

To: Dr. Robert E. Brackett, Director of the FDA Center for Food Safety and Applied Nutrition
From: Leah
Date: March 31, 2005
Re: Implementation of the Sewage Sludge in Food Production Consumer Notification Act

The Sewage Sludge in Food Production Consumer Notification Act, passed February 10, 2005, raises a complex set of regulatory issues. The Agency should begin the rulemaking process related to this legislation as soon as possible to remain accountable to the statutory timeline for implementation (one year from date of enactment).

Overview of the Sewage Sludge in Food Production Consumer Notification Act

As written, the Act requires labeling of food produced on land to which sewage sludge has been applied within the preceding year. It would amend the Food, Drug, and Cosmetic Act, and the egg, meat, and poultry inspection laws to consider as adulterated any sewage-fertilized food product, unless consumers are properly notified through a package label or posted sign.

It is assumed that the Agency will have prime regulatory jurisdiction only over Section 2a of the statute, i.e. that dealing with food other than eggs, meat, and poultry. This memo focuses primarily on implementation strategies for Section 2a, while providing guidance for cooperation with allied agencies, namely the USDA and EPA.

Key regulatory issues

The mandates of this act effectively require dual streams of regulatory action. Outwardly, the Act deals with labeling issues for sludge-fertilized food, and would take precedent from other labeling rules such as those for irradiated food or safe handling statements for shell eggs. These considerations fall neatly within the Agency's realm of expertise. To enable such labeling, however, the identity of food produced on sludge-fertilized land must be preserved from farm to table. No system currently exists to segregate sludge-produced food from the rest of the food supply. Development of such a tracking process will be required to fulfill the intent of the legislation.

Consultation with other agencies

Compliance mechanisms for identity preservation (IP) of sludge-fertilized foods will be most effective if developed in conjunction with the USDA. Per Sections 2b-d of the Act, sludge-fertilized animal feed as well as meat and poultry grazed on land to which sewage sludge was applied will also have to be segregated and labeled. This memo assumes that the Food Safety and Inspection Service of the USDA will oversee these activities. Since agricultural application of sewage sludge similarly affects commodities intended for both human and animal consumption, a unified IP system seems in order. Meetings between representatives of the FDA CFSAN and USDA FSIS should be scheduled as soon as possible to begin this process. Additionally, the USDA National Organic Program could provide guidance on the IP practices used in the organic food stream. The Agency should investigate where new enforcement mechanisms can piggyback on existing USDA activities, such as farm inspections and farm record-keeping.

The EPA regulates the use and disposal of sewage sludge under 40 CFR 503 with the aim of controlling sludge-bourn pathogens and pollutants. CFSAN and FSIS should work closely with the EPA Biosolids Program to build on existing regulatory definitions and record-keeping procedures.

Areas needing rule-making

The Act itself provides few specific provisions for rules. The following section raises questions that the rule-making process should address.

Identity Preservation: Definitions, Record-keeping, Testing, Enforcement

The burden of crop segregation and identity preservation rests largely on the food industry. It is food producers who must label sludge-produced foods and who therefore require information about crop production practices. The Agency will be responsible initially for definition setting, and routinely for monitoring the agri-food industry for compliance. The rule must set out a clear definition of sewage sludge. Farmers use a range of soil inputs, including composted waste materials, so regulatory language must precisely delineate regulated materials. The rule also must specify whether any amount of applied sludge activates the rule or whether there is a lower limit. The rule should strive for consistency with EPA definitions where possible.

Currently, under the 503 rule, persons who apply bulk sewage sludge to land, i.e. that that is not sold or given away in a bag or other container, are mandated to keep records on the location, date, and pollutant content of the application (Sec503.17). Sewage sludge incorporated into retail products is not regulated in this way. The rule must specify whether land to which these retail products have been applied will qualify for crop segregation and, if so, how this application should be tracked. Additionally, the rule should outline requirements for a uniform food documentation system that will allow actors throughout the food supply chain to vouch for the identity of sludge-produced food. The rule should also specify federal monitoring procedures for this system. As it is likely impossible to discern whether food, once harvested and processed, was produced on sludge-fertilized land, such documentation will be essential for the Agency to independently assess the veracity of producers' claims. The rule must also set a tolerance level, specifying the percentage sludge-ingredients in a processed food that will necessitate a sludge label.

