Chapter 13

Food Safety Issues and Policy Options

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Chapter 13
Food Safety Issues and Policy Options

Biotechnology rekindles many of the same scientific issues concerning food safety raised by previous agricultural technologies. What is substantially different, however, is the climate in which this new class of technologies is being introduced. Society in general is more skeptical of the need for new technologies. Scientific illiteracy combined with a lack of knowledge about agriculture leads some people to misunderstand how and why biotechnologies will be used. Scandals involving institutions that develop and regulate these technologies have shaken the public's confidence in the ability of these institutions to carry out their activities responsibly. These factors lead to a high level of uncertainty among the public, and a desire for a high level of scrutiny in the development and use of new technologies. Consumers generally are willing to accept some risk if it is accompanied by a clear benefit to them. New biotechnologies that appear to or are perceived to put consumers at risk, but whose benefits accrue to someone else, are likely to meet with more consumer resistance.

The extent to which the public accepts or resists these new technologies will be influenced greatly by its confidence in the ability of the Federal regulatory agencies to protect public health and safety. Public confidence will decline if people feel that safety standards are too lax, cannot be adequately established due to scientific uncertainty, or arise through a process that is flawed or corrupt. Even if consumers have confidence that the established safety standards are adequate, they may worry about adequate enforcement. Enforcement may become more difficult if labels cannot be verified, imports increase, or if fewer or inappropriate resources are allocated to enforcement.

In addition to public confusion, uncertainty exists within industry as to how new food technologies will be regulated. After considerable delay, the Food and Drug Administration (FDA) in May 1992, released preliminary guidelines with respect to new biotechnology-derived food products. The Environmental Protection Agency (EPA) has yet to establish guidelines on data requirements needed to determine residue tolerances for pesticidal plants, and the Food Safety Inspection Service (FSIS) has not established guidelines concerning the slaughter of transgenic animals. Genetically engineered products, plants in particular, are approaching the commercialization stage at a faster rate than anticipated even 5 years ago. These agencies no longer have the luxury of long timeframes with which to articulate policy.

Uncertainty over how these products will be regulated must end. Additionally, there is a general need to regain public confidence in the regulatory agencies responsible for determining the safety of new biotechnology products. As a result of this study, OTA concludes that:

- At present consumers and producers are in limbo. Clear federal regulatory policies are needed. Preliminary FDA guidelines just released are still subject to public comments and possible revisions before receiving final approval. EPA, FSIS, and Agricultural Marketing Service (AMS) have not yet published regulations and guidelines concerning how they intend to address biotechnology food products. Both FDA and EPA need to establish scientific criteria needed to assess the safety of those products they decide to regulate.
- Public confidence in Federal regulatory institutions has been shaken. There is a general need to reestablish the credibility of these agencies so that the public will have confidence that Federal regulatory decisions concerning new biotechnology products are appropriate. Three areas that need to be addressed include: 1) public input into the decisionmaking process, 2) evaluation of the tradeoffs between industry competitive positions and the public's right to be adequately informed about health and safety issues that affect them, and 3) improved enforcement of regulations.
- Traditional approaches to food safety assessment are inadequate to assure the safety of biotechnology food products. A new food safety approach is needed. New analytical techniques must be developed.
- The United States imports billions of dollars worth of food products each year. The United States is not the only country capable of genetically engineering foods. International coordination on regulatory issues dated to biotechnology food products is imperative.

ISSUE: ESTABLISHMENT OF FEDERAL REGULATIONS AND GUIDELINES FOR BIOTECHNOLOGY FOOD PRODUCTS

Findings

In the first half of the 1980s, it was anticipated that animal biotechnologies would be developed more quickly

than plant biotechnologies because more was known about animal physiology than plant physiology. Several major scientific breakthroughs were considered necessary to speed the development of transgenic plants. Those breakthroughs have occurred, and now FDA and EPA no longer have the luxury of continuing to delay the establishment of final regulations and guidelines. Several transgenic plants are in various stages of field testing, and Federal regulatory agencies are being asked to provide advisory opinions concerning the regulatory status of these products. Transgenic plants are approaching commercialization, and scientific guidelines for assessing the safety of these plants, where required, will be needed. Continued delay in finalizing these regulations will slow the commercialization of new biotechnology products, putting American industry at a competitive disadvantage, while continuing to undermine public confidence in the ability of regulatory agencies to establish a clear policy concerning biotechnology.

