Rulemaking, Public Comments and Participation: A Case Study of Genetically Engineered Organisms

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Abstract

For the oversight of emerging technologies and their products, public comment periods on proposed federal rules is one of the most popular methods of gaining public insight into public values and opinions about emerging technologies in federal rulemaking. Many science and technology scholars suggest that this level of participation is not effective, or broad enough according to democratic and ethical principles. In this analysis, we set out to examine this issue using the case study of genetically engineered organisms (GEOs) in the food supply and recent proposed rule changes coming from the primary regulatory body for these products, the USDA’s Animal and Plant Health and Inspection Services (USDA-APHIS).

This paper addresses the issue of public participation looking at the following areas of research: 1) what are the substantial differences between the old and new proposed regulations for GEOs, 2) what stakeholder groups comment on proposed rules 3) what do the comments say about the proposed rule (as expressed through formal public comments on the Federal Register notice) and 4) to what degree should these comments be taken into consideration by the agency in final rule-making process? Stakeholder groups that have participated in the comment period on this new rule have been identified and the substance of their comments have been examined in order to consider group-diversity and potential patterns of opinions based on affiliation, expertise, demographics, or culture to determine the extent and substance of participation through comment and rule making. Stakeholders were identified, and public comments from these stakeholders were analyzed based on thematic coding schemes in the software NVivo. Areas were identified from these comments that need to be addressed if APHIS should choose to publish the final rule. The method of public participation also was examined using democratic theory and the literature on public participation, including perspectives and social goals of public participation. Negotiated rulemaking was identified as a method to resolve conflict between competing interests and educate and inform the public about issues.
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<th>Term</th>
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<tr>
<td>APHIS</td>
<td>Animal and Plant Health Inspection Service</td>
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<td>APA</td>
<td>Administrative Procedure Act</td>
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<td>BRS</td>
<td>Biotechnology Regulation Service</td>
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<td>CEQ</td>
<td>Council on Environmental Quality</td>
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<td>CFRB</td>
<td>Coordinated Framework for the Regulation of Biotechnology</td>
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<tr>
<td>EA</td>
<td>Environmental assessment</td>
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<td>EIS</td>
<td>Environmental Impact Statement</td>
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<td>EPA</td>
<td>Environmental Protection Agency</td>
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<td>EU</td>
<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FIFRA</td>
<td>Federal Insecticide, Fungicide and Rodenticide Act</td>
</tr>
<tr>
<td>FFDCA</td>
<td>Federal Food and Drug Substances Control Act</td>
</tr>
<tr>
<td>FONSI</td>
<td>Finding of No Significant Impact</td>
</tr>
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<td>FPPA</td>
<td>Federal Plant Pest Act</td>
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<tr>
<td>GEO</td>
<td>Genetically engineered organism</td>
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<td>GMO</td>
<td>Genetically modified organism</td>
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<td>IRFA</td>
<td>Initial regulatory flexibility analysis</td>
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<td>NEPA</td>
<td>National Environmental Policy Act</td>
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<tr>
<td>NGO</td>
<td>Non-governmental Organization</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>NIH</td>
<td>National Institute of Health</td>
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<td>OSTP</td>
<td>Office of Science and Technology Policy</td>
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<td>RAC</td>
<td>Recombinant DNA Advisory Committee</td>
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<td>rDNA</td>
<td>Recombinant DNA</td>
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<tr>
<td>RFA</td>
<td>Regulatory Flexibility Act</td>
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<td>TSCA</td>
<td>Toxic Substance Control Act</td>
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<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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Chapter 1: Introduction and Background Information

Genetically engineered crops have been a point of contention since they were first introduced into the market in 1996. Genetically engineered crops are defined as having their DNA altered through the addition of DNA from a different species or deletion of part of its own DNA. The level of regulation for genetically engineered organisms has been protested by many different stakeholder groups, some stressing that it is not high enough, some that there is too much regulation in place (Federal Register, 2008). On October 9, 2008 the United States Department of Agriculture, Animal, Plant Health Inspection Service (USDA-APHIS) released potential new regulations for genetically engineered organisms. These proposed regulations were responded to by several thousand comments from the public.

These new regulations are warranted, there have been many changes and much has been learned in the field of genetic engineering since the regulations were first published for field trials in 1987 and for commercial, interstate commerce in 1994. New techniques in genetic engineering have become available that make the process more precise, but these new techniques might not actually fall under the current regulations for genetically engineered organisms (Kuzma and Kototovich, in press). When the regulatory framework was originally established, USDA-APHIS along with other governmental agencies had little experience regulating genetically engineered organisms. USDA-APHIS now has over 15 years of experience in regulating genetically engineered organisms.
All of these factors, and many others, contributed to the publishing of the proposed rules by USDA-APHIS. The presence and regulation of genetically modified organisms to stakeholders both in this country and around the world is an extremely contentious issue. Therefore, the method and response of public participation in the rulemaking process is particularly important. This paper will examine the public comments submitted on this proposed rule to explore the public’s participation in the federal rulemaking process as it relates to genetically engineered organisms. By examining the number of comments submitted, who they were submitted by, and the content of the comments, this paper will evaluate the public participation process of federal rulemaking.

Why do we care about the regulation of genetically engineered organisms if they are already being grown in fields and sold on the market? Why are we examining regulations and the public’s opinions of genetically engineered organisms now? Understanding how regulation of genetically engineered organisms “failed” can help when it comes time to regulate the next technology that will affect people on a daily basis and has the potential to have an impact on the surrounding environment.

This chapter will present background about the rulemaking process and demonstrate how public participation is a necessary part of this process, as well as
present a brief history of regulation regarding genetically engineered organisms\(^1\), and a brief overview of the history of the public’s opinion of genetically engineered organisms.

**The Process of Federal Agency Rulemaking**

In 1946 the Administrative Procedure Act (APA) was passed. This act gives federal agencies the ability to make federal rules for issues that fall under their jurisdiction (Lubbers, 2006). These rules carry just as much weight as if they had come from congressional legislation, presidential executive orders, or by judicial decision (Kerwin, 2003). Agencies are required by the APA to provide public notice about the rules they are proposing, information that the rules are based on, an opportunity for public comment on those rules and judicial review of the rulemaking process. The APA mandates that rulemaking include an opportunity for written comments but leaves it up to the individual agency if they wish to allow an oral presentation of data and views. This method of public participation has been criticized for not being adequate. Most citizens might know that the process of rulemaking exists, but have little to no idea that they are able to participate, much less how they would go about doing so. A large percentage of the public have little to no idea this method exists and most people have never used it (Carlitz and Gunn 2002). Instead they rely on voting as their primary form of civic engagement. The original purpose of public comments was intended to supplement the

\(^1\) Genetically engineered will refer to plants or organisms that have been modified through the addition or purposeful deletion of part of their genome. These are the organisms or crops that will be regulated by the proposed rule from APHIS. Genetically modified will refer to plants or organisms that have been modified using marker assisted or traditional breeding methods. (NRC, 2000)
knowledge of the agency so that they had all important information gathered together in order to form a final rule (Lubbers, 2006). The APA does not state an amount of time over which these written comments are to be collected.

There are two types of rulemaking, formal and informal. Formal rulemaking requires public hearings and in these hearings parties have the right to present their own evidence and conduct cross-examinations of witnesses and submit rebuttal evidence. This form of rulemaking is used only when a statute other than the APA requires the rule to be on the record, and it is used infrequently. Informal rulemaking, better known as notice-and-comment rule making, is one of the most common forms of rulemaking used by agencies with rule making abilities. This power comes from section 553 of the Administrative Procedure Act (Lubbers, 2006). Notice-and-comment rulemaking involves three steps; the publication of a notice of proposed rulemaking, the opportunity for public comment and possibly other forms of participation, and the publication of the final rule and accompanying statements of bias and purpose at least 30 days before the rule goes into effect (Lubbers, 2006). These requirements are the procedural floor, an agency can go above and beyond them. Informal rulemaking doesn’t require public hearings to be held, although this doesn’t mean that an agency cannot choose to have them. After all comments have been submitted and when formulating the final rule, agencies are required to respond to “significant” written comments and explain how any problems or issues raised by the comments were addressed. Significant comments have been defined as those that if adopted would require a significant change in the proposed rule. This doesn’t mean that the agency is required to address every submitted comment,
rather that they must address all the major and significant issues raised by the written comments. The agency is also required to show the resolutions that lead the agency to the final rule.

**Figure 1:** The Federal rulemaking process

Rulemaking by federal agencies can come about from congressional and judicial pressure, public petitions for rule making (which many agencies do not have a method to deal with) or by priority setting from the agency itself. Public participation is a required aspect of rulemaking, one that many experts think does not make up a large enough part of the overall rulemaking process. The APA does not state that public participation must be taken into account by an agency when rule making at all, only that the agency is required to solicit public comments (Kerwin, 2003). How federal agencies take public comments into account when formatting a final rule is an area that hasn’t been well
studied, to our knowledge. Addressing the issue of public comment and rulemaking as a form of public participation, and how and to what extent federal rulemaking agencies address public comments in the rulemaking process is important given its pervasive use as the standard for promulgating rules and regulations. Federal rulemaking agencies are operated by non-elected officials; public comments are one of the only ways that the public is allowed to have an influence on rules that will pertain to them.

Procedural decisions made by an agency can augment the rulemaking process in the long run. Such decisions might include more advanced notice of proposed rulemaking and negotiated rulemaking. Advance notice of proposed rulemaking notifies the public that the agency is considering an area for rulemaking and can request written comments on the appropriate scope of the rulemaking or on specific topics (Lubbers, 2006).

Negotiated rulemaking brings interested parties to the rulemaking table at the beginning of the process (see “Public Participation” section below). The purpose of this is to foster cooperative efforts to achieve solutions to regulatory problems. With successful public participation, rules are less likely to be challenged in litigation (Lubbers, 2006). The process involves an agency representative speaking on behalf of an agency, and a committee of representatives from all affected interests to negotiate the basis of a proposed rule. The goal of this group is to reach a consensus on a text that all parties can accept (Lubbers, 2006). This does not replace the conventional rulemaking process, but rather serves as the basis for the proposed rule published by the agency. Obviously this tactic isn’t always possible or realistic in all rulemaking situations, the most common
uses of this process are usually for those questions of “how to regulate” and not “what to regulate” (Fiorino, 1988).

One reason that negotiated rulemaking might be more successful and inclusive than conventional rulemaking is that in negotiated rulemaking, agencies post a formal notice of negotiated rulemaking and solicit comments from potential participants. Because the agency is legally bound to address all parties that submit comments, it is fairly certain that a representation of all interested parties whether directly or indirectly, will be represented in the negotiated rulemaking (Langbein and Kerwin, 2000). The agency then takes the comments and concerns expressed in the negotiated rulemaking process and use them to write the rule. In contrast, in conventional or non-negotiated informal rulemaking all parties submit comments to the agency and the agency alone is responsible for writing the rule. In a study of conventional rulemaking participants and negotiated rulemaking participants, the negotiated rulemaking participant’s assessment of the final rule was much more positive than that of a conventional rulemaking participant. The Environmental Protection Agency (EPA) has used negotiated rulemaking in many situations, the first being in 1984.

**Public Participation**

Public agencies and governmental administrators typically have approached the management of governmental policy in a managerial method. Public participation usually is viewed as an obstacle to this management strategy. The move from a managerialism structure to more of a pluralism structure happened during President Lyndon Johnson’s
term (Beierle and Crawford, 2002). The pluralism view of management is that government administrators were arbitrators among different interests within the public and were not a source themselves of objective decision making in the public interest. Using pluralism the contingent public good was to be debated and arrived at by negotiation among interests in the public (Beierle and Crawford, 2002). Currently we are shifting from a pluralism form of view to public participation (Beierle and Crawford 2002).

Society expectations about public participation have evolved from accountability to being representative to what the public really wants. In 1990, congress passed the Negotiated Rulemaking Act. This allows agencies to use formal negotiations among interest groups to develop proposed regulations. Public participation is viewed as a way to look and deal with “wicked problems” or “problems with no solutions, only temporary and imperfect resolutions” (Beierle and Crawford 2002). In federal rulemaking participation is limited to advisory committees, citizen juries, focus groups, public forums (i.e. town halls) and formally mediated negotiations in which parties write regulations (Beierle and Crawford 2002). There are five “social goals” of public participation: Goal 1) incorporating public values into decisions, Goal 2) Improving the substantive quality of decisions, Goal 3) Resolving conflict among competing interests, Goal 4) Building trust in institutions, Goal 5) Educating and informing the public. (Beierle and Crawford 2002)

There are several ways to determine if public participation is successful. In environmental decisions, five stages have been created to determine the success of public
participation. 1) Measuring the output of the public participation process, for example determining concerns and recommendations put forth by the written public comments. 2) Determining whether there was a decision or commitment on the part of the lead agency. 3) Examining the actual law, regulation or policy as changed or written. 4) Assessing actions taken on the ground to affect the quality of the environment, and 5) looking at whether changes and hopefully improvements take place in environmental quality. The implementation process for public participation can be stalled or delayed by external forces such as disagreements, conflicts not really being resolved, political intervention, or changes in circumstances making implementation undesirable (Beierle and Crawford 2002).

In a study of public participation in environmental rulemaking (Beierle and Crawford 2002), it was found that process has a very strong relationship with success. Generally more intensive participatory mechanisms are more successful across cases. However, these methods are expensive and less likely to engage the wider public, and they usually only attract from a single socioeconomic class. Independent variables of the public participation process can have an effect on the success or failure of rulemaking. They are responsiveness of the lead agency, motivation of the participants, quality of deliberations, and the degree of public control (Beierle and Crawford 2002). This same study outlines methods to determine the most effective method of public participation. Because the situations which require public participation vary, the same method of public participation isn’t optimal for every rulemaking situation. The agency needs to be willing and able to make some commitments to the public involved in the rulemaking process.
These commitments vary from some degree of flexibility and open mindedness to the process or recognizing the legitimacy of public values and understand that these values may lead to priorities and conclusions that agencies find wrong (Beierle and Crawford 2002). The goals of the process need to be identified and public engagement needs to be designed surrounding the needs of the rulemaking situation. Questions that should be considered are how much influence should the public have? What kind of engagement is appropriate? What role should government play? Finally the process should be selected and evaluation should be conducted after the process is over (Beierle and Crawford 2002).

The Federal Register as an Opportunity for Participation

The Federal Register Act was passed in 1935 by Congress. It requires that all documents having general applicability and legal effect must be filed with the Office of the Federal Register. All documents throughout the process of proposing and finalizing a new rule are published in the Federal Register and are made available for public inspection (Federal Register Act). This publication provides for official notice of a document’s existence to the public and is mandated by the APA (Lubbers, 2006). In 1994 the Office of the Federal Register began posting the daily Federal Register and the Code of Federal Regulations online. Comments on proposed rules are now filed online for every proposed rule and can be viewed online. The benefits of switching to an online system are that it is now easier for members of the public to submit comments, which encourages more of the public to participate and can make it easier for a wider
demographic to submit comments. An online system is also much more user friendly. All comments can be viewed online and it is easier to find specific notices and to group comments together that are related either by submitter or by topic (Lubbers, 2006). For the agency the cost of managing and operating an electronic system will be less than the operation of a paper system (Carlitz and Gunn 2002). Concerns with rulemaking expanding to electronic posting are not all documents are posted online, the easier access and higher comment submissions means that federal agencies need to be able to analyze and process a higher number of comments (Lubbers, 2006).

