, fungi, and plants into the weeds (8).

Reduced effectiveness of pesticides

Just as some populations of mosquitoes developedresistance to the now-banned pesticide DDT, many people are concerned thatinsects will become resistant to Bt or other crops that have been

geneticallymodifiedto produce their own pesticides.there are several possible solutions to the three problems mentioned above. Two ways to ensure that non-target species will not receive introduced genes from GM plants are to create GM plants that are male sterile (do not produce pollen) or to modify the GM plant so that the pollen does not contain the introduced gene. another possible solution is to create buffer zones around fields of GM crops (8).

Human health risks

allergenicity Many children in the US and Europe have developed life-threatening allergies to peanuts and other foods. there is a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions (33). Extensive testing of GM foods may be required to avoid the possibility of harm to consumers with food allergies. labeling of GM foods and food products will acquire new importance.

unknown effects on human health there is a growing concern that introducing foreign

genes into food plants may have an unexpected and negative impact on human health (22). Yet critics say that this paper, like the monarch butterfly data, is flawed and does not hold up to scientific scrutiny. Moreover, the gene introduced into the potatoes was a snowdrop flower lectin, a substance known to be toxic to mammals (30). The scientists who created this variety of potato chose to use the lectin gene simply to test the methodology, and these potatoes were never intended for human or animal consumption.

Economic Concerns

Bringing a GM food to market is a lengthy and costly process. yet consumer advocates are worried that patenting these new plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds for GM crops, patent enforcement may also be difficult, as the contention of the farmers that they involuntarily grew Monsanto-engineered strains. one way to combat possible patent infringement is to introduce a suicide gene into GM plants. these plants would be viable for only one growing season and would produce sterile seeds that do not germinate. farmers would need to buy a fresh supply of seeds each year. However, this would be financially disastrous for farmers (32).

Classification of biotechnology opponents

Opponents concerns can be classified into two broad categories. on the one hand, some see the very act of using genetic technology to raise ethical issues that would not apply to other applications of food and agricultural technology. on the other hand, some believe that specific applications of biotechnology raise ethical issues that are not being adequately addressed, even if these issues may be raised in connection to other, more conventional types of agricultural technology (21,43) .

Responses to opponents

Uncertainty and the Precautionary Principle

Many of these ethical issues involve uncertainty about the risks or outcomes associated with biotechnology. theprecautionaryprinciple has been suggested as the appropriate decision rule to utilize in response to suchsituations. it suggests that decision makers should not permit technological innovations to goforward simply because alleged harms have not been proven to exist. however, it is notclear how the precautionary principle should be applied in the case of food and agricultural biotechnology (43, 7) .

Consent, Labels and Consumer Choice

Various proposals for labeling products of biotechnology have been discussed. on the one hand, these proposals are supported by aninformed-consent approach to issues in food safety, and may be the most satisfactoryresponse to concerns based on religious values, emotional repugnance and other intrinsicobjections to biotechnology. labels might give individuals who have these concerns anopportunity of exit, to opt out of a food system that causes them anxiety or concern. on theother hand, labels may stigmatize bioengineered foods, and may not provide information thatwould be useful for consumers trying to make choices on the basis of nutrition and food safety (43, 26) .

Religious views on genetically modified foods and biotechnology

Public acceptance of genetically modified crops is partly rooted in religious views. however, the views of different religions and their potential influence on consumers' decisions have not been systematically examined and summarized in a brief overview. we review the positions of the Judaism, Islam and Christianity – the three major monotheistic religions to which more than 55% of humanity adheres to – on the controversies aroused by GM technology.

Islam: Islam too forbids eating of pork, and Islamic scholars have also raised concern about the theoretical production of foods with genes from pigs. a seminar of Islamic scholars in Kuwait on genetics and genetic engineering in October 1998 concluded that although there are fears about the possibility of the harmful effects of GM food technology and GM food products on human beings and the environment, there are no laws within Islam which stop the genetic modification of food crops and animals and in 2003,

the Indonesian Ulemas Council (MUI) approved the importation and consumption of genetically modified food products by Indonesian Muslims voices in opposition to GMOs argue, based on the Quran, that there is no need for genetic modification of food crops because God created everything perfectly and man does not have any right to manipulate anything that God has created nor to tamper with it (34).