As discussed in chapter 10, FDA is wrestling with whether or not to classify transgenic plants as food additives. In May 1992, FDA published a preliminary proposal regarding the regulation of new varieties of genetically modified crops. This policy states that FDA is concerned with the characteristics of the food product and not with the method used to produce the product. Thus, new genetically modified crop varieties will not automatically be required to obtain a food additive regulation. New varieties that do not contain new toxicants, elevated levels of inherent toxicants, altered nutrient composition or bioavailability, or enhanced allergenic potential may be regarded as not significantly different from conventionally produced new varieties that are generally regarded as safe. These varieties could be marketed without premarket oversight by FDA. The adulteration clauses of the Federal Food, Drug, and Cosmetic Act could be used to remove these varieties from the market if FDA disagrees with a firm's safety evaluation. Varieties that contain substances (either gene expression products or unintended products) that differ significantly in structure, function, and composition from substances currently contained in foods may be required to obtain a food additive regulation.

The lack of a priori oversight of some new varieties, however, may still leave considerable uncertainties in the minds of the public, at least for the first generation of products developed. Public confidence in the process may still require at least a minimum review of the product prior to commercial release. Such review may consist of notifying FDA of the development of a transgenic crop and provision of a minimum level of data so that FDA can make a determination as to whether a food additive petition will be needed. Such a notification process could be open to the public so that any significant concerns can be identified. Additionally, public interest groups have expressed opposition to the policy and have threatened legal action to prevent its implementation. The policy is currently open to public comment, and could be subject to revision. Congress may yet be required to intervene in the development of food biotechnology regulations if differences cannot be resolved in a timely fashion. If such action is needed, several options are available to Congress.

Policy Options

Option: Congress could monitor the development of regulations and conduct oversight hearings of FDA and EPA to determine why final regulations and guidelines do not exist and to have them report back to Congress with recommendations in these areas within a specified period of time.

This would be a strong signal to the executive branch that Congress is concerned about the delay in providing guidance to the private sector for these new technologies. An oversight hearing would provide the agencies with an opportunity to explain their rationale and concerns in establishing regulations for these new products and allow Congress the opportunity to provide guidance and direction to the agencies.

Congress and the executive branch through EPA, FDA, and USDA have a number of options for regulating transgenic organisms. The following illustrates options available.

Option: Congress or FDA could establish categorical exclusions to the requirement of a food additive regulation for certain transgenic organisms and require a case-by-case approach for the remaining products.

Essentially, this is the policy chosen by FDA. Transgenic organisms that involve gene products that are widely present in the current food supply, and do not introduce new toxicants, elevate levels of existing toxicants, alter the composition or bioavailability of nutrients, or transfer allergenic components, and that use safe marker and promoter sequences can be excluded from the need for a food additive regulation. These products do not introduce new food compounds into the food supply and they have no unintended effects. Therefore, FDA states that they can be classified as GRAS because they are equivalent to traditional new varieties that historically have been given GRAS status. Only products that contain compo-

nents that are significantly different in structure, function, and composition may be required to obtain a food additive regulation on a case-by-case basis. This option is a risk based option that requires extensive safety testing for products that are not normally found in the food supply, and less testing for products that contain substances already widely consumed. It places responsibility for the initial food safety assessment with industry. Lack of FDA oversight, especially for the first generation of biotechnology-derived food products, may raise public concerns. A number of public interest groups have indicated their opposition to this policy.

Option: Congress or FDA could establish a policy similar to the preliminary policy articulated by FDA, and include a formal notification procedure.

Such a policy would require the establishment of a system for notifying FDA when a new transgenic crop is marketed. As currently outlined, FDA policy allows firms to determine if a new variety contains components that are already widely consumed. Thus, firms can make a determination about the GRAS status of new biotechnology products without consulting FDA. In the beginning, it is highly probable that most firms will consult FDA prior to marketing a new biotechnology-derived variety, but they are not required to do so. This situation is likely to create considerable apprehension among the public. Thus, a formal system of notification may be desirable.

The notification process could include safety data the company used to determine that the product was GRAS. Such data includes the identity of the host and donor organisms, information on the genetic construct, and information on the physiology of the gene product. Additional information required could include compositional data. A comparison of nutrient and toxic component levels in transgenic and counterpart traditional crops could be included, as well as data on allergens. This type of information will be available in the development of transgenic organisms and is required for a company to make its determination of the regulatory status of the product. Thus, requiring this information to be on record with FDA should not present undue burdens on industry. However, requiring FDA to review and act on this information for all transgenic crops will place a strain on the agency's resources. Most likely FDA will need additional resources to implement this policy.

The notification process could be open to the public so that they can raise concerns and issues regarding transgenic organisms. It may also be useful for FDA to use an advisory committee to comment on the data presented. If an advisory committee is used, representatives from the public could be included along with technical representatives.

Such a policy might be effective for the safety assessment of the first biotechnology food products developed. It would allow FDA to provide at least minimal oversight over all biotechnology food products, assure the public that scientific information is available, and thus, might alleviate some public concern. In the short run, such a policy may appear to result in unnecessary regulation of these products. However, it may be the price industry must pay to have their products accepted by the public, at least in the initial stages of commercializing biotechnology food products.

Option: Congress or FDA could require a food additive petition for all transgenic crops.