Using electronic systems to aid in the information services and tools provided to the public in the process of rulemaking is typically called E-governance. This can have obstacles for rulemaking agencies, such as they must adjust how they should structure their proceedings, and how they process the received comments (Carlitz and Gunn 2002). The type of public participation that was discussed in the APA is difficult to achieve without using E-governance. Previous paper based systems limited the public involvement. In order to follow the rulemaking process, one had to either live in Washington D.C. so that they could have access to the docket on a daily basis or have a proxy who was willing to look it up for them (Carlitz and Gunn 2002). When using an electronic docket system the base for public participation also increases.

When using the Federal Register online, an agency now has an opportunity to format its process to be easier for the public to access and review other comments made as well as allow easier access to solicit comments from a much wider base than previously (Carlitz and Gunn 2002). An electronic rulemaking system should increase
transparency between agencies or between agencies and the public (Carlitz and Gunn 2002). Using an electronic system and reaching out to the public to inform them of the rulemaking process and that they have a role in which they can participate, could result in greater public participation in rulemaking. This could result in greater and different points of view in the process of rulemaking and great public participation has been shown to lead to better rules, rules that are more widely accepted and that are less likely to be challenged in court (Carlitz and Gunn 2002). The current system is biased towards experts and professionals, those that are knowledgeable about the federal rulemaking process and system (Carlitz and Gunn 2002).

**Overarching Statutes that Apply to Rule-Making**

There are many federal statutes that must be considered when an agency is proposing new rules. One of these is the National Environmental Policy Act (NEPA) which was created to direct agencies to give special attention to specific environmental values during the decision making process (McHughen and Smyth 2008). Federal agencies are required to investigate the potential consequences and environmental impacts before making decisions that could have environmental risks. If the agency decides that there are no significant environmental effects that will take place, the item falls into a categorical exemption and the application for environmental action is approved. If the application is determined to possibly have significant environmental effects, the agency is responsible for conducting and publishing an environmental assessment or EA. This document is a critical analysis of the proposed environmental
release. If the agency deems that the danger is insignificant from the application, they will publish a FONSI which provides the rationale for the agencies decision and the application is approved. If after the EA is published if additional evidence is needed, an Environmental Impact Statement (EIS) is conducted and published (McHughen and Smyth 2008). An EIS is required to be conducted for all “major federal actions significantly affecting the quality of the human environment” (Lubbers, 2006). The process of publishing an EIS is complex. A draft is published to the federal register and the public has a 45 day comment period (McHughen and Smyth 2008). Other forms of public opinion can be used as well, like public forums. Agencies must pay attention to the comments made on an EIS and respond to significant comments just like they would to those made on a proposed rule (McHughen and Smyth 2008). The Council on Environmental Quality (CEQ) has adopted regulations binding on all agencies that set forth uniform standards for conducting environmental reviews that all agencies are bound to (Lubbers, 2006).

The Regulatory Flexibility Act (RFA) was passed in 1980. It directs agencies to consider the potential impact of regulations on small businesses and other small entities. The agency must take into consideration alternatives that might have less of an impact on small businesses. The Act does not require or mandate a particular outcome, just the consideration of other alternatives that might be less impactful on small businesses. An initial regulatory flexibility analysis (IRFA) must be published in the Federal Register. If these small businesses are determined to be affected by the proposed rule they must be given the opportunity to participate in rulemaking (Lubbers, 2006).
The Paperwork Reduction Act passed in 1986 and again in 1995 requires the Office of Management and Budget to coordinate federal information policy. This was intended to reduce the amount of paperwork and cost for individuals, small businesses, federal, state, and local governments (Ludders, 2006).

There is a huge amount of work that an agency must work through to even propose a new rule. These regulations and restrictions have all grown out of necessity of the bureaucratic process, and it’s easy to see how public participation can get lost in all of the requirements. Public participation is a very important part of rulemaking and agencies need to be sure that it does not get lost in all of the other requirements. Since agency rulemaking is done by unelected officials, public participation in rule making is the only way for the opinions of citizen to be heard on rules that directly affect them. The process of public participation in the rulemaking process for agencies is unique in the democracy of the U.S. U.S. Agencies can take advantage of the unique opportunity presented to them by taking public input into consideration.

**Historical Review of Genetically Engineered Organism’s Oversight**

Genetically engineered organisms in the environment have been formally regulated since 1976 (NIH guidelines, 1976). Genetically engineered organisms, especially crops, have been a point of contention since they first entered the market in 1996, with some consumers and organizations calling them “Frankenfoods”. Regulation of genetically engineered crops is still a contentious issue, with some stakeholders arguing for more regulation and other stakeholders arguing for less.
The oversight of genetically engineered organisms (GEO’s) began at the Asilomar conference (Kuzma et. al, 2009b). This conference brought together scientists, lawyers and the media to discuss the potential regulation of laboratory experiments with recombinant DNA (rDNA) (Kuzma et. al, 2009a). The conference decided that while there were many unknowns about working with rDNA, it was important for the research process to precede as long as the appropriate precautions were put into place (Berg, 1975). Consensus of precautions that should be incorporated into research practices included making containment a principle part of research practices and that this containment should match the estimated risk (Berg et. al. 1975). It was agreed that precautions and standards of protection should be greater in scope at the beginning of research with rDNA, then as more is known about rDNA, the standards of protection should be decreased (Berg et. al. 1975). It was also agreed that as research progresses, precautions and safety standards must be reexamined from time to time (Berg et. al. 1975).

Following the conference a committee at the National Institute of Health (NIH) was formed called the Recombinant DNA Advisory Committee (RAC). The Office of Science and Technology Policy agreed with the recommendations of the Asilomar Conference that rDNA was not inherently risky and further determined that the products of genetic engineering, not the process should be regulated. Because of this no new regulations would be needed in order to regulate GEO’s, and they would fit into the existing laws and statutes (Kuzma et. al., 2009b). The framework for regulation was based on the fact that no new laws were needed for GEO’s, and they fell under the
regulation of current federal laws for pesticides, food, plant pests, etc. (Kuzma et. al, 2009a).

In the mid 1980’s when GEO’s began to move from the lab to the market and environmental release became a concern, the Office of Science and Technology Policy drafted the Coordinated Framework for the Regulation of Biotechnology (CFRB), in which three agencies would take the lead on regulating GEOs. The framework was made up of representatives from the EPA, USDA and FDA. The committee was instructed to use the Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Federal Food and Drug Substances Control Act (FFDCA) and the Federal Plant Pest Act (FPPA) along with the authority of their three agencies to regulate GEO’s and their products (Kuzma et al., 2009a). The CFRB is still the basis for the regulatory framework of GEO’s today. Most genetically engineered organisms fall under the previously mentioned federal rules and also fall under the responsibility of one or more federal agencies. Genetically engineered plants that are regulated as plant pests under FPPA because either the plants themselves can be considered pests or because the engineered sequences are from viruses and bacteria that cause plant disease (Kuzma et al., 2009a). If a plant is engineered with pesticide-like proteins, it will be regulated under FIFRA and FFCDA as pesticides by the EPA (Kuzma et. al, 2009a). Genetically engineered microorganisms were regulated as toxic chemicals under TSCA. Finally, genetically engineered or bioengineered foods were reviewed under FFDCA by the FDA through a voluntary consultation mechanism (Kuzma, 2009a). Genetically engineered animals, trees, insects, fish or plant produced pharmaceuticals were not specified in the
CFRB and this has caused some confusion today as these products enter the market. In 2008 the FDA proposed to oversee genetically engineered animals as “investigational new animal drugs” (Kuzma et. al., 2009a).

Traditionally the USDA has been the primary regulator of genetically engineered organisms that will be applied to agricultural uses, such as genetically engineered crops, because most are produced in the U.S. by companies. Their responsibility is to protect agricultural crops and the environment from the release of potential pests. The responsibility of the United States Department of Agriculture (USDA) as they relate to the regulation of GEOs largely falls under the branch of the Animal Health and Plant Inspection Service (APHIS). Within APHIS, the Biotechnology Regulation Service (BRS) manages the permitting and notification process for GEOs that may pose a risk to plant health. Currently, the USDA regulates all GEOs on a case-by-case basis. This is done to make sure that each GEO is checked to see where gene insert give a different gene expression or if there is potential for other features to be affected differently.

Prior to putting a product into interstate commerce, under the current regulations, most field trials are approved under the notification procedure. This is the quickest and easiest process and is designed for the most familiar GE crops (McHughen and Smyth 2008). The notification process involves the submission of a letter to USDA-APHIS that includes how the GE plant would meet six criteria, including not being a noxious weed or containing any human or animal sequences. Those applicants that do not meet the requirements of the notification procedure, must go through the field trial permitting process. Usually if a plant must go through this process either the plant itself or the gene
inserted is a noxious weed. The permit procedure requires a much larger amount of information and data than the notification procedure (McHughen and Smyth 2008). In 1992, the USDA proposed to deregulate, or remove regulatory oversight, for GE plants that were deemed to not pose an environmental risk (McHughen and Smyth 2008). As of 2008, 74 GE species had been granted deregulated status. In order to deregulate a plant APHIS must publish at minimum two documents, and EA and a determination of nonregulated status (McHughen and Smyth 2008).

The first field trials of GMO plants in the US were approved in 1987. As of 2007 over 12,000 regulated field trials have been approved (McHughen and Smyth 2008). As of October 2008, there has been more than 13,000 environmental releases of GE plants (USDA, 2008). The most common agronomically engineered traits are herbicide tolerance, insect protection, delayed ripening and disease resistance (McHughen and Smyth, 2008).

An article is regulated under field trials until the USDA approves its nonregulated status. Then it can be moved from state to state and released for interstate commerce without further oversight from the USDA. If an article does not receive nonregulated status from the USDA, it can still be released commercially, but cannot be moved from state to state. If two non-regulated articles are bred together they will likely have to go through the deregulation process again. In 1992, the USDA proposed to deregulate, or remove regulatory oversight, for GE plants that were deemed to not pose an environmental risk (McHughen and Smyth, 2008). As of 2008, 74 GE species had been granted deregulated status. In order to deregulate a plant APHIS must publish at
minimum two documents, and EA and a determination of nonregulated status (McHughen and Smyth, 2008).

Worldwide not all releases of genetically engineered crops into the environment have been approved. In 2001, the scientific journal Nature published a brief article stating that transgenic maize pollen had been found in Mexico, even though the growing of genetically engineered corn in Mexico was illegal. The part of Mexico where the transgenic genes were found has a wide variety of native species of maize, and concerns were expressed about the ability of the genetically engineered maize to mix with and contaminate native maize species (Quist and Chapela, 2001). While this study was questioned and later redacted by Nature, it still served to question the strength of regulation of genetically engineered organisms. Regulation of genetically engineered crops and the food system also was called into question when the presence of Starlink corn was detected in the U.S. human food supply. Starlink corn was approved for U.S. animal feed but had not been approved for use in the U.S. human food supply because of concerns that it could possibly be a moderate food allergen (Lin et. al., 2001). Both of these instances, among others, have had a negative effect on the public opinion of both genetically engineered corps and their regulation in the U.S.

There has also not been a genetically engineered animal put on the market or approved for environmental release, although genetically engineered salmon has recently been approved for human consumption by an advisory panel to the Federal Drug Administration (FDA) and could potentially be the first genetically engineered animal on the market for human consumption (VMAC, 2010). These fish grow twice as fast as
normal salmon and require less food to reach market size. With faster growing fish, inland operations could become more economically viable, reducing the need for ocean pens (AquaBounty, 2011).

There have also been a number of lawsuits brought against the USDA over their regulation of GEO’s. The most notable of these is genetically engineered alfalfa. In 2005, USDA-APHIS first proposed to deregulate genetically engineered alfalfa. A lawsuit filed by organic alfalfa growers and non-profits, was brought against USDA-APHIS to challenge this ruling. In 2007, a court ruled that USDA-APHIS had violated NEPA by not requiring an environmental impact statement (EIS) before the decision was made to deregulate genetically engineered alfalfa, subsequently all planting of genetically engineered alfalfa was to be banned. The draft EIS was released in 2009 and the final EIS was published in December 2010. As of January 27, 2011, USDA-APHIS has again announced that it will deregulate (or approve for interstate commercial release) genetically engineered alfalfa against the opinion of environmental groups, organic farmers, and many biologists (USDA, 2011).

In part prompted by these lawsuits and experiences with GEO regulation on Thursday October 9, 2008 USDA-APHIS released new proposed rules for the regulation of genetically engineered organisms (GEOs). These rules proposed to change the way that genetically engineered organisms are regulated by USDA-APHIS. The proposed rules include new regulations that would allow the USDA to incorporate noxious weed regulations into the regulation of GEO’s. They also state that USDA will no longer continue to regulate GEO’s that are microorganisms, since this responsibility also falls
under the EPA’s jurisdiction under TSCA. The main purpose of the proposed rules would be to restructure the current regulation system for GEOs.

Currently the old regulations provide for two different methods of regulating GEO’s. As discussed above, the old regulations employ the notification procedure, an administratively streamlined procedure. This procedure has generalized performance standards already included in the regulation. All conditions and regulations for GEO’s approved under the notification procedure are the same, and they cannot be tailored to a specific GEO. The second method, the permit procedure is designed for GEO’s that do not qualify for release under the notification procedure (for description, see above). This procedure requires more information about the GEO to be released and the conditions and regulations that are to apply to the GEO can be specifically structured around that GEO. The 2009 proposed regulations would combine these two procedures into a modified permit system with different tiers instead of a notification procedure. All potential releases would be sorted into a permit category based on their general risks and management issues. The proposed changes to the regulations will be further discussed in the following chapter.

The Public and Genetically Engineered Crops

In the past decade, genetically engineered crops have entered into markets all around the world. In 2005 genetically engineered crops were grown on 500 million hectares worldwide, in 2010 the accumulative acreage of genetically engineered crops grown worldwide reached 1 billion hectares (ISAAA, 2010). The U.S. is the highest
producer of genetically engineered crops, with 66.8 million acres of maize, soybean, cotton, canola, sugar beet, and alfalfa being the largest produced genetically engineered crops (ISAAA, 2010). 29 countries currently plant genetically engineered crops, 19 of them are developing countries and 10 of them are industrial countries (ISAAA, 2010). The top ten largest growers of genetically engineered crops in 2010 were the U.S. (66.8 million hectares), Brazil (25.4 million hectares), Argentina (22.9 million hectares), India (9.4 million hectares), Canada (8.8 million hectares), China (3.5 million hectares), Paraguay (2.6 million hectares), Pakistan (2.4 million hectares), South Africa (2.2 million hectares) and Uruguay (1.1 million hectares). Most are engineered with herbicide tolerant (e.g. Roundup Ready) or insect resistant (e.g. Bt crops) genes.

Acceptance of genetically engineered crops has been different around the world. In Europe, where there has been a history of food safety scares, foods containing genetically modified crops were not met with a positive attitude. The E.U. responded to genetically engineered crops by placing a moratorium on new approvals from 1998-2005 (PEW, 2005). Prior to 1998 two rules were introduced to regulate genetically engineered crops. The first in 1990 established a process that would assess and approve all genetically engineered organisms before they were released into the environment. Prior to 1998, 11 crops were approved for release using this method. The second was passed in 1997, this required the labeling of food products that contained or consisted of genetically modified organisms (PEW, 2005). In 1998, member states passed a vote to block approval of genetically engineered crops. This de facto moratorium was protested against by the U.S., Canada, and Argentina through the World Trade Organization (WTO).
Concerns were raised that the EU’s moratorium on genetically engineered organisms affected African nation’s acceptance of genetically engineered crops as food aid, thus resulting in furthering famine in these countries (Paarlberg, 2001). In 2003, the EU proposed new legislation for the regulation of genetically engineered crops and food products containing or consisting of genetically engineered organisms. This legislation called for strict labeling rules, traceability, and approval. All food products containing more than 0.9 percent genetically engineered products must be labeled as such and must be traceable throughout the food system. Since these rules have gone into effect, thirty eight crops have been approved to be grown in the EU (PEW, 2005). The U.S. has taken a completely opposite approach and does not require the labeling of genetically engineered foods and approves the growing of multiple crops for human consumption as described above.