Labeling

The rule should set standards for the text, size, and placement of package labels as well as for alternative labeling mechanisms for unpackaged foods. The Agency must determine whether a nationally uniform label will be implemented, as in the case of the radura symbol, or whether processors will have some flexibility. The Agency might consider convening focus groups or administering direct mail surveys to refine the proposed labeling regulations so that they are the most useful to the consumer.

Under 21 USC 321n, misbranding of a product includes both the inclusion of misleading facts on a label and the failure to include facts material. In this light, a firm that fails to label a food product produced with sewage sludge would be in noncompliance with this law. It is worth noting that in other major IP systems – mandatory organic segregation, voluntary non-GMO labeling, white and high-oil corn, food-grade soy beans -- the differentiated products are understood to command a premium in the marketplace. There is an economic incentive for producers to invest in crop segregation. In the case of sludge-fertilized foods, maintaining the identity of these crops will potentially damage a producer's market share. This dynamic could raise regulatory implications around non-compliance. The rule must clearly specify the consequences of non-compliance.

Trade

The Agency will have to take a position on the sludge labeling requirements for imported foods. If the rule mandates stringent labeling and therefore international implementation of sludge IP systems, it will likely confront trade barrier issues at the WTO, but it will maintain the integrity of the legislation. Relaxing the standards required of importing countries, especially for those below a certain income cut-off may be an alternate route. The Agency should seek guidance on this issue from the Office of the U.S. Trade Representative.

Rulemaking Process

The Agency should issue a Notice of Proposed Rulemaking upon completion of preliminary analyses.

Analyses required prior to implementation

With anticipated costs well over \$100 million, the Act will be considered significant and will be subject to OMB approval. An Economic Impact Analysis should be conducted immediately. In preliminary analysis, the costs of this legislation may outweigh the benefits and may prove a serious hurdle in gaining administrative go-ahead. Producers will have to shoulder the very real costs of implementing a new crop segregation system.¹ Food processors will also incur costs to design and print new labels. The Agency will need to fund new monitoring and enforcement systems. Conversely, the benefits to human health of avoiding sludge-fertilized foods are little documented, if known at all. However, if in the long-term effect, this legislation shapes consumer demand in such a way as to reduce the amount of sludge applied to agricultural land, there may be some quantifiable health benefits for communities and ecosystems located near sites of sludge application. Agency economists, in consultation with the ERS, should fully explore the impact of the law in this regard.

The Agency must also conduct an Unfunded Mandates Reform Act analysis, a Protection of Children Analysis, and an analysis of impacts under the Paperwork Reduction Act. The rule will increase the record-keeping burden for both private and public entities and the Agency will have to justify the burdensome hours to OIRA. Additionally, the rule will affect many small entities, including small farmers, food processors, grocery stores and smaller markets. The Agency must investigate regulatory options that would lessen the rule's economic impact on these actors.

Public comments and final rule publication timeframe

Following the FDA Administrative Practices and Procedures Manual Sec10.40 the proposal will provide 60 days for comment. Any interested person can request an extension to the comment period and the Director should grant an extension if there are sufficient grounds for such a request. A number of comments should be expected, as this is a novel and unregulated issue area. A summary of interest groups will be addressed in a follow-up memo. The Agency should incorporate comments and other relevant materials into a Final Rule, which should be published not less than 30 days before the rule's effective date. The final rule must also provide a timeline for industry implementation. Since a long process of analysis and public comment should be anticipated, the statutory timeframe is likely unrealistically short.

Budgetary Implications

The statute provides no guidance on the budgetary implications of the Act. As some preliminary guidance, the Agency has estimated that it would need a budget of \$56 million per year to enforce country-of-origin labeling mandates, which hold similar regulatory responsibilities to sludge labeling.² Funding needs will become clearer to the Agency as the rulemaking process progresses and the OMB will also be active in scoring the promulgated rules. It is assumed that funds to support Agency enforcement activities will be appropriated from discretionary funds.

¹ As some indication of costs, the National Corn Grower's Association estimates that identity preservation costs for non-GMO corn at a 98% purity level are \$52/acre. If we factor this estimate across the current acreage of sludge-fertilized cropland (Sewage sludge is applied to .01% of total agricultural land in the U.S. According to the most recent data from 1997, U.S. cropland and grazing/pasture land totaled 1035 million acres so sludge land would approximate 10.53 million acres), the rough costs of this legislation will be over \$500 million to producers alone. Available at: <http://www.ers.usda.gov/Briefing/LandUse/majorlandusechapter.htm>

² Food Marketing Institute. *Mandatory Country-of-Origin Labeling*. Available at: http://www.fmi.org/media/bg/COOLabeling_02.pdf