This policy would force all transgenic food products to undergo a premarket safety approval process. Such a process would be tantamount to regulating the process rather than the product. It would not be based on the risks involved with the product itself, but rather would reflect a categorical determination that the process of genetic engineering is inherently risky, an assumption not established by scientific data. This policy would likely delay commercialization of transgenic crops already being developed and possibly could inhibit the development of additional transgenic crops. Such a policy, however, would not be inconsistent with a broad interpretation of the food additive definition. It probably would soothe some consumer fears and uncertainties about these products.

Option: Congress or FDA could establish some categorical exclusions of transgenic food products from the requirement of a food additive petition, and require all other biotechnology products to meet the requirements for a food additive petition.

Once again categorical exclusions might include transgenic crops that do not contain components that are significantly different from those currently present in the food supply and for which unsafe, unintended components have not been introduced. This policy would be more risk-based than requiring all transgenic organisms to meet the rigors of a food additive petition, because transgenic organisms that are essentially the same as products that have historically been viewed as safe would not be required to undergo premarket approval. This policy would ease some of the burden on industry. There may still be public apprehension with respect to those products that have been excluded.

Option: Congress or FDA could establish a policy in which the gene expression product is classified as a food additive if it would have been classified as such if added during the processing stages, and excluding from the food additive definition gene products that would not have been classified as a food additive if produced by traditional means.

A policy similar to this has been recommended by a group of food manufacturers (i.e., the International Food Biotechnology Council). Gene products that might be excluded as food additives are those that would code for agronomic functions such as drought resistance. Genes products that might be classified as food additives are those that would be considered a food additive if added during the processing stage, such as natural preservatives. However, this policy seems to be based more on the intended use of the gene product rather than any safety risk that that gene product may pose. Such a policy may be consistent with how FDA has historically interpreted the food additive amendment, but would be difficult to justify on scientific grounds.

Option: Congress or FDA could establish a policy that the need for a food additive petition be determined on a case-by-case basis for each transgenic organism.

Such a policy would allow FDA to provide oversight of all biotechnology products. This would provide the public with an assurance that all transgenic organisms would be reviewed by FDA. However, continuation of this type of policy indefinitely could overwhelm FDA, since the number of products that could be developed is large. At some point, FDA will likely need to categorize some products as GRAS, just as it does with chemical additives.

FDA is not alone in slowly establishing regulations regarding biotechnology food products; EPA has also failed to provide guidelines for establishing or exempting pesticidal biotechnology products from the requirements of residue tolerances. EPA generally exempts microbial pesticides from the requirement of a pesticide tolerance, and it is possible that microbial pesticides produced by genetic engineering techniques will also be exempted. EPA however, has not clarified how it will handle pesticidal whole plants with respect to the need to establish tolerances. Clarification is needed. Pesticidal transgenic plants are already in advanced stages of field testing, and applications to register some of these products will soon be forthcoming. Guidelines outlining what substances (e.g., the whole plant, plant extracts, single gene products) require a tolerance are needed. Additionally, because State agencies, FDA, and USDA rather than EPA enforce the tolerances, EPA needs to work closely with the appropriate agencies in establishing tolerances. EPA does meet with officials from FDA and United States Department of Agriculture (USDA). However, EPA has not adequately worked with States in establishing these tolerances.

Option: EPA may wish to hold workshops with State regulators to clarify and establish its policy position with respect to biotechnology food products.

State laws may not be compatible with EPA regulations, and some States may lack the authority or expertise to carry out EPA regulations with respect to pesticidal biotechnology products. New laws may need to be passed or old laws amended. Personnel and laboratory assay methods may need to be changed. States cannot plan for new contingencies because EPA has not kept the States informed about its intentions. In fact, it is only recently that EPA has even contracted to compile a list of contact persons in State agencies. This lack of cooperation and coordination with the States could easily lead to significant delays and difficulties with State implementation of EPA regulations with respect to pesticidal biotechnology products. Congressional hearings and oversight may be necessary if EPA does not rectify this situation.

FSIS's food safety responsibilities with respect to biotechnology products lies primarily with animal inspection. FSIS will be responsible for inspecting transgenic livestock. Transgenic livestock will not be commercially available for several years. However, transgenic research is proceeding. Given the high cost and the inefficiency of the research, many researchers would like to be able to slaughter experimental animals in which attempts to insert genes failed. FSIS plans to release guidelines in the near future concerning the slaughter of these experimental animals. Of particular interest will be guidelines concerning the slaughter and potential food use of transgenic animals that produce pharmaceuticals.

Option: Congress or EPA could establish guidelines for the safety evaluation required to establish pesticide tolerances for whole plants.