Overall, the American public’s knowledge about genetically engineered food is very poor. The PEW Initiative on Food and Biotechnology conducted five years of public opinion polls on the public opinion and knowledge of biotechnology in the marketplace (Hallman et al., 2002, Hallman et al., 2003, and The Mellman Group Inc., 2006). In 2001, “only 41% of Americans were aware that genetically engineered food products are currently for sale in supermarkets” (Hallman, 2002). Twenty eight percent weren’t sure if genetically engineered food products were available for sale and 32% didn’t think they were on sale at all. A large number of respondents did not have a basic understanding of genetics. A quarter of respondents did not realize that tomatoes contain genes and did not know that the father determines the sex of his offspring (Hallman et al., 2002). Given this
knowledge, 66% of Americans believed that genetic engineering would make the quality of their lives better however, 56% stated that they also had concerns about biotechnology. When asked about labeling, 90% of Americans said they wanted genetically engineered food labeled as such, but less than half said they would be willing to pay any more to have food labeled (Hallman et al., 2002). Finally, 75% of respondents agreed that genetically engineered crops need to be regulated and only 29% believed the government has the necessary tools to properly enforce this regulation.

Two years later when the second stage of the study was conducted the knowledge of Americans about agricultural biotechnology and food production hadn’t changed from 2001. However, the amount of respondents that approved of genetically engineered plants, dropped 9%. The number of respondents that thought genetically engineered crops would improve their quality of life also fell from 59% in 2001 to 39% in 2003. The amount of respondents that said they wanted labels placed on food products that contained or were made from genetically engineered food products increased from 90% in 2001 to 94% in 2003. The second survey also focused on the demographics of people that responded and found that age, education, and sex were all significant contributors to the acceptance of genetically engineered products (Hallman et al., 2003)

These findings seem to still be true 8 years later. Environmental health, gene flow, consumer choice, and labeling were top concerns of people eight years previously and were all mentioned in the top ten concerns of the public within the public comments. These concerns included maintaining and protecting the environment, and protecting the right of consumers to choose what they want to consume. This is a positive sign for this
method of public participation in that it is a reflection of the set of concerns expressed through other means and venues. However, it is a poor reflection of the opportunity for this method of participation to include the general public, as only a minority is even aware of GEOs and fewer that new rules are being proposed.

Ever since their introduction into the market in the late 1990’s, genetically engineered organisms, especially as crops, have been controversial. Supporters for GEO’s argue that they reduce the use of pesticides and insecticides and increase yields as well as increase food security and the sustainability of poor farmers worldwide. Opponents of GEO’s argue that there hasn’t been enough testing done to prove they are safe for human or animal consumption, creating a food safety concern. Other concerns include that the altered genes will mix with native species, creating herbicide resistant weeds or insecticide resistant pests.

Outline of Paper

As discussed above, there are many forms of public participation that can be used to meet the requirements of the APA. Public meetings, public comments, hearings, and negotiated rulemaking all are potential paths that an agency could take to involve the public. Are the methods of public participation that the USDA-APHIS currently employs adequate to engage a range of citizens and stakeholders? Do they sufficiently involve the public to express diverse concerns? Finding a method of public participation that addresses these questions is important to consider when determining a method of public participation for rulemaking at the federal level. Little research has been done to answer
these questions. This paper will examine the public participation in the 2008 USDA proposed rule “Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms” to see if the public participation reflects diverse groups and concerns and to examine how the agency might change the proposed rule to address the comments. The paper also explores the adequacy of this method of public participation as judged by the inclusion of a wide variety of stakeholders, whether comments are collected in an independent and unbiased manner, the timing of involving the public effect on the final policy, and the transparency of information and opportunities for participation to the public (Rowe and Frewer 2000). Based on public participation in previous rules, the starting hypothesis was that a majority of the comments would come from NGO’s (largely advocacy groups in consumer and environmental areas) and that individual citizens would be mostly unaware of the opportunity to comment on the proposed rule. However, we found that Individuals commented in large numbers, far outweighing the absolute number of comments from other stakeholder groups. We present potential explanations for why this was the case in the discussion and how it reflects on comment and rulemaking as a form of participation. After the analysis of the comments, their nature, and the participants, we use democratic theory from political science to interpret the data and explore the question of adequacy of comment and rule-making as a mode of public participation.

This chapter presented background on the federal rulemaking process, a history of the regulation of genetically engineered organisms, and previous public opinions on genetically engineered organisms. The next chapter will present the methodology behind
the research and methods used to sort the comments into stakeholder groups and how concerns were identified and coded for. Chapter 3 presents the results of a qualitative content analysis on a random selection of public comments including questions such as: who commented on the proposed rule? What views/concerns do stakeholder groups have about the proposed rule and genetically modified organisms? What are the strength of their opinions? Chapter 4 is a discussion of these results and what they mean for public participation in federal rulemaking. This discussion will return to the question of how public participation should be measured and what makes good public participation, ultimately reflection on the question of what an agency in a democratic government should do in order to determine they are instituting an appropriate method of public participation.
Chapter 2: Methodology

The previous section outlines the requirements for federal rulemaking, the history of regulating genetically engineered organisms, and a history of the public’s opinion of genetically engineered organisms. In order to address the question of adequate public participation, the public comments on USDA-APHIS’s proposed rule “Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms” were examined. When a rule is proposed and open for comments from the public, all submitted comments that an agency receives are posted online. Comments on this proposed rule were viewed online at the Federal Registers website. www.regulations.gov/#!docketDetail;D=APHIS-2008-0023. Since the number of comments on this proposed rule was so large, a smaller random selection of comments was chosen for analysis. This chapter presents a detailed methodology for this research including the random selection of comments, the determination of the stakeholder groups, the coding of selected comments and analysis of the content of the comments. These comments were uploaded to and coded using a software program NVivo (QSR International, http://www.qsrinternational.com/products_nvivo.aspx). This software was used to organize and code the data for the analysis. This software was used because of the ability and ease of coding and keeping all the information in the same place.

General Research Design and Methods

The data for this research came directly from the federal register (www.regulations.gov/#!docketDetail;D=APHIS-2008-0023). All comments are
submitted by the public either electronically or through writing and are then scanned to be collectively posted online in the federal register. The period of time for this public comment period was open from October 9, 2008 and extended twice until it finally closed on March 17, 2009. There were a total of 6021 comments (some containing more than one file that commented on the proposed rule) submitted to USDA-APHIS during the extended open comment period. Usually a submitted comment that contained more than one file contained a collection of form letters, petitions or multiple news and journal articles. Each submission that was given an identification number by the Federal Register was counted as one individual comment in this analysis.

In order to address the research goal of determining whether this form of public participation is an adequate method of engaging the public in the rulemaking process (i.e. representative of interest groups and concerns) the profile of who commented and the content of the comments were analyzed. Two random samples of 1000 comments each were taken from the total submitted comments. The first random 1000 comments were selected for initial analysis. A second 1000 comments were selected for secondary analysis to ensure that a 1000 sample was representative of the 6021 submitted comments. In order to determine randomized selections for further analysis, the numbers 1-6021 were entered into an excel spreadsheet. These numbers corresponded with the numbers that the Federal Register assigns each submitted comment. Using the command, RAND( ), random numbers were generated next to each Federal Register number. The randomly assigned numbers were then sorted lowest to highest. The first random
thousand were selected for initial analysis. The second thousand were selected for secondary analysis, and compared to the first batch of a thousand.

Figure 2: A diagram of the random selection process for comments submitted on the proposed rule.

In order to ensure that a representative sample was taken of the submitted comments, the breakdowns of the initial and secondary analysis were compared to one another. The results of original and form letter comments were similar between both the initial and secondary analysis (table 3). The variation between the two random samples was not statistically different, indicating that our two sub-samples constitute a fair representation of the total submitted comments.
Table 1: A breakdown of the initial and secondary data collections by stakeholder groups

<table>
<thead>
<tr>
<th></th>
<th>Initial Data Collection</th>
<th>Secondary Data Collection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Form Letter</td>
<td>Original Comment</td>
<td>Total</td>
</tr>
<tr>
<td>Academia</td>
<td>0</td>
<td>3</td>
<td><strong>3</strong></td>
</tr>
<tr>
<td>Community Group</td>
<td>5</td>
<td>3</td>
<td><strong>8</strong></td>
</tr>
<tr>
<td>Individuals</td>
<td>680</td>
<td>243</td>
<td><strong>923</strong></td>
</tr>
<tr>
<td>Conventional Farmers</td>
<td>0</td>
<td>3</td>
<td><strong>3</strong></td>
</tr>
<tr>
<td>Governmental Organizations</td>
<td>0</td>
<td>3</td>
<td><strong>3</strong></td>
</tr>
<tr>
<td>Industry</td>
<td>0</td>
<td>4</td>
<td><strong>4</strong></td>
</tr>
<tr>
<td>International Individuals</td>
<td>5</td>
<td>2</td>
<td><strong>7</strong></td>
</tr>
<tr>
<td>Native Americans</td>
<td>0</td>
<td>1</td>
<td><strong>1</strong></td>
</tr>
<tr>
<td>NGO</td>
<td>3</td>
<td>16</td>
<td><strong>19</strong></td>
</tr>
<tr>
<td>Organic and Alternative Farmers and Advocacy Groups</td>
<td>12</td>
<td>13</td>
<td><strong>25</strong></td>
</tr>
<tr>
<td>Total</td>
<td>705</td>
<td>291</td>
<td><strong>996</strong></td>
</tr>
<tr>
<td>Overall Total</td>
<td><strong>996</strong></td>
<td><strong>999</strong></td>
<td><strong>1995</strong></td>
</tr>
</tbody>
</table>

The single largest group commenting on the proposed rule was individuals, making up over 90% of total comments analyzed. A majority of the comments submitted by individuals were form letters, although the largest number of original comments also came from individuals. All comments from individuals were evaluated to be original or not original. Original comments were those that demonstrated the submitted document was the individual’s own thoughts about the issue, a form letter was identified by its format and wording as it was common among multiple submissions.
Figure 3: The most common type of form letter present in the submitted comments.

<table>
<thead>
<tr>
<th>To whom it may concern,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docket No. APHIS-2008-0023</td>
</tr>
<tr>
<td>Regulatory Analysis and Development</td>
</tr>
<tr>
<td>PPD, APHIS, Station 3A-03.8</td>
</tr>
<tr>
<td>4700 River Road Unit 118</td>
</tr>
<tr>
<td>Riverdale, MD 20737-1238.</td>
</tr>
</tbody>
</table>


I am very concerned about the risks posed by genetically engineered crops. They threaten human health, family farmers, and the environment. I urge USDA to withdraw the proposed rule, publish the Environmental Impact Statement for public review and comment, and suspend all new GE crop approvals in the interim.

After USDA releases the EIS, a comment period of at least 90 days is needed so the public has the opportunity to fully participate in a transparent process on this important issue. This will not only aid in the development of the final EIS but also in the drafting of a new proposed rule. The current proposed rule does little to close the loopholes in the regulations the rule is designed to replace and it creates more gaps than it fills.

Sincerely,

Original comments and form letters submitted by all stakeholders were separated for content analysis. Five types of form letters were identified and analyzed for content.

The most common type of form letter is shown below (Figure 1). Other form letters contained similar information; they all were negative towards the proposed rule and requested it be withdrawn.
Table 2: Number of original comments analyzed per stakeholder groups

<table>
<thead>
<tr>
<th>Stakeholder Group</th>
<th>Number of Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia</td>
<td>8</td>
</tr>
<tr>
<td>Community Group</td>
<td>6</td>
</tr>
<tr>
<td>Conventional Farmers</td>
<td>5</td>
</tr>
<tr>
<td>Governmental Organizations</td>
<td>5</td>
</tr>
<tr>
<td>Individuals</td>
<td>96</td>
</tr>
<tr>
<td>Industry</td>
<td>11</td>
</tr>
<tr>
<td>International Individual</td>
<td>4</td>
</tr>
<tr>
<td>Native American</td>
<td>3</td>
</tr>
<tr>
<td>NGO</td>
<td>22</td>
</tr>
<tr>
<td>Organic and Alternative</td>
<td>26</td>
</tr>
<tr>
<td>Farmers</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>186</strong></td>
</tr>
</tbody>
</table>

Since the number of original comments submitted by individuals was so large (over 200), a smaller random sample of 50 was taken from both the initial and secondary data collection using the same RAND() command in excel. These 100 original comments were then used for content analysis. All the other stakeholder groups had much smaller numbers and were used in their entirety.

Figure 4: The random selection process for Individual original comments.
Research Questions

To address the first research question, who is commenting on the proposed rule, combined randomly selected comments from both the initial and secondary analysis, were used to sort the comments into the appropriate stakeholder group according to how they self-identified themselves in their submitted comment. In the Federal Register, submitters of comments have the option to identify themselves as belonging to an organization. These self-identified organizations were used to sort comments into their respective stakeholder group. The following groups were identified as stakeholders, Academics, Community Groups, Conventional Farmers and Advocacy Groups, Governmental Organizations, Individuals, Industry, International Individuals, Native Americans, NGO, and Organic and Alternative Farmers and Advocacy Groups. (See Table 4) When a comment was identified as coming from a member of an organization, an internet search was done to determine into which stakeholder group the comment belonged. Individuals was used as a catch-all group, if the commentator did not identify him or herself in the space provided for an organization, and there was no identification in the comment itself, it was placed in the individual stakeholder group. If an individual self-identified with belonging to a college or university, but was not identified by the organization as a professor or a member of the staff (according to a websearch), they were categorized as an individual.
Table 3: Stakeholder Groups. These are the definitions of the stakeholder groups that all comments were sorted into and analyzed. The results for each stakeholder group will be compared against one another.