Table 1: Adapted from article of (3)

Main advantages	Reference(s)
High yield productions	Wisniewski et al., 2002; van Meijl and van Tongeren, 2004; Egelyng, 2000; Kuiper et al., 2002; Uzogara, 2000
Cheaper products	van Meijl and van Tongeren, 2004
Greater drought resistance	Sharma, 2003

Main disadvantages	Reference(s)
Less quality of foods	Phillips, 1994; Young and Lewis, 1995; Hobbs and Plunkett, 2000; Knoppers and Mathios, 1998
Antibiotic resistance	Hileman, 1999a; Phillips, 1994; AgResearch, 2001; Malarkey, 2003
Potential toxicity from GM foods	Phillips, 1994; Malarkey, 2003
Possible creation of allergenicity	Billings, 1999; Coleman, 1996; Nordlee et al., 1996; Malarkey, 2003; AgResearch, 2001
Unintentional gene transfer from GM to non-GM crops or to wild plants	Hileman, 1999a; Kaiser, 1996; Rissler and Mellon, 1993, 1996; AgResearch, 2001; Downey and Beckie, 2002; Haslberger, 2001; Rieger et al., 2002; Gilligan et al., 2003; Hucl and Matus-Cadiz, 2001, Soregaroli and Wesseler, 2003
Possible creation of new viruses and toxins	Phillips, 1994; AgResearch, 2001; Malarkey, 2003; Patterson and Painter, 1999; Weihl and Roos, 1999
Limited access to seeds through patenting of GM food plants	Lustgarden, 1994; Koch, 1998
Threat to crop genetic diversity	Koch, 1998; Phillips, 1994; AgResearch, 2001
Religious/cultural/ethical concerns	Crist, 1996; Robinson, 1997; Thompson, 1997; Dyer, 1996; Wilmut et al., 1997; Woodard and Underwood, 1997; Schardt, 1994; Share, 1994
Concerns for lack of labeling	Federal Register, 1992; Hoef et al., 1998; Cummins, 1997; Weiss, 1998
Concerns of animal rights group	Kaiser, 1996; Koenig, 1999; Dyer, 1996; Wilmut et al., 1997
Concerns of organic and traditional farmers	Koch, 1998; AgResearch, 2001
Fear of the unknown impacts	Koch, 1998; Longman, 1999; AgResearch, 2001
The risk of the GM plant itself becoming a weed	AgResearch, 2001
Concerns over the wider ecosystem because of direct and indirect effects on no target species	ACRE, 1997; Mantegazzini, 1986; Diamond, 1997
Environmental concerns	Longman, 1999; OECD, 1993; Raybould and Gray, 1993; Ellstrand, 1992; Ellstrand and Hoffman, 1990

Christianity: Views of Rome on genetic engineering In 1999, after two years of discussions, the Vatican's pontifical academy for lifestated that modifying the genes of plants and animals is theologically acceptable. theguardian reported that Bishop ElioSgreccia, vice- president of the pontifical academy, said: We are increasingly encouraged that the advantages of genetic engineering of plants and animals are greater than the risks. The risks should be carefully followed through openness, analysis and controls, but without a sense of alarm.referring to genetically modified products such as corn and soya, Sgreccia added: We give it a prudent 'yes' We cannot agree with the position of some groups that say it is against the will of God to meddle with the genetic make-up of plants and animals (28,36).

Judaism: There is no consensus in the views of Jewish religious leaders, scholars and commentators on whether Jews can eat GM food products or engage in research in the area of GM food technology.

one perspective emphasizes that humanity was created in God's image and this means that humanity can partner with God in the perfection of everything in the world, and therefore Jewish law accepts genetic engineering to save and prolong human life as well as increase the quality or quantity of the world's food supply.

Other perspectives hold that GM food technology is a violation of Kilavim, the mixed breeding of crops or livestock, and that because God made "distinctions in the natural world, Jews must honor them (42).
Based on analysis of Omobowale *et al* in 2009, these results were obtained: first there is no consensus on whether GM food technology should be banned or accepted by the religious groups discussed. second, there is also no monolithic view of beliefs within each religion with respect to GM food technology, a situation, which gives room for different interpretations of issues. third, there is no agreement on what should be prescribed for the followers of each religion with regards to GM food products and the comments by the religious leaders are intended to simply provide guidance about GM food technology. fourth, competing with the influence exerted on consumers by religion are several other interests like the media, environmental activists, scientists and the food industry, all of which function as sources of information for consumers. thus, these religions, while assisting adherents in forming opinions, can only be one of the many factors that can be expected to influence consumers' decisions on GM food technology.