Currently, EPA does have guidelines for transgenic pesticidal microorganisms, but has yet to establish such guidelines for whole plants. Transgenic plants producing pesticidal compounds, such as Bt producing plants, are completing small-scale field trials. Guidance from EPA for dealing with such plants can no longer be delayed. Establishment of safety guidelines will require a new assessment paradigm (discussed later). Additionally, be-

cause States, FDA, and USDA enforce pesticide tolerances, EPA needs to work closely with appropriate agencies in establishing tolerances. EPA's work with States needs improvement in this area. Only recently has EPA even begun to compile a list of contact persons in State agencies. This ignoring of States could easily lead to State laws that are incompatible with Federal regulations, or to gaps in State authority or expertise to carry out Federal regulations. Congressional hearings and oversight may be necessary if EPA does not improve this situation.

Option: Congress or USDA -FSIS could establish guidelines concerning transgenic animals.

USDA-FSIS plans to release guidelines in the near future concerning the slaughter of experimental animals in which gene transfer attempts failed. Guidelines concerning the slaughter of transgenic livestock are still in early draft form. Of particular interest will be guidelines concerning the slaughter and potential food use of transgenic animals that produce pharmaceuticals. FSIS and FDA have established a joint committee to deal with issues that jointly affect the two agencies. Careful monitoring of how successful this committee is may be required.

Option: Congress may wish to monitor the development of guidelines established for the slaughter of transgenic livestock that produce pharmaceuticals.

The first transgenic livestock to be available may well be animals engineered to produce pharmaceuticals. FDA and FSIS will share food-safety responsibilities for these animals, and the two agencies have established a joint committee to deal with issues that jointly affect them. Careful monitoring of how successful this committee is may be required.

ISSUE: PUBLIC CONFIDENCE IN THE DECISIONMAKING PROCESS

Findings

One method of enhancing public confidence in the regulatory process is to make that process more open and accessible to the public. Decisions made in secret and not explained to the public often are greeted with distrust.

Opponents of increased public input in regulatory processes argue that citizens lack the training needed to understand complicated scientific and technical issues, and as such their participation only delays the agency's decisionmaking without offering any offsetting benefits. Critics also fear that public representatives may act in emotional and irrational ways and make unreasonable demands. Those who support increased public input argue that such input is invaluable in establishing the legitimacy of regulatory decisions. Indications also exist that public participation can encourage agencies to focus on a wider range of issues and values than they normally would. And, it is hard to deny public participation in regulatory processes in a democratic society.

The public will not make regulatory decisions—that is the responsibility of the State and Federal agencies whose statutory authority requires them to ensure a safe and wholesome food supply. However, public confidence that these agencies are fulfilling their responsibilities will be enhanced if there are mechanisms available for public questions and concerns to be heard and addressed prior to decisions by the regulatory agency. At present, public input into the regulatory process consists of notification and comment procedures and participation on advisory committees.

The rationale for using advisory committees is to provide expert knowledge to agencies and to enhance the credibility of their final decisions. Including public representatives in addition to technical experts and possibly industry representatives not only ensures that a broader range of issues will be addressed, it also may forestall public outcry about issues that, if aired, are not likely to raise public concerns. If the public accepts decisions because the solutions appear valid and the process was fair, industry is likely to lose less money, time, and credibility than if the decision was made based solely on industry views. Even for highly technical committees, public members force experts to express their answers in terms and concepts understandable to most people (3). However, "the public" may also include special interests who can use their membership on advisory bodies to promote private concerns. A real danger exists in allowing special interest groups to exercise undue influence on the government or to dominate advisory committees that deal with matters in which they have vested interests (3).

With these dangers in mind, Congress passed the Federal Advisory Committee Act in 1972 (5 USC app 2), which generally stipulates that the need for advisory committees must be reviewed and substantiated, that the public must have access to advisory committee meetings and all records and documents relied on by committee members, that the membership on all advisory committees be fairly balanced with respect to viewpoints and functions,

and that committees act only in an advisory capacity and be independent of agency influence. Closed sessions can be held when trade secrets or confidential commercial information is considered, for matters involving the review of investigative files, or for review of matters that would constitute an invasion of privacy. Public notice is required and public participation is encouraged. Minutes and reports must be available for public inspection (3).

The FDA uses notification and comment procedures for decisions concerning food additives and advisory committees for decisions concerning drugs. Any person may petition FDA to establish a regulation to approve the use of a food additive (21 U.S.C. 409(b)(l)). If FDA concurs that a regulation is required, it must publish a notice of that decision in the Federal Register. Any person who might be adversely affected by the proposed decision has 30 days to request a hearing. Additionally, FDA relies on input from scientific organizations, such as the National Academy of Science (NAS) and the Federation of American Societies for Experimental Biology (FASEB), and consultants for issues concerning food additives.

FDA is not required to publish the notification of the receipt of a new drug petition, except in the case of some veterinary drugs. Administration of veterinary drugs may involve release of organisms into the environment. Under such circumstances, FDA may be required to comply with National Environmental Policy Act (NEPA) requirements for public notification and comment.