<table>
<thead>
<tr>
<th>Stakeholder Group</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Academic</strong></td>
<td>This stakeholder group includes members of the academic community. Individuals who identified themselves as students were included as individuals.</td>
</tr>
<tr>
<td><strong>Conventional Farmers and Advocacy Groups</strong></td>
<td>This stakeholder group includes those commentators that came from individuals who stated an affiliation with a conventional farm (i.e. farmers) or commentators who stated an affiliation with an advocacy group for conventional farming, also those commentators which came from sources that support or trade commodities from conventional farming.</td>
</tr>
<tr>
<td><strong>Community Groups</strong></td>
<td>This stakeholder group includes organizations that are supported by members of a specific community. Could include national organizations, but comments submitted were made by local group chapters.</td>
</tr>
<tr>
<td><strong>Governmental Organizations</strong></td>
<td>Includes comments from both domestic governmental groups (i.e. state agricultural agencies) and international governmental groups (i.e. government agencies from other countries), as well as members of the legislature.</td>
</tr>
<tr>
<td><strong>International Individuals</strong></td>
<td>Those individuals who submitted a comment and listed no affiliation in their comment with any group and listed their address as outside of the U.S.</td>
</tr>
<tr>
<td><strong>Individuals</strong></td>
<td>All comments that came from individual citizens who did not state a connection to a particular interest group or an affiliation with another stakeholder group. Includes individuals and those who wished to be identified as consumers.</td>
</tr>
<tr>
<td><strong>Industry</strong></td>
<td>Comments coming from companies who either produce or sell inputs and outputs for agriculture. This group includes both conventional industry producers such as biotech companies and organic industry producers.</td>
</tr>
<tr>
<td><strong>Native Americans</strong></td>
<td>Includes comments from Native American tribes and groups.</td>
</tr>
<tr>
<td><strong>NGO</strong></td>
<td>All comments made from organizations that are non-governmental, but also do not fall into other categories. Reflecting a wide range of interests and opinions about food and agriculture.</td>
</tr>
<tr>
<td><strong>Organic Farmers and Advocacy Groups</strong></td>
<td>Includes all comments that come from individual organic farmers and those individuals that stated an affiliation with a particular organic or alternative farming interest group.</td>
</tr>
</tbody>
</table>
The second research question asked what views/concerns do stakeholder groups have about the proposed rule and genetically modified organisms. In order to address this question, it was split into two parts. The first part examined the content of the original responses. The second part examined the content and amount of form letters submitted. All of the comments were divided into these two groups and then further separated down into stakeholder groups. All of these comments were coded and analyzed for concerns regarding the proposed rule and genetically modified organisms using the computer software program NVivo. Also, if it was possible to determine the attitude of the writer towards GEO crops in general the comment was categorized as being negative, positive, or neutral. The strength of the attitude of the comment (how positive or negative) was also coded by the researcher. Analysis was done on the main concerns expressed in each stakeholder group and compared against one another. The comments were examined for similarities and differences in concerns expressed with both the proposed rule and GEO’s overall.
In order to analyze the concerns expressed in the original comments categories of concerns, or codes, were created. These codes were created using bottom-up theory and thematic analysis. Bottom-up theory is the creation of theory through the exploration of data (Gibson, 2009). Using bottom-up theory allowed hypotheses to be generated from the comments, rather than using theories created prior to conductions the content analysis. This theory was used in order to let it arise from engagement in the research rather than imposing what the author thinks should be present in the research (Gibson, 2009). Thematic analysis refers to the process of analyzing data according to commonalities, relationships and differences across a data set (Gibson, 2009). Codes were created if they fell into the following circumstances; 1) a theme was expressed more than once, 2) Something was stated with intensity or strong emphasis and 3) Comments expressing different opinions about the same topic. After each code was created, code
definitions were made for each code by outlining a basic rule that must be fulfilled in order for a comment to be coded in a specific code.

After a preliminary reading of comments, codes were created (See Table 5). After the codes were created, the randomly selected comments were each read through and coded for areas of support and concern based on its content. All comments were coded for all areas of concern that were present. (i.e. if a comment expressed concern or support for both gene flow and consumer choice both areas were coded.) If a code became too complex or general, then codes were split into two separate codes. If two codes became too intertwined and difficult to distinguish they were merged into the same code (Gibson, 2009). An index of all decisions made during the coding process was kept. This was useful to keep track of all the changes made and proved to be a useful tool for reflecting on the development of the coding system (Table 5). In the process of coding, it was realized that for some codes, a subsection emerged during the coding process. These were created as tree nodes or sub-nodes of the original nodes.

Table 4: Coding Categories. These categories were used to identify concerns and support expressed in the original comments. Each category will be coded using NVivo.

<table>
<thead>
<tr>
<th>Consumer Choice</th>
<th>Consumers’ right to choose if they want to consume food that has been genetically modified.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling</td>
<td>Labeling food products if they contain or used genetically modified organisms in any part of their production.</td>
</tr>
<tr>
<td>Gene Flow</td>
<td>The spread of genetically modified genes to conventionally bred or native plants and the impacts that could have.</td>
</tr>
<tr>
<td>Threat to organic farming</td>
<td>The threat of gene flow poses a threat to organic farming, in that a crop cannot be sold as organic if it contains genes that have been genetically modified.</td>
</tr>
<tr>
<td>Low Level Presence</td>
<td>Low level presence of GEO’s in the marketplace (especially the food supply) and whether that is acceptable.</td>
</tr>
<tr>
<td>Environmental</td>
<td>Unknown factors affecting environmental health</td>
</tr>
<tr>
<td>Concerns</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td>Human and Animal Health</td>
<td>Unknown factors that could affect human and animal health from eating food containing genetic engineered genes.</td>
</tr>
<tr>
<td>Exemption from Regulation</td>
<td>Concerns or support expressed for genetically engineered items that might be considered exempt from regulation</td>
</tr>
<tr>
<td>Non-regulated Status</td>
<td>After a genetically engineered product has been on the market for a certain period of time without any issues or causes for concern, whether the proposed rules should deregulate it to a non-regulated status. Also, whether similar products would qualify for the same non-regulated status.</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
<td>The proposed rule does not specifically mention the regulation of pharmaceutical crops. Separate regulation of pharmaceutical crops needs to be addressed in this rule or in separate legislation.</td>
</tr>
<tr>
<td>Event-by-Event Regulation</td>
<td>The appropriateness of using event-by-event regulation for regulating genetically engineered organisms and the time constraints that comes with event-by-event regulation.</td>
</tr>
<tr>
<td>Product vs. Process Regulation</td>
<td>At what point should regulation be focused on? Some argue that the end product is what needs to be regulated, others argue for regulating the process that is used to produce a product.</td>
</tr>
<tr>
<td>Precautionary Principle</td>
<td>Products of genetic engineering should be regulated strictly until more it is certain that they are not harmful to humans, animals, or the environment</td>
</tr>
<tr>
<td>Matrix and Assignment of Categories</td>
<td>The proposed rules currently propose a matrix system to assign GEO’s to different regulatory categories. Is this an appropriate system for regulating GEO’s.</td>
</tr>
<tr>
<td>Science Based Approach</td>
<td>The proposed rules should regulate in a process that is strictly science based. This would remove subjectivity from the regulations and ensure that all products that need to be regulated will be.</td>
</tr>
<tr>
<td>Scope of Regulations</td>
<td>The scope of regulations is not broad enough to cover all the potential hazards or problems that could arise from this issue or is too broad and is restricting research and development in this area.</td>
</tr>
<tr>
<td>Regulating only Recombinant DNA</td>
<td>Currently the definition of a GEO according to APHIS is anything modified using recombinant DNA techniques. New methods allow genetic modification without the use of recombinant DNA techniques. These would not be covered in the current proposed regulations.</td>
</tr>
<tr>
<td>State vs. Federal Regulations</td>
<td>The wording of the proposed rule seems to suggest that federal regulation would trump state regulation.</td>
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</table>
Who decides regulation?

Some language in the proposed rule is unclear if the regulators would decide what new products would need to be regulated or if the producers/creators of a new GEO would be able to decide if their product is regulated.

Wording of Proposed Rule

The wording of the proposed rule was confusing to some in certain areas; requests were made that this wording should be clarified.

Changes in Regulation Affecting Research

The proposed rules do not separate out research that is done by academics compared to research that is done by industry. The proposed rules would not affect each sector’s research differently and some researchers argue that they should.

Limitations

The coding for this study was done by one researcher and therefore subject to bias and mistakes. In order to verify the results and to make sure there was no bias in the study, coding should also be done by a second researcher. A random selection of comments was chosen to be analyzed for this analysis. This analysis did not examine every single comment submitted to the proposed rule.
Chapter 3: Current Regulations vs. Proposed Regulations

The legislative authority for USDA-APHIS comes from the Plant Protection Act (PPA) of 2000 which consolidated related responsibilities from several previous statutes, including the Plant Quarantine Act, the Federal Plant Pest Act (FPPA), and the Federal Noxious Weed Act (McHughen, 2008). USDA-APHIS has proposed this new rule in order to 1) align the regulations to the PPA since the previous rules were enacted in 1987 and the PPA contains provisions that were not in effect when the old regulations were written, and 2) respond to new trends and technology that have emerged in the 20 years that have passed since the current regulation was written. The proposed rule also seeks to incorporate the previous 20 years’ experience that USDA-APHIS has regulating genetically engineered organisms along with new provisions required in the 2008 farm bill. (USDA, 2008).

There are three major new changes from the current regulations to the proposed rule. The first major change in the proposed rule includes new regulations that allow the USDA to incorporate noxious weed regulations into their scope of regulations for genetically engineered organisms. All new genetically engineered organisms will now be evaluated to determine if they pose a risk as a noxious weed. The USDA defines a noxious weed as “Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health or the environment.” (USDA, 2008) In order to determine if a plant qualifies as a noxious weed, the USDA will first determine if the plant causes direct
injury or damage to agriculture or the environment. If damage or injury is established, the evaluation moves on to determine if any indirect damage is done to “other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health or the environment”. AHPIS will often quantify harm or injury done by noxious weeds in terms of economic loss.

All GEO’s will be evaluated for noxious weed status, until the potential risk of noxious weeds can be evaluated. The current regulations cover what are called “regulated articles”. These are genetically engineered organisms that are either known to be plant pests or are thought to be plant pests. A list of these known plant pests is kept by APHIS and petitioners can petition to add or remove a plant pest to or from this list. The proposed regulations add definition and clarify what will be regulated. The goal of making this change was to make it easier to identify when a new genetically engineered organism would need to undergo regulations and under what category they fall.

**Figure 6:** The criteria under the proposed rule for determining the importation, interstate movement, and release into the environment of a new genetically engineered organism.

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<tr>
<th>i)</th>
<th>The unmodified parent plant from which the GE plant was derived is a plant pest or noxious weed, or</th>
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<td>ii)</td>
<td>The trait introduced by genetic engineering could increase the potential for the GE plant to be a plant pest or noxious weed, or</td>
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<td>iii)</td>
<td>The risk that the GE plant poses as a plant pest or noxious weed is unknown, or</td>
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<td>iv)</td>
<td>The Administrator determines that the GE plant poses a plant pest or noxious weed risk.</td>
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The second major change under the proposed rule would be the scope of the proposed rules when it comes to overlapping areas of regulation. Under the current regulations, the USDA and the EPA both regulate GEO’s that qualify as biological control micro-organisms. Under the proposed rule, the USDA no longer intends to regulate GEO’s that are micro-organisms and also qualify to be regulated as biological control organisms by the EPA under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), with the understanding that such GEO’s are not required to be monitored by both agencies (USDA, 2008). The proposed rule would also exclude the regulations of GE microorganisms “where the recipient microorganism is not a plant pest and where the added genetic material was from a donor organism that is well characterized and contains only non-coding regulatory regions”\(^2\) (USDA, 2008). USDA-APHIS states “that there is no need for such genetically engineered organisms to be evaluated by both agencies”. EPA is responsible for examining the environmental safety of such organisms, and this includes plants. To have USDA regulate plants again separately is too much of a redundancy.

Currently, the regulations provide for two methods of regulating genetically engineered organisms. One, the notification procedure is an administration streamlined procedure, which has generalized performance standards already included in the

\(^2\) Non-coding regulatory regions: Sections of DNA that do not code for protein expression (Makalowski, 2007).
regulation. The term itself is misleading, no notification is made directly to the public about the release of the genetically engineered organisms in either form of regulation. In order to enroll for regulation under notification, the applicant must submit a letter to USDA-APHIS that documents how the GEO meets the six designated criteria and standards set forth by the regulation (i.e. must not be a noxious weed, not engineered with any human or animal pathogens, etc.). If approved, the regulation process and importation and transport within the U.S. are the same for every GEO. The setup of the notification procedure can make it very difficult to ensure compliance and to enforce the regulations. Also, because it is a streamlined process the standards are fairly ambiguous and USDA-APHIS does not have the ability to add conditions to the notification procedure.

The second method currently in place for regulating a GEO is the permit procedure. The permit procedure for use by all GEO’s that do not qualify for release under the notification procedure. This procedure requires much more data about the GEO that is to be regulated than the notification procedure and the application process is not as streamlined. However, with the permit, the conditions and regulations can be specifically structured around the individual GEO.

Under the new proposed rule, all applications for authorization of importation, interstate movement and release into the environment would be conducted under a reorganized and slightly modified permit procedure. The proposed rule would technically eliminate the notification procedure. The USDA does not feel that this method is providing the best regulation. In this procedure the application for permits for interstate
movement and importation would be fairly similar to what it is now. Environmental release permits, would however undergo a major restructuring.

All applicants for environmental release permits would initially be sorted by general risks and management issues, which would then be followed by an evaluation to fully determine the risk of release. This would become the primary basis for adding the future permit conditions (USDA, 2008). The grouping of applications into categories is not to suggest that all GEO’s in a similar group will require the same oversight that will be determined by an individual evaluation done by the USDA.

All potential releases will be sorted into categories that can be treated similarly based on the risk of persistence in the environment without human intervention (low, moderate, high, severe) and/or sorted based on the trait engineered into the plant based on definitions of plant pests and noxious weeds (low, moderate, high, severe) (USDA, 2008). Categories A-D will be for GE plants and category E will provide for all non-plant organisms. The proposed rule does not give clear definitions or examples of what each category will cover. Nor does it state if an applicant would be responsible for applying to a specific category or if USDA-APHIS would place each applicant in the appropriate category.

USDA-APHIS is correct in addressing new regulations for genetically engineered organisms. The two current methods of regulation do not offer the flexibility needed to regulate genetically engineered organisms effectively. The new rule has the potential to allow USDA-APHIS the flexibility they need to regulate effectively. With multiple categories for regulation, USDA-APHIS could tailor the regulation needs more
specifically to applicants. However, as the rule stands now it is confusing for both regulators and applicants. The rule gives no specific details about the new categories and does not specify who will be responsible for which part of the regulation. USDA-APHIS needs to address these issues if they intend to formally publish the rule. Without these guidelines the new system will be confusing for both regulators and applicants. In the next chapter, the public comments are reviewed for their critiques of the proposed rule.

Some of them address the same issues and concerns expressed here, while others express a much more rigorous critique of genetically engineered organisms overall.

What was the public participation process in this rule?

When the proposed rule was initially published on October 9, 2008 the original period for public comments was open until November 24, 2008. By the time this period for public comments had closed, USDA-APHIS had received approximately 15,000 comments (Federal Register, Supplemental Materials, 2008). On January 16, 2009 a notice was published in the federal register that reopened the public comment period for another 60 days, from January 16- March 17, 2009. USDA-APHIS also decided to consider public comments received after the comment period had originally been closed, November 24, 2008 and before the comment period officially became reopen again. In the same notice, USDA-APHIS also requested more comments addressing the following four issues. 1) Scope of the regulation and which GE organisms should be regulated. 2) Incorporation into the USDA-APHIS part 340 regulations into the Plant Protection Act’s noxious weed authority. 3) Elimination of the notification procedure and revision of the
permit procedure. 4) Environmental release permit categories and regulation of GE crops that produce pharmaceutical and industrial compounds. These four areas were identified for comment by USDA-APHIS because in some cases they had been identified by consumers but the consumers had failed to provide specific suggestions about how the proposed rule should be modified to address these concerns (Federal Register, 2009a).

Public forums were held during the original comment period in order to solicit public opinions in person. Three forums were held, one in Davis, CA on October 28, 2009, the second in Kansas City, MO on October 30, 2008 and the third in Riverdale, MD on November 13, 2009. A fourth public forum was held in Riverdale, MD on April 29 and 30, 2009. Besides a scoping period held on March 13, 2009 in Riverdale, MD, this was the only public forum held during the extended comment period. The focus of this meeting was to discuss the key concerns that were presented thus far in the public comments. The comment period was then extended 60 days past the last day of this meeting to June 29, 2009.

After the Public Scoping Meeting on Proposed Regulations held on March 13, 2009, USDA-APHIS published a document to the Federal Register stating issues identified through written comments and other issues identified during the public meeting as well as a list of questions to be asked at the next meeting to be held at the end of April, 2009.