Labeling of Genetically Modified Foods

Whether or not to require labeling of food produced from crops that are genetically modified (GM) using recombinant DNA technology is a key issue in the ongoing debate over the risks and benefits of using biotechnology in agriculture. The U.S. government regulates GM food technologies, but once GM crops are approved they are considered to be substantially equivalent to their conventional counterparts in terms of safety. Therefore, there is no federal requirement for labeling food that contains GM ingredients. Bills and ballot initiatives requiring mandatory labeling have been introduced and voted on in several states. The first states to have approved some form of mandatory labeling are Connecticut, Maine, and Vermont. Under U.S. law, companies may voluntarily label food products to inform consumers as to whether they do or do not contain ingredients from GM crops(19).
There are many questions that must be answered if labeling of GM foods becomes mandatory. First, are consumers willing to absorb the cost of such an initiative? If the foodproduction industry is required to label GM foods, factories will need to construct twoseparate processing streams and monitor the production lines accordingly. Farmers mustbe able to keep GM crops and non-GM crops from mixing during planting, harvesting and shipping (29). It is almost assured that industry will pass along these additional costs toconsumers in the form of higher prices. Secondly, what are the acceptable limits of GM contamination in non-GM products? The EC has determined that 1% is an acceptable limit of cross-contamination, yet many consumer interest groups argue that only 0% is acceptable. Some companies such as Gerber baby foods and Frito-Lay have pledged to avoid use of GM foods in any of their products. But who is going to monitor these companies for compliance and what is the penalty if they fail? Once again, the FDA does not have the resources to carry out testing to ensure compliance.

What are the roles of government in agricultural biotechnology?

Governments around the world are hard at work to establish a regulatory process to monitorthe effects of and approve new varieties of GM plants. yet depending on the political,social and economic climate within a region or country, different governments are respondingin different ways (18).
In Japan, the Ministry of Health and Welfare has announced that health testing of GMfoods will be mandatory as of April 2001. Currently, testing of GM foods is voluntary.Japanese supermarkets are offering both GM foods and unmodified foods, and customersare beginning to show a strong preference for unmodified fruits and vegetables (38).
In the newly emerging field of biotechnology, Japan so far is generally considered to be lagging somewhat behind the US. Through the judicious application of industrial policy to encourage the growth of the industry, however, Japan is rapidly gaining on the US lead. Joint ventures between large Japanese Companies specializing in areas such as chemicals and food and new American biotechnology companies play a key role in the technology-transfer process (44). The Department of Biotechnology (DBT) is an Indian government department, under the Ministry of Science and Technologyresponsible for administrating development and commercialization in the field of modern biology and biotechnology in India. It was set up in 1986.through several research and development projects, demonstrations, grants and creation of infrastructural facilities a clear visible impact of this field has been seen. The department has made significant achievements in the growth and application of biotechnology in the broad areas of agriculture, health care, animal sciences, environment, and industry. the proven technologies at the laboratory level have been scaled up and demonstrated in field.
patenting of innovations, technology transfer to industries and close interaction with them have given a new direction to biotechnology research in India. Initiatives have been taken to promote transgenic research in plants with emphasis on pest and disease resistance, nutritional quality, silk-worm genome analysis etc.
on the other hand, molecular biology of human genetic disorders, brain research, plant genome research, development, validation and commercialization of diagnostic kits and vaccines for communicable

diseases, food biotechnology, biodiversity conservation and bioprospecting, setting up of micropropagation parks and biotechnology based development for SC/ST, rural areas, women and for different States (5).

Commercial biotechnology has taken longer to catch fire in Europe. Within recent years, however, several European governments have awakened to the potential benefits of a strong biotechnology sector. "Politically, Europe is becoming a more conducive environment for biotech businesses," states European Life Sciences 99, a report issued by consulting firm Ernst & Young. "Governments are looking for ways of establishing supportive infrastructure and changing tax regimes to encourage venture capital investment and entrepreneurial risk taking."

Specific regions in Europe, often stimulated by national and local governments, have started their own aggressive efforts to create effective local bases for industrial biotechnology. To set up successful clusters, however, these regions need more than government support. Just as in the case of North America (see *Science* advertising supplement, May 7, 1999, page 989), significant factors include good relations with academic departments that specialize in the life sciences, the availability of educated venture capital, and the development of critical masses of companies involved in biotechnology and related activities.

Three other factors that have had relatively little impact in North America influence the growth of biotechnology in Europe. They are state organization of scientific activity, which in some countries controls what scientists can and cannot contribute to commercial enterprises; an attitude toward failure that is far more conservative than that in the New World; and public opinion, which is frequently against the growth of biotechnology.