Public participation in the drug approval process comes primarily from the use of advisory committees, although public participation in these committees is limited. Advisory committees advise and recommend policy, but do not make regulations themselves. Congress mandated the use of advisory committees for drugs, and currently FDA has 38 standing advisory committees most of which are concerned with human drugs and medical devices. There is one veterinary drug advisory committee. Only technical experts can be voting members of FDA advisory committees. However, industry and public representatives serve on such committees also but as non-voting members (l).

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires EPA to publish a notice of receipt of any pesticide registration that involves a new ingredient or new use. EPA must also publish a notice of the receipt of any Environmental Use Permit (EUP) that is of regional or national significance. EUP's are required before pesticides can undergo field trials of greater than 10 land acres or 1 surface acre of water. Notifications are published in the Federal Register and the public has 30 days to provide written comments. EPA also publishes a notice of the issuance of pesticide regulations and EUP's. If public comments indicate that there is sufficient interest or that it would otherwise be in the public interest, EPA can hold a public hearing concerning an application.

EPA may seek additional advice concerning petitions that raise significant issues via intra- or interagency reviews and advisory committees. EPA has established a standing committee for biotechnology, the Biotechnology Science Advisory Committee (BSAC) which is composed of 9 scientists and 2 persons from the public. EPA tries to draw a distinction between truly private citizens and representatives of public interest groups (40 CFR 25.7(c)(l)(iand ii)).

The Poultry Products Inspection Act; the Federal Meat Inspection Act; and the Virus, Serum, Toxin Act do not require public comment concerning agency regulations. USDA (primarily Agricultural Plant Health Inspection Service [APHIS]) has voluntarily notified State agencies and the public when environmental releases might occur. The USDA has established a standing advisory committee for biotechnology = mthe Agricultural Biotechnology Research Advisory Committee (ABRAC), which is composed of 11 scientists and 2 lawyers. This committee advises on regulatory matters as well as research issues.

Policy Options

Option: Congress could direct agencies (FDA, USDA) to establish a mechanism to allow for increased public participation and to report its results to Congress.

This option sends a clear message to the agencies that Congress is concerned about the public's view of regulatory agencies and that the public should be more involved in the decisionmaking process. It gives maximum flexibility to the agencies to determine the method of incorporating the public's input.

A number of mechanisms are available. For example, Federal agencies could establish criteria by which local agencies can be notified any time significant risk or unique questions arise that are pertinent to them. Agencies may wish to adopt a procedure similar to that used by FIFRA, i.e., notification of petitions received, and if public interest warrants, an informal hearing. Increasing public participation will require increased resources and risk politicizing decisions, but could also enhance public confidence in the regulatory process. It might cost less in the long run.

Option: Congress could direct the agencies to increase the use of advisory committees for decisions involving biotechnology and to change the composition of their membership to increase the number of nontechnical public representatives.

For FDA, advisory committees could help establish GRAS and the minimum information needed for food additive applications of genetically engineered whole foods. These committees could be used as a first screening mechanism to see if a food additive petition is actually needed. Public meetings help assure the scientific validity of the process. EPA might also use advisory committees to establish tolerances for genetically engineered plants with pesticidal properties. This might be helpful since in-house expertise to handle this responsibility seems to be lacking. Advisory committees might also prove useful to USDA in establishing a policy on transgenic animals. The credibility of any advisory committee will be enhanced if it includes public representatives.

FDA may need to consider granting current nonvoting members of its advisory committees the right of full voting membership. And they may need to expand the list of technical fields beyond MDs from which experts are drawn.

Use of advisory committees presents some logistical problems and requires additional resources, but provides expertise that currently may be missing. Additionally, the possibility that nontechnical representatives will pursue political agendas and unnecessarily delay committee decisions exists. However, used properly, such representatives can focus the attention of the committee on issues that might otherwise be overlooked and provide legitimacy to committee decisions.

Option: Congress could direct the agencies (EPA, FDA, USDA) to change the notification procedures for advisory committee meetings.

The standard method of notification involves publication in the Federal Register. Few members of the public know what the Federal Register is, much less read it regularly. Also, notices published are written by and for those knowledgeable in the field and, thus, the general public might not recognize what the issue is. Additionally, most meetings are held in Washington, DC. Agencies could have committees convene in different cities and publish announcements, other then the Federal Register, that are more likely to be noticed by a wider public. Such activities are likely to be more expensive than current ones, however; but make the decision-making process more accessible to the public.

Option: Congress could direct agencies (EPA, FDA, USDA) to establish a mechanism to *allow for public input, even if not required by law.*

Agencies may wish to establish criteria by which local agencies and the public can be notified anytime significant risk or unique questions arise that are pertinent to them. Agencies may wish to adopt a procedure that publishes notification of petitions received, and where comments are such to indicate that there is sufficient public interest or unique questions, an informal hearing can be held.