Issues that USDA-APHIS identified through the written comments included: 1) the scope of the regulations and which genetically engineered organisms should be regulated, 2) incorporation of PPA Noxious Weed provisions, 3) elimination of
notification procedure and revision of permitting procedure, and 4) regulation of genetically engineered crops producing pharmaceutical or industrial compounds. Other issues identified during the meeting included how USDA-APHIS will deal with LLP, long term monitoring of deregulated crops, consideration of economic impacts in deregulation process, transparency and public participation in regulatory procedures, “Functionally different” products, imports, clarification of the statutory and regulatory authority (PPA), case studies/examples of the regulatory processes.

Questions were also identified that will be addressed at the next public meeting. Selected examples include, when it comes to noxious weeds, is the agency’s proposal clear? If not, what clarity is needed? What are the advantages/disadvantages of the proposed system? Is this truly a substantive change? Should all GEOs be regulated by USDA? If not, what characteristics should trigger regulation? If genetic engineering changes the functionality of the crop or plant should it be regulated differently? Will a developer decide if the organism regulated process is voluntary, or should the process be mandatory? What are aspects of the notification system that should be continued in the proposal, what aspects are useful for continued use, what are not? Should a tiered permitting system incorporated in the proposed rule?
Chapter 4: Who is commenting and what are they saying?

Analysis of Comments

One of the goals of this paper is to determine who is commenting on the proposed rule in order to determine if public comments are an effective form of public engagement in rulemaking. The methodology for selecting stakeholder groups was discussed in Chapter 2.

The proposed rule affects all consumers in the U.S. by affecting how genetically engineered organisms and crops would enter into the food system and ecosystems, however only a very small set of U.S. citizens commented on the proposed rule. The 2010 census put the U.S. population at approximately 309 million people and only 6000 comments were made on the proposed rule, meaning that less than 0.001% of the population commented on this proposed rule. The citizens who choose to comment on the proposed rule were not picked at random or chosen by their peers to represent them in this process. Those that commented on this proposed rule did so because they chose to. It was an issue that was important to them and that they felt they needed to express their opinion on.

Stakeholder groups were identified according to the methodology of this paper. The stakeholder groups identified in this analysis are the following, Academia, Community Groups, Conventional Farmers and Advocacy Groups, Governmental Organizations, Individuals, Industry, International Individuals, Native Americans, Non-governmental organizations (NGO), Organic and Alternative Farmers and Advocacy Groups.
The highest number of original comments came from individuals, with 96 original comments analyzed. The second highest amount of comments came from Organic and Alternative Farmers and Advocacy Groups with 26 comments, followed closely by NGO’s with 22 original comments. The smallest commenting stakeholder groups were Native Americans and International Individuals, with three and four comments respectively (See Figure 3).

**Figure 7: The Total Number of Comments Analyzed from each Stakeholder Group**

Breakdown of Stakeholder groups

Comments were sorted into stakeholder groups by how they self-identified themselves (See Chapter 2: Methodology). While some of the stakeholder groups represent homogeneous populations, such as academia, community groups, international individuals, and Native Americans, other groups represent a wider variety of the population such as conventional farmers, governmental organizations, industry, NGO’s and Organic and Alternative Farmers. Conventional Farmers and Advocacy Groups
stakeholder group was made up of one county farm bureau, three national conventional farming associations, one non-profit organization, and one conventional beef farmer. The Industry stakeholder group contained a wide range of comments, ranging from comments from major biotech companies to comments from companies producing food made from all organic ingredients. Governmental Organizations included two state agencies, one congressman, and two comments from the governments of other countries. The Conventional farmers and Advocacy groups stakeholders contained comments from two farmers, one lobbying organization and two industry organizations. The Organic and Alternative Farmers and Advocacy groups stakeholder group was composed of eight farmers, organic and alternative farming advocacy groups and three organic industry organizations. While the NGO stakeholder group contained a large number of comments overall, many of these comments were submitted by the same organization. One organization had eleven separate comments present in the random selection for analysis. Many of these comments were actually articles taken from various sources such as periodicals and journals and submitted to the federal register as comments. Some of the comments from NGO’s also included form letters with hundreds of signatures.

Tone of Stakeholders Comments

Overall the comments that were submitted on the proposed rule had a negative tone to them. This is to be expected, if the effort is being made to write a comment, it would not be expected that they would write in support of the proposed rule. Instead stakeholders and citizens would write to make sure that changes or improvements they feel could be made, will be made before the final rule is put into place. Of all the
stakeholder groups the individual stakeholder group had the most negative comments overall, both in amount and in strength of negativity. There were 96 Individual comments analyzed, 89 of them were recorded as negative. There were no positive comments recorded in the Individual stakeholder group.
Figure 8: The concerns of stakeholder groups within each coding category
Top Ten Concerns Overall

The top ten concerns across all categories coded for where environmental health (52 coded concerns), human and animal health (46 coded concerns), gene flow (43 coded concerns), pharmaceuticals (41 coded concerns), matrix and assignment of categories (38 coded concerns), consumer choice (33 coded concerns), low level presence (31 coded concerns), who decides regulation (30 coded concerns), labeling (30 coded concerns), and threat to organic farming (30 coded concerns). These top concerns were unsurprising, due to the past concerns expressed about genetically engineered crops (Hallman et al., 2002, Hallman et al., 2003, The Mellman Group Inc., 2006).

The concern that involved the fewest amount of stakeholder groups was the threat to organic farming which only had three stakeholder groups express concerns. Low level presence, especially in the food supply, had concerns from the widest range of stakeholder groups with ten groups commenting in this area in many case low level presence was mentioned along with the threat to organic farming. Concerns were expressed that a low level presence of genetically engineered crops in the organic food supply could be dangerous to organic farmers³.

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³ In order to be labeled organic by the USDA, products can only contain 5% of ingredients produced using non-organically produced materials (USDA, 2008b)
Environmental health concerns were expressed by community groups, individuals, industry, international individuals, Native Americans, NGO, and organic and alternative farmers and advocacy groups. There were no statements that genetically engineered products benefited environmental health. Human and animal health concerns were expressed by community groups, individuals, industry, international individuals, Native Americans, NGO, and organic and alternative farmers and advocacy groups. There were no stakeholder groups that expressed that genetically engineered products benefited human and animal health. Gene flow concerns were expressed by academia, community groups, conventional farmers and advocacy groups, individuals, Native Americans, NGO and organic and alternative farmers and advocacy groups. There were no stakeholder groups that argued in support of gene flow or that it would be a desirable
event. Concerns with the regulation of plants genetically engineered to produce pharmaceuticals were expressed by academia, conventional farmers and advocacy groups, governmental organizations, individuals, industry, international individuals, Native Americans, NGO, and organic and alternative farmers and advocacy groups. There were no stakeholder groups that came out in support of pharmaceutical crops. Stakeholder groups concerned with the proposed matrix and assignment of categories included academia, conventional farmers and advocacy groups, governmental organizations, industry, Native Americans, NGO, and organic and alternative farmers and advocacy groups. Generally concern was expressed over the lack of clarification about how the proposed matrix would be implemented. For example, it is unclear if an applicant will choose the category that they will be applying to for regulation or if USDA-APHIS will place the applicant into a category. While there were no direct expressions of support, many stakeholder groups wanted clarification about how genetically engineered items would be regulated under the new proposed category system.

Support for consumer choice was expressed by community groups, individuals, industry, NGO, and organic and alternative farmers and advocacy groups. There were no stakeholder groups that expressed concern over too much consumer choice. Overall, the low level presence suggestion in the proposed rule raised concerns. These concerns were expressed by academia, community groups, conventional farmers and advocacy groups, governmental organizations, individuals, industry, Native Americans, NGO and organic and alternative farmers and advocacy groups.
In the proposed rule USDA-APHIS stated that they planned to incorporate previously proposed protocols for dealing with low level presence incidents. This would give USDA-APHIS the ability to take remedial action in the case an unapproved for release item were to be found in the seed or grain supply. This low level support statement did not address the presence of genetically modified seed in the organic food supply, which many of the comments made by individuals addressed. Cautious support for the low level presence incorporation into the proposed rule was expressed by academics, conventional farmers and advocacy groups and industry, many of these comments expressed support as long as the implementation of the low level presence rule could be handled appropriately.

**Figure 10:** Amount of support and concern expressed for the top 10 highest coded nodes

Concerns were expressed by academics, conventional farmers and advocacy groups, governmental organizations, individuals, industry, international individuals,
Native Americans, NGO and organic and alternative farmers and advocacy groups regarding the determination of who would decide the regulation of a new crop. The statement in the proposed rule reads, “Under the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in §340.0 to determine whether the GE organism is subject to the regulations.” Nowhere in the proposed rule does it state who the “responsible person” would be. No stakeholder groups expressed support for this statement in the proposed rule. All comments regarded it as unclear and confusing and expressed a need for USDA-APHIS to better describe what was meant before publishing the final rule.

Many groups were in support of labeling products that are made with genetically engineered products. These groups were community groups, governmental organizations, individuals, international individuals, NGO and organic and alternative farmers and advocacy groups. There were no concerns expressed about labeling, only support was expressed for the right to know what is in food products that we eat. Concerns were also expressed about the potential threat to organic farming. Stakeholder groups concerned about this were individuals, NGO’s and organic and alternative farmers and advocacy groups. All concerns expressed in this coding category expressed concern that genetically engineered crops pose a threat to organic farming. The categories of labeling and threat to organic farming have some overlap. The category labeling was applied when the comment specifically used the word “label”. Threat to organic farming was a broader category used when a concern was expressed about how genetically engineered crops pose a threat to organic farmers.
Table 5: Stakeholder groups and the top ten categories coded for in NVivo. An X was placed in the graph if a comment expressed either support or concern for each coding category at least once.

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<td>Conventional Farmers and Advocacy Groups</td>
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<td>Native Americans</td>
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<td>Organic and Alternative Farmers and Advocacy Groups</td>
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Top two concerns from each stakeholder group

Each stakeholder group had their own areas of concern. The top two areas of concern for each stakeholder group are addressed in this section as well as an explanation.

The top two concerns from academics were matrix and assignment of categories (10 coded references) and exemption from regulation (7 coded references). Most academic researchers were concerned over the lack of definition of each category. This could make it difficult for researchers applying for permits to know what information they should contain in their application. As one comment states, “By treating each case as a unique situation, it makes it impossible to predict precisely in which category a proposed product would be assigned” (APHIS-2008-0023-0432). Another comment points out that the proposed rule simply states that “Category A will be similar in regulatory oversight to environmental release notifications under the current system, and Categories B and C will be similar in regulatory oversight to various permits that have been issued under the current system” (APHIS-2008-0023-0392). This doesn’t provide much information to potential applicants about the new category system. It is difficult for a system to become more transparent if applicants do not know which category their application falls into, or what information is necessary to even complete their application. A detailed description is needed of each category beyond what is currently stated in the proposed rules.

The second highest concern expressed by researchers was exemption from regulation. This coding category included concerns and support expressed for genetically
engineered organisms that might be considered exempt from regulation. These comments were split between the regulation of interstate transport of seeds (3 coded references) and the regulation of “familiar” genetically engineered plants (4 coded comments). The interstate transportation of research materials is important to academic researchers and has an effect on the speed and ability of their research to be conducted. As one academic states, “I had to apply for a permit to mail a few transgenic tomato seeds to a colleague at a university in another state for strictly research purposes. If my colleague had been at a university in my own state, no permit would have been necessary…Transgenic Arabidopsis seeds have been conditionally exempt from this permit requirement since 1990…the ease with which transgenic stocks of Arabidopsis can be exchanged among researchers is critical to facilitating its use as a model scientific system” (APHIS-2008-0023-0392). Clearly something needs to be done to address this issue to encourage research in all areas.

Members of the academic community felt that the regulation of “familiar” genetically engineered plants should be exempt from regulation. The category of “familiar” genetically engineered organisms concerns the regulation of cisgenic/intragenic crops, random “knock-out,” overexpression, or antisense libraries (APHIS-2008-0023-3368) should be exempt from regulation or at the very least should be regulated under a lower level in the category system proposed by the new rule.

Other areas of concern that were high among academics were low level presence, regulating only recombinant DNA, regulations affecting research, and using a science based approach to regulate genetically engineered material (4 concerns per each
The top two concerns for community groups were human and animal health (6 coded references) and labeling (4 coded references). In general the concerns expressed by community groups objected to the use of genetically engineered organisms. One comment states, “I demand that the USDA prevent the production, use and shipment of GMOs...I do not want the food containing GMOs and will not purchase products containing them. I will only use and purchase foods which advertise the absence of these ingredients” (APHIS-2008-0023-1252).

Concerns expressed by community groups for human and animal health included potential allergic reactions, the rise of food allergies and cancer rates, and a general want to know about what is contained in food that they consume. As one comment states “People need to be aware of the contents of their food, just as the need to be aware of the risks, benefits and alternatives to medical and surgical treatment is recognized and provided for by the doctrine of informed consent” (APHIS-2008-0023-5083). Many of the community groups that provided comments felt they had a right to know if they were consuming genetically engineered products so that they could make choices to protect their health and their family’s health. This concern went hand in hand with the second highest concern expressed by community groups, labeling. One comment states that “the American Public Health Association has recommended the labeling of any food products that contain genetically modified organisms” (APHIS-2008-0023-5083). This identifies labeling as a right to know issue. Many comments expressed that labeling of products containing or made from genetically engineered crops is done in other developed
countries, “…40 countries require labeling of genetically engineered food, including the European Union, Australia, Japan, Russia, China, New Zealand, Brazil and South Africa” (APHIS-2008-0023-5083). In order to sell their products in these countries, U.S. food makers must currently label their products as containing or being derived from genetically engineered products. Many of these comments express the opinion that since some U.S. food manufactures must already do this to market their products to other countries, the same should be done here. Other concerns that were important for community groups included environmental health and gene flow (2 coded references per category).

Conventional farmers and advocacy groups top concern was the scope of regulations, which was broken down to include who decides regulation (8 coded references in total), the second highest concern was exemption from regulation (3 coded references). The comments from conventional farmer and advocacy groups support the regulatory authority of USDA-APHIS under the PPA of 2000 and they recognize that the rules do need to be updated and improved. However, concern was expressed over ambiguous wording in the proposed rule. The proposed rule states that “under the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in §340.0 to determine whether the GE organism is subject to the regulations.” (Federal Register, 2008) This seemed to state that a developer would have the choice to submit their product for regulation or not. If this was the intent, it would weaken the authority of USDA-APHIS by giving power to the developer. “Suggesting that a developer, researcher, importer, or other party could unilaterally determine
the regulatory status of a GE organism could undermine the credibility of USDA-APHIS’ entire regulatory process.” (APHIS-2008-0023-0300) The wording of this section in the proposed rule needs to be clarified before the final rule is published so that both regulators and developers are on the same page.

The second highest area of concern for conventional farmers and advocacy groups was exemption from regulation. They suggested having a category using the concept of familiarity to exempt certain types of genetically engineered organisms from regulation. “Allowing for an exclusion mechanism would provide USDA-APHIS with regulatory flexibility, would provide the regulated community with a transparent process they could potentially utilize, and would facilitate the more efficient use of USDA-APHIS resources.” (APHIS-2008-0023-0428).

The top concern of governmental organizations was the matrix and assignment of categories (5 coded references) and pharmaceuticals (2 coded references). Concerns of governmental organizations with matrix and assignment of categories include many concerns with the categories themselves. Concerns were expressed over how much of an improvement the categories would actually be compared to the current system of regulating on a case by case basis. The current two tiered system is complex and causes problems for USDA-APHIS, “…although the current two tiered system is not perfect, the proposed three tiered system could prove to be unmanageable by the USDA.” (APHIS-2008-0023-0554) The process for assigning applications to categories needs to better defined as well as how applications will be determined to fit into each category. More
information was also requested about the role persistent risk and the potential harm or damage the engineered trait might play in determining the factor for regulation.