Thus, the continent that created Dolly the sheep, the world's first cloned mammal, is now in the midst of a raging debate about the acceptability and labeling of genetically modified foods. "The public believes it has the right to have a say in the debate, not just as a consumer but also because it is subsidizing much of the scientific enterprise through research grants and tax breaks," states the Ernst & Young report. "The public is looking to the politicians to focus on the detail to ensure that it is not exposed to avoidable risk."

Attitudes toward risk also differentiate Europe from North America in terms of growth opportunities for the biotechnology industry. "The culture is still very negative towards people who have failed in business," says William Powlett Smith, who works in Ernst & Young's British branch. "It's very difficult to obtain backing once you've gone bust once."

Such attitudes do not have an entirely negative impact. Financial caution seems to act as a kind of Darwinian screen, one that acts very fast. "In comparison with typical U.S. companies, German biotechnology companies have to get their first revenues very quickly," says Ralf Kindervater, general manager of Bio start, a broker that helps biotechnology start-ups in Jena, Germany. "That means that the start-ups are rather healthy. They don't have to keep going from one financing round to the next."

In Europe, anti-GM food protestors have been especially active. In the last few years

Europe has experienced two major foods scares: bovine spongiform encephalopathy (madcow disease) in Great Britain and dioxin-tainted foods originating from Belgium. Thesefood scares have undermined consumer confidence about the European food supply, andcitizens are disinclined to trust government information about GM foods. In response tothe public outcry, Europe now requires mandatory food labeling of GM foods in stores,and the European Commission (EC) has established a 1% threshold for contamination ofunmodified foods with GM food products.

In 2005, Iran's first genetically modified (GM) rice was approved by national authorities and is being grown commercially for human consumption. In addition to GM rice, Iran has produced several GM plants in the laboratory, such as insect-resistant maize; cotton; potatoes and sugar beets; herbicide-resistant canola; salinity- and drought-tolerant wheat; and blight-resistant maize and wheat. However, there is much opposition to transgenic crop plants (23).

The federal government of the United States developed a coordinated framework for the regulation of biotechnology in 1986 to provide for the regulatory oversight of organisms derived through genetic engineering. The three principal agencies that have provided primary guidance to the experimental testing, approval, and eventual commercial release of these organisms to date are the USDA's Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). The approach taken in the Coordinated Framework is grounded in the judgment of the National Academy of Sciences that the potential risks associated with these organisms fall into the same general categories as those created by traditionally bred organisms.

Products are regulated according to their intended use, with some products being regulated under more than one agency. All government regulatory agencies have a responsibility to ensure that the implementation of regulatory decisions, including approval of field tests and eventual deregulation of approved biotech crops, does not adversely impact human health or the environment.

In the United States, the regulatory process is confused because there are three differentgovernment agencies that have jurisdiction over GM foods. To put it very simply, theEPA evaluates GM plants for environmental safety, the USDA evaluates whether theplant is safe to grow, and the FDA evaluates whether the plant is safe to eat. The EPA isresponsible for regulating substances such as pesticides or toxins that may cause harm tothe environment. GM crops such as B.t. pesticide-laced corn or herbicide-tolerant cropsbut not foods modified for their nutritional value fall under the purview of the EPA.
TheUSDA is responsible for GM crops that do not fall under the umbrella of the EPA such asdrought-tolerant or disease-tolerant crops, crops grown for animal feeds, or whole fruits,vegetables and grains for human consumption. The FDA historically has been concerned with pharmaceuticals, cosmetics and food products and additives, not whole foods. Undercurrent guidelines, a genetically-modified ear of corn sold at a produce stand is not regulatedby the FDA because it is a whole food, but a box of cornflakes is regulated becauseit is a food product. The FDA's stance is that GM foods are substantially equivalent tounmodified, "natural" foods, and therefore not subject to FDA regulation (17,18).

CONCLUSION

Although GM food is important and beneficial, it should be adopted under conditions that avoid potential risks. Time and effort must be devoted to on-farm trials before any interventions in this regard. Policy makers and researchers in developing countries should carefully assess environmental risks (such as the major risks to biodiversity, the prospects of insufficient out-crossing distances, the relative absence of clear labeling and other threats to seed purity, adjacent traditional food production) before farmers change their conventional farming methods to GM. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy and food labeling. Finally, the public understanding should be sufficiently promoted on both GM and OF methods to recognize the health foods. Private and public sector leaders should also understand the level of consumer's awareness and acceptability of new products. This will enable them to plan a strategy for improvement the quality and quantity of agricultural products.

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