Option: Congress could direct agencies (EPA, FDA, USDA) to increase the use of advisory committees for decisions involving biotechnology.

For FDA, advisory committees could be helpful in helping establish GRAS status and minimum information needed for food additive applications of genetically engineered whole foods. These committees could be used as a first screening mechanism to see if a food additive petition is actually needed. Also, if the meeting is public, greater assurance of the scientific validity of the process would be provided. The EPA might also use advisory committees to establish tolerances for genetically engineered plants with pesticidal properties. This might be particularly helpful since in-house expertise to handle this responsibility appears to be lacking. Use of advisory committees might also give greater credibility to USDA policy on transgenic animals, since its expertise lies mainly with inspection for microorganisms and disease rather than toxicology assessments. However, the credibility of these advisory committees will be enhanced if they include public representatives.

Option: Congress may wish to appoint a task force to study the role of independent safety testing of biotechnology products.

Independent testing is unlikely to be popular with industry. However, there is a growing perception that companies are withholding negative data, and the safety review conducted by regulatory agencies is not made using accurate and complete data. Enhanced subpoena data by the regulatory agencies, most notably FDA, could be useful. Additionally, it may be worthwhile to consider establishing independent testing of products. FDA, for example, rather than companies could choose outside investigators to perform selected safety assessments, and these contractors could report results directly to FDA rather than companies. A study to consider the broad range of implications of such a change would be warranted before implementation.

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ISSUE: TRADEOFFS BETWEEN INDUSTRY COMPETITIVENESS AND SOCIETY'S RIGHT TO BE INFORMED

Findings

Public interest groups argue that industry claims too much scientific data as confidential business information (CBI), thereby limiting the amount of health and safety data available to the public. Industry feels that there is too little protection of proprietary data, and this situation adversely affects their competitive position. Achieving the proper balance between protecting proprietary rights and disclosing health and safety data to the public is a delicate undertaking.

Disclosure practices are regulated by the Trade Secrets Act and the Freedom of Information Act. The Secrets Act (18 U.S.C. 1905) of 1982 subjects government employees to criminal penalties for the disclosure of proprietary data unless authorized by law. The Freedom of Information Act (5 U.S.C. 522(b)(4)) of 1982 permits agencies to protect trade secrets and commercial and financial information that is privileged or confidential. Both laws seek to protect information that would be of commercial value to a firm's competitor.

The FDA has restrictive CBI policies. Although Congress has mandated that health and safety testing data for new drugs can be released after another manufacturer becomes eligible to sell the drug unless extraordinary circumstances are shown (Drug Price Competition and Patent Term Restoration Act, 1984; PL98-417), little data is actually released. FDA defines extraordinary circumstances to include any claim that the data is CBI, including a claim that it could be used by competitors in foreign countries (3).

While FDA usually does not release safety data, in the case of bovine somatotropin (bST) it did. For the first time in FDA history, FDA published an article in a peer reviewed scientific journal (Science) detailing how FDA reached its conclusion that bST was safe for human consumption. Specific safety data was presented. Additionally the National Institutes of Health (NIH) and FDA hosted a scientific meeting with public participation to discuss food safety concerns of bST. Thus, FDA has shown that it can release such information when it is in the public interest.

FIFRA protects CBI, but allows release of health and safety testing data to be disclosed for registered pesticides. Also, data concerning production, distribution, sale, or inventories of a pesticide may be released in connection with a public proceeding if disclosure is in the public interest (7 U.S. C. 136h). Thus, FIFRA permits the release of health and safety data after the decision is made but not during the process.

After notification of a food additive or pesticide registration petition has been published, requests for safety data can be made under the Freedom of Information Act (FOIA). However, sometimes it is not possible for agencies to determine whether or not information is CBI in the time allotted to them to make a regulatory decision. Attempts to mitigate these problems include requesting that companies restrict their CBI claims and that they justify their claims of confidentiality at the time they submit a petition.

Currently, biotechnology firms have limited the availability of CBI involving environmental release to those public interest groups needing current information in order to participate in EPA cases. However, this condition exists because of voluntary cooperation of the firms, and this cooperation could be withdrawn at any time.

Decisions to disclose CBI focus on whether or not such disclosure will be harmful to the company. No attempt is made to weigh this harm against the public's right to be informed about health and safety issues that might affect them. Other countries, most notably Canada, have taken the approach that disclosure of health data is authorized if it is in the public interest as it relates to public health, public safety, or protection of the environment and if it clearly outweighs in importance the financial loss to the competitive position of a company or person (Access to Information Act, Canada Statute 3324).

Policy Options

Option: Congress could encourage FDA to publish more scientific review articles and hold public meetings in cases that generate public interest.