Concerns with plants producing pharmaceuticals were only expressed by state departments of agriculture within the U.S. Both agencies that submitted comments expressed concern with regulating plants producing pharmaceuticals using the same methodology used to regulate genetically modified crops. “Assessing the toxicity or potential harm of these compounds in the same way that compounds that provide e.g. insect resistance, misses the point” (APHIS-2008-0023-0467). Since the goal of a pharmaceutical crop is completely different than that of a crop designed to produce an insecticide, regulation for these two crops should be done differently. Concern was also expressed over using any type of food or feed crop to produce pharmaceuticals. “…the inherent risks in using food/feed crops for drug production are best avoided altogether” (APHIS-2008-0023-0467).

The top two concerns of the Individual stakeholder group were consumer choice (24 coded references) and environmental concerns (20 coded references). A majority of the comments expressed by Individuals addressing consumer choice objected to the use of genetically engineered crops (63%). Many expressed that they had a right to know whether or not the food they consume came from genetically engineered products. “I feel the public should be informed and be able to make a choice for themselves, as to whether or not they would like to subject their bodies to that kind of genetically enhanced food without knowing how it might effect human physiology, growth, aging and reproduction” (APHIS-2008-0023-0210). Comments expressed by Individuals that called for consumer
choice thought this should be done by labeling. Labeling (19 coded references) was the third most popular coded category for Individuals. Individuals supported labeling because they felt it is within their rights to know if they are consuming genetically engineered products or not. “I want NO Genetically Modified Organisms or Products in my grocery store or in my environment. We have done fine without them for thousands of years. There is no useful need for these products.” (APHIS-2008-0023-3255).

Environmental health was the second highest area of concern among Individuals. A majority of comments in this area also rejected any use of genetically engineered crops (60%). “I am deeply concerned about the impact on our environment of genetically engineered crops. So much is unknown about these contrived crops and the potential consequences of them being released into the atmosphere” (APHIS-2008-0023-5484). The health of the environment is important to the Individual stakeholder group. Concerns expressed included the increase use of pesticides and herbicides in agriculture which poses an increased risk to the environment. “GMO's are altering and limiting our food crop options, adversely effecting beneficial insects, parasites, bacteria etc. that our current science is still to primative to appreciate the positive and essential health benefits of to our land and ourselves” (APHIS-2008-0023-1570). The threat to biodiversity was viewed by many individuals as not a worthwhile risk to environmental health.

Industry’s top two concerns were matrix and assignment of categories (12 coded references) and the scope of regulations (8 coded references). The Industry stakeholder group submits the most applications for genetically engineered organisms to USDA-APHIS. Therefore most of their comments addressed the proposed matrix and category
system that would replace the current notification and permit system. Many comments supported in principle the tiered approach to regulation, but expressed doubt that such regulation could be executed to the extent necessary. The majority of comments addressed concerns of how the categories are defined and how an applicant would know what to include in their application. Without good definitions of categories the application process would be much more difficult for stakeholders from Industry to file applications. The proposed rule implies that an application would be placed into the appropriate category by USDA-APHIS. “…to appropriately place a permit application into a specific category would…require(s) more than a casual review – at which point the reviewer has already become quite familiar with most details of the GE organism. To initiate another “detailed review” at this point seems redundant.” (APHIS-2008-0023-0434). Other potential problems that Industry stakeholders anticipate with the proposed category system include “…without clear understanding of which category a GE organism will be placed, applicants would be forced to plan for the worst possible scenario and … consequently prepare and submit sufficient data to meet the demands of the higher category rather than face potential delays due to resubmission” (APHIS-2008-0023-0434). This excess information could slow the application process for USDA-APHIS and result in longer waiting periods for applicants.

Many of the comments from the Industry stakeholder group expressed concern that there is no category in the proposed rules for organisms which are considered to be low risk. “A “NOT-HARMFUL” (near zero) risk category is critically needed and can be scientifically justified. Some traits have proven, less than a “low” risk potential.”
Industry stakeholders argued that such a category is needed in order to reflect the risk of such organisms and to make the most of USDA-APHIS previous 20 years of experience regulating genetically engineered organisms.

Overall, the comments from Industry stakeholders can be summed up with the following “…we believe that the proposed changes would make the current system essentially unworkable. USDA-APHIS should therefore further clarify its policies and procedures for the proposed changes to the field trial permitting system, and related recordkeeping and enforcement procedures, and allow time for comment before implementing such changes.” (APHIS-2008-0023-0398).

The second largest concern to the Industry stakeholder group is the scope of the regulations. This category was broken down to include a smaller category, regulation of only recombinant DNA (coded references). This node included concerns from industry about what specifically constitutes noxious weed risk and the regulation of non-viable plant material. For non-viable plant material, USDA-APHIS needs to be clearer about what will trigger regulation and what the regulation will be regulated. The science of genetic engineering is progressing rapidly, while all genetic engineering used to be done using recombinant DNA technology, new advances allow genetic engineering to be done without using recombinant DNA. Therefore “Emerging technologies may lead to transgenic products produced via methods that will not trigger review under USDA-APHIS’s current regulations…” (APHIS-2008-0023-0465). If these products don’t fall under the regulation of the proposed rule, where will they be regulated? There are already new existing technologies that do not necessarily fall under these regulations. For
example an argument could be made that crops resulting from a process called TagMo (Targeted Gene Modification) would not fall under the regulations for genetically engineered crops and therefore requires no regulation beyond that for conventional bred crops (Kuzma, in press).

International Individuals top two concerns were human and animal health (3 coded concerns) and who decides regulation (2 coded concerns). International Individuals concerns with human and animal health were how the regulation of genetically engineered organisms in the U.S. had an effect on citizens of other countries, especially those that currently ban the growth or marketing of products containing genetically modified organisms. “THESE DECISIONS ULTIMATELY AFFECT CITIZENS IN OTHER PARTS OF THE WORLD, TOO. IT IS NOT JUST AN ISSUE FOR THE UNITED STATES PLEASE CONSIDER THE WIDER IMPLICATIONS OF US ACTIONS AND LEGISLATION.” (APHIS-2008-0023-3141)

International individuals also expressed concerns over wording in the proposed rule that seemed to suggest that the developers of genetically engineered organisms will have the authority to decide if their product needs to be approved by USDA-APHIS or not. “The new rules would allow biotech companies to self-assess the safety of their own experimental GE crops to determine if the USDA should regulate them, allowing many crops that should be regulated to endanger life and livelihoods.” (APHIS-2008-0023-5456). This is concerning to international individuals because they feel that genetically engineered organisms must be strictly regulated
Native American top three concerns were environmental concerns (3 coded references), gene flow (3 coded references), and human and animal health (3 coded references). Native American communities hold traditional crops like wild rice very sacred. Recent attempts to genetically map/engineer crops like these have made Native American stakeholders concerned with keeping their traditional crop free of unmodified genes. The flow of genes from genetically modified crops to traditional crops such as wild rice puts the Native American culture at risk. “We view GE organisms as a potential, long-term threat to continued annual rice yield, and have repeatedly expressed our sovereign opposition to genetic engineering of food at state, regional and national levels” (APHIS-2008-0023-5396). Environmental health and gene flow shared similar concerns, mainly the protection of the native species of crops. “…especially those crops engineered to withstand repeated applications of herbicides and crops that produce drugs and industrial chemicals. They threaten human health, biodiversity, centers of origin, indigenous varieties, soil organisms and wildlife, possibly including essential pollinators like bees” (APHIS-2008-0023-4878).

Concern from Native American stakeholders about human and animal health included comments such as “These life forms have not been proven safe for health or the environment. Companies keep their research secret and, to our knowledge, there has been no post-market investigation to determine if or how these life forms affect human health” (APHIS-2008-0023-4878). Comments such as this one argue for the regulation of new technologies under the precautionary principle. The theory behind the precautionary principle is that all new technologies should be proven safe before they are allowed onto
the market. If there are any concerns about the safety of a new technology, the technology should not proceed (Foster et al., 2000).

NGOs top two concerns were environmental concerns (18 coded references) and gene flow (14 coded concerns) which was broken down to include the threat to organic farming (additional 10 coded concerns). Environmental concerns that were expressed by NGOs included many possible consequences of using genetically engineered organisms. “Possible risks of GEOs could include: (1) creating new or more vigorous pests and pathogens; (2) exacerbating the effects of existing pests through hybridization with related transgenic organisms; (3) harm to nontarget species, such as soil organisms, non-pest insects, birds, and other animals; (4) disruption of biotic communities, including agroecosystems; and (5) irreparable loss or changes in species diversity or genetic diversity within species.” (APHIS-2008-0023-5551). Other concerns include the accidental release of genetically engineered material unapproved for human consumption into the food supply and the lack of genetically engineered crops meeting the claims they are marketed with.

The second highest area of concern for NGOs was the threat of gene flow. “Among concerns of opponents to these crops are claims that pollen movement will cause unacceptable levels of gene flow from GM to non-GM crops or to related weedy species, resulting in genetic pollution of the environment” (APHIS-2008-0023-5552). Examples of gene flow presented in the comments stated that genetically engineered genes have already been found in non-genetically engineered papaya plants in Hawaii as well as herbicide and pesticide resistant weeds found in some agricultural fields. Also
NGO stakeholder groups expressed concern that pollen from genetically engineered crops could travel great distances to cross pollenate non-genetically engineered crops or mix with native species. The presence of genetically engineered genes in plants that are not genetically engineered is very damaging to organic farming. In order to be sold in the U.S. as an organic product, a crop cannot contain any genetically engineered genes. Many NGOs argued that genetic drift makes it difficult to ensure that organic crops do not contain any genetically engineered genes. “An alarming study showed that certain genetically modified crops were more likely to cross-pollinate than crops that were not genetically modified.” (APHIS-2008-0023-5551)

Organic and Alternative Farmers and Advocacy Groups top two concerns were pharmaceuticals (12 coded references) and state versus federal regulation (7 coded references). Pharmaceutical producing plants were not specifically addressed by the proposed rule and comments submitted by organic and alternative farmers and advocacy groups addressed this issue. “…the USDA should ban outdoor cultivation of pharmaceutical-producing GE (food) crops so that untested drugs don’t find their way to the nation’s food supply.” (APHIS-2008-0023-0419) This comment and many others called for stricter regulations of plants that are capable of producing pharmaceuticals.

The second largest concern of Organic and Alternative Farmers and Advocacy Groups was state vs. federal regulation. “…the rule includes language that bars state or local regulation of GE crops that are more protective than its own weak rule. I strongly oppose such preemptive language that would bar local or state authorities from putting meaningful regulations or restrictions on GE crops in place that best suit their
communities” (APHIS-2008-0023-0545). Currently state or local regulations can be stronger than regulations USDA-APHIS has in place. “[The] 2007 Farm Bill clearly demonstrates the fact that USDA-APHIS had no objection to states and local governments exercising valid state’s rights and powers in regulating GE crops on issues vitally important to the interests of their farmers and the agriculture industry in their states/localities.” (APHIS-2008-0023-0477) This stakeholder group wishes to have the power to use their local laws and policies to address the regulation of genetically engineered crops locally.
Table 6: Each stakeholder group and the top two or three issues they expressed.

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Academia</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Matrix and Assignment of Categories (10 coded references)</td>
<td>Exemption from Regulation (7 coded references)</td>
</tr>
<tr>
<td>• How will this affect academic research?</td>
<td>• Interstate transportation of non-viable plants exempt from regulations</td>
</tr>
<tr>
<td>• More streamlined or transparent?</td>
<td>• Cis-genic engineering should be exempt from regulations</td>
</tr>
<tr>
<td>• How will applicants know what the requirements are for application under the new rule</td>
<td></td>
</tr>
<tr>
<td><strong>Community Groups</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Human and Animal Health (6 coded references)</td>
<td>Labeling (4 coded references)</td>
</tr>
<tr>
<td>• Potential allergic reactions</td>
<td>• Right to know</td>
</tr>
<tr>
<td>• Right to know what they consume</td>
<td>• Concerned with other countries that require labeling of GEO’s</td>
</tr>
<tr>
<td><strong>Conventional Farmers and Advocacy Groups</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Scope of Regulations (5 coded references)</td>
<td>Who Decided Regulation (3 coded references)</td>
</tr>
<tr>
<td>• Recognize the authority of APHIS under the PPA of 2000</td>
<td>• Ambiguous statement in proposed rule needs to be changed</td>
</tr>
<tr>
<td>• How will regulation be triggered?</td>
<td>Exemption from Regulation (3 coded references)</td>
</tr>
<tr>
<td>• Use the principle of familiarity to create a new category</td>
<td></td>
</tr>
<tr>
<td><strong>Individuals</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Consumer Choice (24 coded references)</td>
<td>Environmental Concerns (20 coded references)</td>
</tr>
<tr>
<td>• Object to use of genetically engineered crops overall</td>
<td>• Object to use of genetically engineered crops overall</td>
</tr>
<tr>
<td>• Labeling of products containing genetically engineered products</td>
<td>• Increased use of pesticides and herbicides.</td>
</tr>
<tr>
<td>• Right to know</td>
<td>• Damage to natural environment</td>
</tr>
<tr>
<td><strong>International Individuals</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Human and Animal Health (3 coded references)</td>
<td>Who Decides Regulation (2 coded references)</td>
</tr>
<tr>
<td>• Effect of U.S. regulations on other countries</td>
<td>• Genetically engineered organisms must be regulated</td>
</tr>
<tr>
<td><strong>Industry</strong></td>
<td><strong>Issue</strong></td>
</tr>
<tr>
<td>Matrix and Assignment of Categories (15 coded reference)</td>
<td>Regulating on only genetic engineered material through rDNA ( coded references)</td>
</tr>
<tr>
<td>• Proposed system could take longer to approve</td>
<td>• Regulation of non-viable plant material</td>
</tr>
<tr>
<td><strong>Governmental Organizations</strong></td>
<td><strong>Matrix and Assignment of Categories (5 coded references)</strong></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>A clearer definition of each category is needed including what is necessary to apply to each one</td>
</tr>
<tr>
<td></td>
<td>Need low risk, high familiarity category</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Native Americans</strong></th>
<th><strong>Environmental Concerns (3 coded references)</strong></th>
<th><strong>Human and Animal Health (3 coded references)</strong></th>
<th><strong>Gene Flow (3 coded references)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potential loss of a traditional crop (Overlapping concerns with gene flow)</td>
<td>Unknown effects</td>
<td>Threaten biodiversity</td>
</tr>
<tr>
<td></td>
<td>Threat to biodiversity and wildlife</td>
<td></td>
<td>Threaten traditional crop</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NGO</strong></th>
<th><strong>Environmental Concerns (8 coded references)</strong></th>
<th><strong>Gene Flow (coded references)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Herbicide resistant weeds</td>
<td>Threat to organic farming</td>
</tr>
<tr>
<td></td>
<td>Harm to nontarget species</td>
<td>Weed and insect resistance to pesticides and herbicides</td>
</tr>
<tr>
<td></td>
<td>Loss of diversity</td>
<td>Threat to native varieties</td>
</tr>
<tr>
<td></td>
<td>Creating new or more vigorous pests</td>
<td>Ability of genetically engineered pollen to travel long distances.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Organic and Alternative Farmers and Advocacy Groups</strong></th>
<th><strong>Pharmaceuticals (12 coded references)</strong></th>
<th><strong>State vs. Federal Regulation (coded references)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Need specified regulations</td>
<td>Proposed rule would preempt state and local rules</td>
</tr>
<tr>
<td></td>
<td>Shouldn’t be grown in the general food crop</td>
<td>Want to be able to have state and local laws and policies tailored to regulate genetically engineered organisms locally.</td>
</tr>
</tbody>
</table>
Figure 11: Diagram of top two stakeholder group concerns across all stakeholder groups. Red boxes are stakeholder groups, black boxes are coded references. Black lines indicate the top area of coded references in a particular stakeholder group. Blue lines indicate the second highest area of coded references in a particular stakeholder group.
Chapter 6: Discussion of Results

The previous chapters of this paper have discussed the federal rulemaking process, the history of regulation for genetically engineered organisms, the public opinion and knowledge of genetically engineered organisms, the methodology for this study and presented the results of a content analysis of a random sampling of comments. This chapter will focus on whether this case study of Federal Register comments on rule making reflects adequate public participation and use democratic theory to interpret the results of the content analysis on comments. This chapter will also discuss how the findings of this content analysis might be incorporated into rulemaking at the federal level should APHIS want to act on the results of this form of public participation.