Clearly it is possible for FDA to release health and safety information to the public as they have done for bST. The public controversy surrounding this product apparently outweighed any competitive disadvantage that disclosure of this information imposed on the firms producing bST. Such a policy might prove useful in re-

sponding to public concerns about other biotechnology products and potentially could enhance the accountability and credibility of FDA decisions.

Option: Congress could conduct oversight to provide increased guidance to regulatory agencies attempting to encourage firms to reduce CBI voluntarily.

Congress could monitor whether health and safety data are being made available as products approach commercialization or if firms withdraw their voluntary cooperation and claim more data as CBI. If firms increase CBI claims, Congress could direct Federal agencies to require firms to justify CBI claims when a petition is submitted rather than waiting until a FOIA request is made. Currently, firms realize that it takes regulators longer to determine the validity of CBI claims than the time allotted to make regulatory decisions. This could encourage some firms to make CBI claims of data that in fact are not confidential.

Congress could also direct agencies to facilitate reconsideration of a decision if CBI data are released after a regulatory decision is made and causes public concern. Currently, firms can avoid disclosure of data during the regulatory process simply by claiming confidentiality and know that the regulatory decision will not be reconsidered. If the decision is allowed to be reconsidered, firms may reduce their CBI claims.

Industry will oppose increased disclosure of safety data because it will erode their competitive position. On the other hand, with the current climate of public skepticism of new technologies and regulatory agencies, increased industry accountability and public disclosure of safety data may be required of business.

Option: Congress could liberalize the CBI policy.

Congress could direct FDA to release data it is currently authorized to release but generally does not. Congress could consider adopting a regulatory policy similar to that used in Canada which would weigh any harm to the "company against the public's right to be informed about safety concerns. Current policy considers only the harm to firms. As a last resort, Congress could force the disclosure of health and safety data. Once again the potential harm to the competitive position of companies must be weighed against the public's right to be aware of potential safety risks and to regain public confidence in the regulatory process. Industry probably will object to an easing of CBI policy. Public support, on the other hand, may be equally strong for disclosure.

ISSUE: SAFETY ASSESSMENT METHODS AND REGULATORY ENFORCEMENT

Findings

Traditional food safety assessment approaches As discussed in chapter 11, are inappropriate for the assessment of whole foods because large enough quantities of the food cannot be fed to test animals without invalidating the results of the test. Thus, a new food safety approach will be required. New assay and testing methods will need to be developed and additional data concerning the normal levels of toxic compounds in foods will be needed. Additional funding will be needed to develop new testing procedures applicable to genetically modified foods.

Preliminary research indicates that a significant component of the public's lack of confidence in regulatory agencies stems from concerns that regulations are not being adequately enforced. For example, research shows that consumers are willing to pay for labels that indicate that Federal pesticide tolerances are in fact being met in apples. For Federal regulatory agencies to regain public credibility and for the public to accept biotechnology products, enhanced enforcement of regulations will need to be an integral component of the regulatory process.

Enhanced enforcement will be difficult. The regulatory agencies do not have the resources to significantly increase enforcement activities. A GAO study found that the regulatory agencies involved in food safety had less staff and funding and a larger workload in 1989 as compared to 1980. Available resources are being stretched.

In addition to the lack of available resources, the food safety regulatory agencies will need to develop new assay procedures and sampling methodologies to track genetically modified organisms. Again, studies show that FDA, for example, has not been quick to develop or adopt new practices in dealing with current food safety problems such as pesticide residues and antibiotics in milk (4, 5). Unlike pesticide residues and antibiotics, multiresidue assays methods for genetic engineering do not exist and may not be possible to construct. Generic verification that a plant has been genetically engineered will be difficult if not impossible. This creates problems in verifying the safety of imported food products unless these products are accompanied by compositional data.

Policy Options

Option: Congress could fund the development of new analytical methodologies and assay procedures through the National Institutes of Health (NIH).

New analytical methods for whole food assessments must be developed not only to determine the safety of genetically modified crops, but to monitor foods once they are marketed commercially. NIH, in coordination with FDA, could provide funding to develop food analytical technologies. These new technologies and assessment procedures would not only be useful in determining the safety of genetically engineered foods, but could also enhance several other research programs such as the designer foods project (cancer research) and nutritional programs.

Option: Congress could provide funds to NIH for the development of databases detailing the normal range of nutritional and toxic components of food.

Major nutrients and toxic substances in food have been identified, but more information is needed to assess these food components, such as the quantities at which these components are normally present in foods and their chronic impacts on humans. Assessment of such information will be needed to determine if genetically modified foods present greater safety risks than do foods currently consumed.

Option: Congress could provide additional resources to the regulatory agencies to carry out their duties.

In the absence of additional staff and funding, FDA will have a difficult time increasing enforcement activities to cover genetically modified products.

Option: Congress could direct FDA and EPA to request that assay procedures developed by firms to detect additives be readily adaptable for use under field conditions.

Currently, when firms submit a food additive petition or a pesticide registration they are required to provide an assay method to detect the residues or additive in the food. Generally, the method provided requires highly sophisticated instrumentation and is generally not compatible with multiresidue assays (i.e., the methods developed usually are single residue only). Agencies might require multiresidue assay methods that are more readily usable under field conditions than they are today. The residues would have to have some similar characteristics for a multiresidue technology to work. Development of such assay methods may create technical difficulties and are likely to create added costs to industry. However, they would improve monitoring and enforcement activities of regulatory agencies, an issue of particular importance to the public.

ISSUE: LABELING FOOD PRODUCTS IN WHICH BIOTECHNOLOGY HAS BEEN USED

Findings

Many consumers have expressed a desire for food that includes products developed with biotechnology to be so labeled. However, while consumers express a desire to have such labels, many of them are not willing to pay much for those labels. (See chapter 12.) For example, approximately one-third of consumers surveyed do not seem willing to pay anything for labels whereas another 5 to possibly 10 percent of consumers seem willing to pay as much as 50 percent higher food prices for labels. The remaining consumers appear willing to pay 5 to possibly 10 percent more for labels. Clearly a labeling proposal that is very expensive will not be popular with most consumers. Additionally, there is the problem of verification. Consumers want labels, but they want those labels to be accurate and verifiable. This is entirely consistent with the desire of consumers that current regulations be enforced. Labeling is not a substitute for an adequate safety assessment, rather it is to provide information to consumers. Labeling, unlike safety, is not a public good. The approach may be to make labeled biotechnology food products available to those willing to pay the added price of the label rather than forcing all consumers to pay higher food prices to incorporate labeling.

FDA has stated in its preliminary policy that generic labeling of biotechnology food products will not be required but selected products may require labeling. Such products may include those for which nutritional composition has been altered or potential allergens introduced. Other options are possible however.

Policy Options

Option: Congress could mandate that all food products containing constituents derived from biotechnology be so labeled.

This certainly would satisfy public desire to be aware that the food they are eating contains products derived using biotechnology. It is also likely to be very expensive and difficult to verify that food products do not contain constituents that have been derived using biotechnology. No generic means exist to identify whether a food constituent, such as a kernel of corn that will be ground into meal, has been genetically engineered or not, and it is unlikely that such a method can be developed. Thus, unlike for pesticides and antibiotics, there is no simple assay method that can be used to determine if the plant from which the corn was derived is a transgenic plant. Thus, to assure that genetically modified products are not used will require that the markets for agricultural commodities be segregated. That is not how many bulk commodities, such as grains, are currently marketed. Entirely new marketing structures will need to be developed. To guarantee the quality control of the crops will require producer oversight, which will be expensive for food processors. That added expense will be passed along to consumers. Thus, the difficulty involved in determining that a product does or does not contain any ingredients derived from biotechnology could become quite expensive. It is not clear that consumers would be willing to pay that added expense.

Option: Congress, through research and extension agencies, could encourage niche markets to be established to satisfiy the concerns of those willing to pay high prices for labeled food signifying that it does not contain genetically engineered food.

An alternative to passing the high cost of verification along to all consumers is to establish a higher priced niche market for biotechnology-free foods that would satisfy the needs of consumers who are concerned enough about biotechnology to be willing to pay higher prices for products not produced with biotechnology. Such a market would be similar to the current organic food market. Organic produce is higher priced than traditionally produced produce but provides an alternative product to consumers who are willing and able to pay higher food prices. Recent legislation has been enacted to help resolve some problems involved with organic produce, such as a lack of a standard definition, grower certification and oversight procedures, etc. Such a policy might also work for biotechnology-free food products, and would have the advantage of passing the extra costs along only to consumers willing to bear them.

INTERNATIONAL COORDINATION

The United States annually imports billions of dollars worth of food products. The United States is not the only country capable of producing biotechnology food products. If U.S. food safety regulations concerning biotechnology substantially differ from other country's regulations, several difficulties could arise. For example, if U.S. policy is substantially stricter than other countries, enforcement will be difficult. As already stated, no generic methods exist to determine genetic modification. Reliance on the word of other countries that their products contain no biotechnologically derived constituents may or may not be acceptable. Likewise, if U.S. regulations are substantially more stringent than other countries, then U.S. producers will likely be at a competitive disadvantage. If U.S. regulations are substantially less stringent than other countries, then exporting U.S. agricultural products could prove difficult. Agricultural commodities are a major export of the United States. Thus, international coordination will be an important issue. Preliminary FDA policy is consistent with the concept of the substantial equivalence of new foods discussed in the Organization for Economic Cooperation and Development (OECD) working papers and with safety assessment procedures discussed in World Health Organization (WHO)/Food and Agricultural Organization (FAO) reports.

CHAPTER 13 REFERENCES

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