What is Good Public Participation?

Public participation is defined as a group of procedures designed to consult, involve, and inform the public; to allow those affected by a decision have input into that decision (Smith, 1983). Recently, governmental bodies have realized that they need to pay more attention to the opinions of the public, especially in the rulemaking process. This realization comes from increased interest in the democratic process, procedural justice, and recognition that improved governmental processes might result in greater public acceptance and trust of governing bodies (Rowe and Frewer, 2000). Previous and some current public engagement procedures focus on regulating the possible risks posed by a new emerging technologies and leave other issues such as values and vested interests unasked or unanswered (Wilsdon and Willis, 2004). In risk management, value
judgments need to be made at all stages (Rowe and Frewer, 2000). The framing of these issues is usually decided upon by the experts; other forms of engagement that might bring the public together to discuss issues are pushed into the background or are not used at all. Most importantly the discussions that happen tend to take place in a vacuum, where different groups such as policy makers, scientists, and members of industry do not communicate with one another (Wilsdon and Willis, 2004). In keeping with democratic theory, all those affected by these rules should have a say in how they are constructed.

There are many different ways that the public participation requirement of the APA can be satisfied, as discussed in Chapter 1. While the APA only states specifically that there must be an opportunity for writing comment, there is no restriction on other forms of public participation that can be used as well (Lubbers, 2006). There is no method or set of criteria to determine what makes a public participation method successful or not (Rowe and Frewer, 2000). This brings forth the question of whether or not the public participation process should be evaluated by the success or acceptance of the rule? (Rowe and Frewer, 2000).

The upstream engagement process has been proposed by many science and technology scholars as a way for regulators to engage the public in discussions about new technologies and the processes that need to be developed to regulate them. Most importantly in the process of public participation and public engagement is the ability to open up the debate to deeper questions both from the public and from experts and expanding beyond the question of risk into values and interests (Wilsdon and Willis, 2004). The public needs to have the space and the opportunity to express their concerns.
This doesn’t mean that the public should take over the process of regulating new technologies but rather that they should have a larger role in helping to direct and guide it (Wilsdon and Willis, 2004). Increased demands for public participation will have an effect on the way resources are applied to research and the way that scientists choose their research topics and conduct their work. Public participation also can influence the political and social climates in which research takes place (Nelkin, 1984).

Deciding on a good public participation process can be difficult. There is no method that is appropriate for every rulemaking instance. The circumstances and the end goal, often times determines the best public engagement strategy to use (Wilsdon and Willis, 2004). Oftentimes members of a public participation process don’t even agree about what makes a public participation process good. In one case study dealing with a forestry rule, researchers determined five different perspectives were present among the participants when it came to choosing a method of public participation (Webler et. al., 2001). Some thought that the process should be legitimate, meaning it was totally open, focused on evidence and does not have a determined “sunset” date (Webler et. al., 2001). Others thought the process should focus on a search for common values, meaning that values and not evidence should be the main focus of the discussion and a “sunset” date was needed (Webler et. al., 2001). The third perspective focused on realizing the democratic principles of fairness and equality. This meant that the quality of the interactions among participants was found to be important as well as build trust and encourage respectfulness (Webler et. al., 2001). The fourth perspective thought that the process should promote equal power among all participants and viewpoints. This
perspective was very focused on not having any participant gain more power in the process than others, all decisions were made based on evidence and not rhetoric or political weight (Webler et. al., 2001). The fifth perspective focused on fostering responsible leadership, this means leaders must listen to all that they heard and take it upon themselves to use that information to make a decision (Webler et. al., 2001). The variety of perspectives on public participation are not limited to just these five. They will vary based on the participants as well as the topic of debate.

These five perspectives are all valid methods of addressing and framing public participation. Notice and comment rulemaking is aligned best with the last perspective mentioned. It is the public’s or participants job to inform the leaders, or agency, as to how the proposed rule could be improved upon and it is the leaders, or agencies, job to listen to and take into account the comments that are submitted by individuals. This is a positive for notice and comment rulemaking in that it satisfies on of the most common perspectives in this study, however notice and comment rulemaking does not come close to addressing any of the other perspectives presented in this study. These other perspectives are equally valid methods of addressing public participation and might be better to address the question at hand. As mentioned previously, the end goal of public engagement will best determine the public participation method, or perspective that should be used.
Forms of Democracy

Democracy is a form of government in which everyone is supposed to have an equal share in the decisions that affect their lives. Different forms of democratic theory exist and attempt to state how to achieve this goal. Three of the most popular of these are direct, representative, and deliberative democracy.

Direct democracy relates to the ability of citizens to vote directly on a law or propositions than to vote for someone to represent them in the making of that law. This form of lawmaking has existed in the U.S. for almost a hundred years. Direct democracy can be done in the form of a referendum, initiative, legislative measure, or propositions (Matsusaka, 2005). Once the item is placed on a ballot, citizens vote directly for or against it. This direct democracy is usually done on the state level, to amend state constitutions; because of this the form and requirements of direct democracy vary from state to state and in the type of items that can be placed on the ballot (Matsusaka, 2005). This form of democracy isn’t thought to be a realistic option for making governmental decisions at the federal level as the amount of people involved makes it impractical.

There is a large amount of data that needs to be gathered on a subject to vote intelligently and to have each voter gather this information themselves in order to make an informed decision is unrealistic (Mueller et.al.,1993). The notice and comment method of public participation does not fit into direct democratic theory. Individuals that submit a comment to the federal register might accept the proposed rule, but want a few changes made; others might reject the rule in its entirety. In direct democratic theory individuals don’t have a choice to accept the proposed rule with caveats, or if certain modifications
are made, they must either accept or reject the rule. In notice and comment rulemaking, individuals that submit comments on a proposed rule are not getting a direct vote for or against the proposed rule; their comments are taken into consideration along other submitted comments and the overall plan of the agency. Taking these factors into account, direct democratic theory does not represent notice and comment rulemaking (see table 7).

Representative democracy is representation by election or appointment of representatives to speak for the population or a segment of it. In a representative democracy, individuals vote for a representative, not for the assembly as a whole (Benoit and Kornhauser, 1994). Elected officials are granted the right to make decisions and pass laws for society as a whole (Kateb, 1981) In this form of democracy, individuals do not have a direct say in what laws are made, they indirectly voice their opinion by voting for a representative who’s thoughts and opinions line up with their own (Kateb, 1981). In representative democracy experts have a special role. Representative democracy requires a division between laypeople and experts (Brown, 2009). Experts come into play in a representative democracy in the form of multiple kinds of advisory bodies. These ensure that there are multiple sites and modes of representation for the public (Brown, 2009). In a representative democracy, a representative is usually elected or appointed by someone who has been elected. In notice and comment rulemaking, the individuals who chose to comment on a proposed rule are looked upon as representative of the rest of society. In this way notice and comment rulemaking and representative democracy fit together. Notice and comment rulemaking mixes both experts and members of the public together,
those that submit comments on behalf of organizations, such as universities might be considered experts but the comments from both individuals and experts are judged in the same space.

Deliberative democracy expresses the need to justify decisions that are made by citizens and their representatives (Gutmann et al., 2004). Leaders in a democracy should give reasons for the decisions they make and in response to concerns expressed by citizens. Deliberative democracy is based on a reason-giving requirement, citizens as member of a society have the right to question the actions of their representatives and ask for the reasoning behind their decisions (Gutmann et al., 2004). A second requirement of deliberative democracy is that it must be accessible to all citizens concerned. If citizens cannot understand the content of the argument presented to them, it is not a deliberative argument. Experts fit into this argument by explaining their findings in a straightforward manner that citizens can understand. Deliberative democracy also needs to be both dynamic and have binding results (for at least a short time).
Table 7: Each type of democracy discussed is listed along with important attributes. Example of how each type of democracy represents the form of public participation that was used in this proposed rule.

<table>
<thead>
<tr>
<th>Type of Democracy</th>
<th>Attribute</th>
<th>Present in this case study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Democracy</td>
<td>Voting directly to approve or oppose the measure</td>
<td>No (Every citizen can submit a comment on the proposed rule, but this is not the same as casting a vote for or against.)</td>
</tr>
<tr>
<td></td>
<td>Public information sessions for all citizens involved</td>
<td>No (Meetings held, but they were not accessible to the public as a whole)</td>
</tr>
<tr>
<td>Representative Democracy</td>
<td>Representatives chosen</td>
<td>Maybe (Commenters are assumed to represent society as a whole, but are not elected to represent the population)</td>
</tr>
<tr>
<td>Deliberative Democracy</td>
<td>Reasoning Giving</td>
<td>Maybe (Officials required to address at least some of the concerns expressed by the public before the rule is put into place.)</td>
</tr>
<tr>
<td></td>
<td>Accessible</td>
<td>Maybe (All citizen are allowed to comment on a proposed rule on the federal register, but not all of the public is aware of this opportunity.)</td>
</tr>
<tr>
<td></td>
<td>Dynamic</td>
<td>Maybe (with the exception of limited public forums, there was no dialogue or discussion back and forth)</td>
</tr>
</tbody>
</table>

Notice and comment rulemaking is not a typical deliberative process, an agency simply publishes its intended rule and the public is allowed to submit their comments. In a somewhat deliberative process, the agency must address how they choose to incorporate or not incorporate these comments into the proposed rule and publish the final rule. Notice and comment rulemaking is supposed to be accessible to all citizens. Everyone, in theory, is supposed to be able to submit a comment to the Federal Register, however not all citizens are aware that the Federal Register exists or choose to make a comment. The head of the USDA is appointed by the President of the United States and
is a cabinet level position. Other officials in the agency are hired, not elected or appointed. However, these officials still have the power to create and enforce rules. As stated by the APA, comments made on proposed rules must be addressed before these rules can be enforced. In this way the public participation process is deliberative, officials must give the reasons for the rules that they put into place and whey they chose to acknowledge comments from the public or not.

In order for a democracy to be functioning, does it need to directly follow theory? Notice and comment rulemaking has some forms of representative and deliberative democratic theory involved in its process, but does not directly align with either of them. Notice and comment rulemaking fits with some aspects of appointed representatives in representative democratic theory and with reasoning in deliberative theory. Direct democratic theory does not fit with notice and comment rulemaking. What does this unclear alignment with different theories mean for notice and comment rulemaking? It does not follow one theory of democracy directly. While this is not a negative aspect alone for notice and comment rulemaking, it does mean that there is the potential for more public involvement in this rulemaking process. It could be better aligned with deliberative democratic theory by adding more of a back and forth between the public and the agency, or it could be better aligned with representative democratic theory by adding elected or appointed representatives to the process. Or both methods could be incorporated into the rulemaking process. When determining how to address this issue, the type of public participation that will best address the process should be taken into consideration. Better forethought by an agency about what they need to get out of public
participation process and choosing an appropriate method might be a better way to insure adequate public participation than relying on democratic theory.

**Interpreting the Results**

Individuals were by far the highest number of commenters on this proposed rule. However, even with this unusually high amount of comments from the public this is a low percentage of the U.S. adult population, less than 0.00001% of the total U.S. population submitted a comment on the proposed rule. (U.S. Census Bureau, 2010). Also, based on the literature and as discussed in Chapter 1, the discussion of genetically engineered crops in the food supply is a very popular and contentious issue with some members of society. This portion of the population would have been more likely to comment negatively on a proposed rule than other members of the public. In contrast to the members of society who are highly aware of genetically engineered organisms there is another large section of society that remains completely unaware of the presence of genetically engineered organism in the food system. It is possible that this issue was popular enough to draw comments from a section of the population that normally would not comment on proposed rules in the federal register, making the amount of comments received from individuals higher than normal but still much less than the adult population of the U.S. Notice and comment rulemaking is not a direct form of democracy, so even with the majority of the comments being negative and calling for the withdrawal of genetically engineered organisms, it does not guarantee that the final rule will reflect this.
Form Letter Majority

Form letters were a large part of individual’s involvement in commenting on this proposed rule. As described in Chapter 2, two thousand comments were randomly selected for analysis, of these 1435 were identified as being form letters, making 72% of the total comments submitted on this proposed rule some type of form letter. The Individual stakeholder group submitted a total of 1842 comments. Of the 1842 comments submitted by Individuals, 1376 were determined to be a type of form letter and 466 were determined to be an original comment. Individuals submitted a large amount of the comments on this proposed rule, both in original comments and a large amount of the form letters (see table 3). Of the 1435 form letters submitted, 1376 of them were submitted by the Individual stakeholder group (96% of form letters were submitted by Individuals).
How will this form letter be addressed by USDA-APHIS? The most popular type of form letter (as shown in chapter 2, figure 1) does not address specifically address any issues of the proposed rule. It objects in general to the use of genetically engineered organisms and the unknowns that they present, but beyond the statement, “The current proposed rule does little to close the loopholes in the regulations the rule is designed to replace and it creates more gaps than it fills.” This form letter does nothing to address specific problems with the proposed rule. How then should USDA-APHIS address this comment? Genetically engineered crops are well established in the marketplace and with farmers. In the 20 years that genetically engineered organisms have been on the market, there has been few if any reported instances of harm done to humans. In general the U.S. is a pro-technology and business environment and does not want to place cumbersome
regulations on an industry. As much as members of this stakeholder groups would support the decision to ban genetically engineered crops it is highly unlikely that USDA-APHIS will do so. But this is the most popular request of all the public comments made on the proposed rule. By ignoring this request, USDA-APHIS could undermine the trust that the public puts in and agency. According to democratic theory, individuals in a democratic government should have a say in the rules that affect them. By not addressing or changing the proposed rule to reflect these comments, USDA-APHIS is disregarding all three of the theories of democracy that were addressed previously, direct, representative, and deliberative democratic theory.

*Addressing Concerns from Original Comments*

The proposed rule that USDA-APHIS published on October 9, 2008 created an interest for many of the consumers who submitted comments on the proposed rule. They were quick to start commenting on the proposed rule; the first comments were posted 5 days after the comment period was open and continued for nine months. Some comments offered critiques of the proposed rule, some gave alternative suggestions for regulating genetically modified organisms, and some called for the removal of genetically engineered organism’s altogether. Based on the randomly selected comments used for this analysis, and notions of good public participation and democratic decision making, some of the changes that USDA-APHIS proposed in the new rule need to be further explained and improved upon. While all stakeholder groups expressed concerns about the proposed rule, there were a few areas were some of them agreed on the actions that USDA-APHIS needs to take. These areas were clarifying the issue of who is deciding
regulation, clarifying the matrix and assignment of categories, clarifying the application process, addressing the regulation of pharmaceutical crops, and clarifying low level presence policy.

To listen to and address the majority of stakeholder concerns (one of the five perspectives on good participation), USDA-APHIS should clarify the issue of who is deciding regulation. This issue was in the top ten issues coded for and was expressed by nine different stakeholder groups (See figure 3). The ambiguous wording in the proposed rule led to a lot of confusion for the stakeholders. The proposed rule states that “under the proposed regulations, the responsible person for a GE organism could correctly apply the criteria in §340.0 to determine whether the GE organism is subject to the regulations.” (Federal Register, 2008) Who does USDA-APHIS see as the “responsible person” in this situation? Does private industry qualify as a “responsible person”? If so do they get to decide when one of their genetically engineered products needs to be regulated by USDA-APHIS? Or is USDA-APHIS itself the only “responsible person” referred to in this statement? All Stakeholder groups that expressed concern over this issue were in agreement that this statement needed to be clarified.

The matrix and assignment of regulatory categories that USDA-APHIS created in the proposed rule need to be clarified and better expressed according to stakeholder comments. Seven stakeholder groups agreed that this needs attention. The proposed rule goes into minimal detail about how applicants will be assigned or placed into categories. The proposed rule describes the placement into categories as being done by a risk assessment based on two factors. The first is the ability of the unmodified recipient plant
species to persist in the wild and the second, the potential of the engineered trait to cause harm (Federal Register, 2008). The proposed rule simply states that a high, moderate and low ranking for each factor will determine into which category an applicant is placed. USDA-APHIS then states that “additional permit requirements could then be applied”.

Members of Academia, Governmental Organizations, Industry and Conventional Farmers and Advocacy Group stakeholder groups did not find this description to be helpful. They were in agreement that more clarification is needed for each category, and Industry and Conventional Farmers and Advocacy Groups want additional clarification of what “additional permit requirements” might be for each category. USDA-APHIS lists the difficulty of having only two rigorously defined categories for regulation as an important reason for writing of this proposed rule. If the categories are to be successful in regulating genetically engineered crops, they should be better defined so that both regulators and applicants will know what to expect from the process.

Along this same line of thought, the application process needs to be clarified. The same stakeholder groups seemed to have interpreted differently who will be deciding what category an applicant fits into. Some expressed concerns that members of industry would be deciding into which category their product would be regulated under. If members of industry could decide in which category their product would be regulated, it would give them more power. However, some members of industry addressed this as a negative in their comments. Some see it as a burden to put on industry and one that might create more problems for regulation and for USDA-APHIS than it would solve.
Other stakeholder groups seemed to have the impression that USDA-APHIS would be the party responsible for determining which category an applicant was placed in.

USDA-APHIS needs to further address the regulation of pharmaceutical crops. All stakeholder groups (except for community groups) had concerns about how USDA-APHIS addressed pharmaceuticals in the proposed rule. Genetically engineered crops that are designed to produce pharmaceuticals might be best off regulated under their own category. This was suggested by the proposed rule however, as proposed by one comment, USDA-APHIS might want to think about proposing a separate rule for addressing the regulation of pharmaceutical producing plants.

After issuing the proposed rule, on Monday November 10, 2008 USDA-APHIS released a correction to the proposed rule. The proposed rule previously stated that “No State or local laws or regulations would be preempted by this rule”. The clarification states that “All State and local laws or regulations that are inconsistent with the rule will be preempted.” (Federal Register, 2008) In many comments this statement was called out as needing to be removed. Many comments stated that if a state or local government wished to enact a law stricter than those of the federal government, they have every right to do so. USDA-APHIS needs to clarify for consumers what this statement entails. Would the proposed rule simply be the minimum or would state and local governments be allowed to enact laws that go above and beyond the proposed rule in regulating the importation, interstate movement and release into the environment of genetically engineered organisms?
On March 29, 2007, before releasing their proposed rule, USDA-APHIS published their current policies for responding to the low-level presence of genetically engineered plant materials occurring in commercial seeds or grain (Federal Register, 2007). Plant breeding may occasionally result in low-level mixing of genes from unintended plant sources. This can occur through natural processes, like the movement of seeds and pollen, or can occur through human control processes such as seed production or plant breeding (Federal Register, 2007). USDA-APHIS is responsible for protecting agriculture and the environment. Through the field testing process, which is required before a product can reach the market, it is possible that some genes enter into the environment or other crops. This has happened before when Starlink corn (approved for only animal consumption) was found in human food products. In their policy on low-level presence, USDA-APHIS states that they will, “respond to the occurrences of regulated materials in commercial seeds and grain with remedial action that is appropriate to the level of risk and warranted by the facts in each case.” (Federal Register, 2007). In every case, USDA-APHIS will initiate an inquiry into the release, determine the risk associated with the release, and determine what regulatory actions are required. USDA-APHIS has authority to do this under the PPA of 2000. In the proposed rule USDA-APHIS stated that the previously published low-level presence policy would be incorporated into the proposed rule. This low-level presence policy would address how USDA-APHIS would deal with the presence in small amounts of regulated genetically engineered plant material in commercial seed or gain that could be used for food or feed. This policy does not mention specifically the presence of genetically engineered plant
material in organic certified food or feed, nor does it state that this policy allows for the low-level presence of items in the food supply. A great number of comments seemed to misunderstand USDA-APHIS’s meaning when it came to this topic and seemed to suggest in their comments that USDA-APHIS would be creating a minimum amount that all genetically engineered plant materials could be present in the food supply under. In the final published rule, USDA-APHIS should state again what they mean by low-level presence and that USDA-APHIS is not setting a threshold amount for the presence of genetically modified plant material in the food and seed supply in general.

As in the form letter comments, a great deal of original comments called for the removal of genetically engineered crops from the marketplace. As mentioned before, in all likelihood genetically modified crops are on the market permanently. While this issue isn’t directly related to the proposed rule this is the only space available for the public to comment on this issue to the federal government. These comments address the values of the individuals submitting them. As mentioned previously, notice and comment rulemaking focuses on the risks the technology presents and does little to ask or address the question of values. Because the issue of removing genetically engineered organisms from the market was brought up by so many participants, it would have been in the best interest of the rule to use a different method for public engagement in formulating this proposed rule. A method that lets the participants express their concerns with the issue, but where the discussion can be steered towards addressing the specific questions of regulation that need to be discussed would have incorporated the preferences and values
of a large number of people commenting without having to disregard a large section of
the public.

**Negotiated Rulemaking and the USDA**

The use of negotiated rulemaking could be beneficial to the USDA in their
rulemaking process. In general, participants of the negotiated rulemaking system express
more satisfaction with the rule than those who participate in conventional rulemaking
(Langbein and Kerwin, 2000). It would make the process more deliberative, as notice and
comment rulemaking only partially fulfills deliberative theory, even if forums that
USDA-APHIS hosted are included. Many of the actions taken by the USDA to regulate
or deregulate genetically engineered organisms have been challenged in court. Rules
made through the negotiated rulemaking process have been shown to be less likely to be
challenged in court and parties who have participated in both conventional and negotiated
rulemaking consider negotiated rulemaking to be “…more satisfying, less expensive, and
more constructive…” (Fiorino, 1988). The EPA has been using the negotiated
rulemaking process since 1984 and has had “success” in this form of regulation. In the
EPA’s experience, negotiated rulemaking works better when addressing “how to”
decisions instead of “what” decisions (Fiorino, 1988). Participants of the negotiated
rulemaking process are more likely to see their counterparts as a source of information
than as an opponent (Longbein and Kerwin, 2000). This would make it an appropriate
method for addressing the questions that this proposed rule is intended to address.
Negotiated rulemaking would have been appropriate in the formation of this proposed rule, especially to address the issue of how the notification and permit systems could have been modified to a new system of regulation under a category system.

The Agricultural Marketing Service (AMS) posted a notice in the Federal Register on November 24, 2010 that announced the Agency’s intent to engage in negotiated rulemaking (USDA, 2011b). This notice listed proposed committee members and opened a 30 day comment period for comments on the list of proposed members and to allow the submission of other names for consideration. The committee proposed by AMS consisted of representatives from organizations representing swine producers, packers of pork, processors of pork, retailers of pork and buyers of wholesale pork, the USDA, and interested parties that participate in swine or pork production (USDA, 2011c). If an organization believes that their interests will not be represented by the organizations chosen by AMS, they can submit an application to AMS for consideration (USDA, 2011c). On January 26, 2011 AMS published a final list of committee members and the time, date, and location of the first meeting (USDA, 2011b). This is the first negotiated rulemaking process that any branch of the USDA has engaged in. This negotiated rulemaking process came about because of the Mandatory Price Reporting Act of 2010 (USDA, 2011b). The negotiated rulemaking committee will be responsible for developing proposed language to amend the Livestock Mandatory Reporting regulations to implement mandatory pork price reporting (USDA, 2011c).

This is an important first step for the USDA into negotiated rulemaking. While it is not a process that guarantees a positive outcome every time, it is an important step for
the USDA to make into other forms of rulemaking besides strict notice-and-comment rulemaking. The appropriate model for public participation might very well vary from case to case. In some cases, notice-and-comment rulemaking will be the best option; in others it might be a good idea for the USDA to use negotiated rulemaking. In other cases, neither of these options might a good enough method for public participation and others will have to be used. The method that will be most effective will depend on the nature and the context of the proposed rule. Planners and participants need to reflect carefully on what they expect of the rule making process. The needs and desires of all the parties must be compared to find the best form of rulemaking for a particular rule. In public participation the goal is to find a process that allows everyone to be heard and have a say in the outcomes of the process (Webler et. al.2001)

Summary of Adequacy of Notice and Comment Rulemaking

The goal of this paper was to determine if notice and comment rulemaking is an adequate method of public participation. As previously mentioned in Chapter 1 there are five “social goals” of public participation: 1) incorporating public values into decisions, 2) Improving the substantive quality of decisions, 3) Resolving conflict among competing interests, 4) Building trust in institutions, 5) Educating and informing the public (Beierle and Crawford, 2002). If we compare these goals to the process of public participation that was used here, only the first goal was addressed, and was not addressed completely. USDA-APHIS solicited public comments from members of society and then the rulemaking process halted. It is unknown if the public values that were found will help
improve the substantive quality or be incorporated into decisions, because no changes or
decisions have been made to the proposed rule after the public comment period. Goals 3,
4 and 5 were not addressed in this public participation process. There was no
collection encouraged between stakeholder groups during the public participation
process, except for the few public forums that were held. The public participation process
did nothing to encourage trust in the institution, although by not publishing the final rule,
USDA-APHIS may have gained a little trust from the individuals who were so against the
proposed rule. The last goal, educating and informing the public was also not met.
USDA-APHIS did not reach out to the public during the public participation process and
attempt to educate the public on the proposed rule or genetically engineered organisms in
geneneral.

The notice and comment rulemaking process is adequate in that it meets the
requirements for public participation as set forth in the APA and that it partially meets
some of the theory behind the deliberative and representative democratic process. It is
one method for addressing public participation in all rulemaking situations, in some case
it will be adequate for addressing and meeting public participation and in others more
will be needed. It is not an adequate method for addressing public participation in that it
is not a deliberative process, there is little back and forth between the agency and the
public. Not all citizens are aware that notice and comment rulemaking exists. This means
that not all viewpoints are expressed or that all citizens are aware that they can have
access to this rulemaking process.
Incorporating negotiated rulemaking in the notice and comment rulemaking process would help meet some of these goals. Representatives of interested parties actually participate in conversations with other representatives and the agency before any rule is written, this would help incorporate some of the public values from the beginning. Members of negotiated rulemaking reported being more likely to view their counterparts as a resource than as the enemy. This might help to address the third and fifth social goals of public participation (resolving conflict among competing interests and educating and informing the public). If USDA-APHIS takes what is presented to them at the negotiated rulemaking sessions and uses it to inform their rulemaking and if participants understand that an institution will listen to their thoughts about proposing new rules, it could work towards increasing trust in the institution and achieving social goal four.

Even if USDA-APHIS decides not to incorporate negotiated rulemaking in certain processes as an institution, they need to incorporate more thought and planning into the public participation process. What goals or outcomes is USDA-APHIS expecting to gain from this public participation process? What does the public expect to gain from this public participation process? Will these methods of public participation, be it notice and comment, public forums, referendums or other methods, help meet the expectations of both the agency and the public? By taking time to ask these questions before starting the process of public participation the agency has the potential to get more out of the rulemaking process.

These are conclusions that have been drawn by examining the proposed rule called “Importation, Interstate Movement, and Release into the Environment of Certain
Genetically Engineered Organisms” and by examining the literature on public participation and engagement as well as democratic theory. In order to further explore if public comments are an adequate method of public participation, more research is needed. Other rules, perhaps those that address less polarizing issues, need to be examined and the public comments and stakeholder group analyzed. This will give further information about public participation methods are adequate and if not, might suggest some that are.

Was this proposed rule successful? The public participation process involved a wide variety of stakeholder groups in this process; they seem to represent a majority of the stakeholder groups affected by this proposed rule. The concerns expressed by these stakeholder groups were also very diverse although many of them did not cover issues of genetically engineered organisms that the proposed rule would address. This is an indication that the public participation process could have been better. A better process might have focused the comments towards the scope of the proposed rule and left out some of the more contentious issues that are related to genetically engineered organisms but that the proposed rule would not effect.

To date, USDA-APHIS has not published the final rule and shows no indication of doing so. If the final rule had been published, a further analysis of the differences between the proposed rule and the final rule would have been a part of this analysis. Comparisons could have been obtained between the proposed rule and the final rule and differences identified. Did just one stakeholder group express concerns that lead to the changes in the proposed rule? Where concerns expressed by multiple stakeholder groups
addressed in the final rule? Without a final rule published this analysis could not be completed.
References


Federal Register. Comment, Comment ID: APHIS-2008-0210

Federal Register. Comment, Comment ID: APHIS-2008-0300

Federal Register. Comment, Comment ID: APHIS-2008-0392

Federal Register. Comment, Comment ID: APHIS-2008-0398

Federal Register. Comment, Comment ID: APHIS-2008-0428

Federal Register. Comment, Comment ID: APHIS-2008-0432

Federal Register. Comment, Comment ID: APHIS-2008-0434

Federal Register. Comment, Comment ID: APHIS-2008-0419

Federal Register. Comment, Comment ID: APHIS-2008-0465

Federal Register. Comment, Comment ID: APHIS-2008-0467

Federal Register. Comment, Comment ID: APHIS-2008-0477

Federal Register. Comment, Comment ID: APHIS-2008-0496
Federal Register. Comment, Comment ID: APHIS-2008-0545

Federal Register. Comment, Comment ID: APHIS-2008-0554

Federal Register. Comment, Comment ID: APHIS-2008-1252

Federal Register. Comment, Comment ID: APHIS-2008-1570

Federal Register. Comment, Comment ID: APHIS-2008-3141

Federal Register. Comment, Comment ID: APHIS-2008-3255

Federal Register. Comment, Comment ID: APHIS-2008-3368

Federal Register. Comment, Comment ID: APHIS-2008-4878

Federal Register. Comment, Comment ID: APHIS-2008-5083

Federal Register. Comment, Comment ID: APHIS-2008-5396

Federal Register. Comment, Comment ID: APHIS-2008-5456

Federal Register. Comment, Comment ID: APHIS-2008-5484

Federal Register. Comment, Comment ID: APHIS-2008-5551

Federal Register. Comment, Comment ID: APHIS-2008-5552


National Environmental Policy Act. Title 7: Agriculture. 42 U.S.C. 4321


USDA, Agricultural Marketing Service. USDA Announces Intent to Establish Negotiated Rulemaking Committee for Changes to Livestock Mandatory Reporting. November 24, 2010 (c)


