INSIDE

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IN FUTURE ISSUES

Class action for anti-trust and tort clims relating to transgenic crops

In July 2001, Devereux, Murphy L.L.C. of St. Louis, Missouri and Cohen, Milstein, Hausfeld & Toll P.L.L.C. of Washington, D.C. filed an amended class action complaint[1] in the federal district court for the Eastern District of Missouri in a case styled *Sample v. Monsanto Company*. In the amended class action complaint, the plaintiffs alleged the following:

> ¶ 3. Plaintiffs seek to represent two classes of United States farmers: 1) United State farmers or farming entities that purchased GM herbicide-resistant soybean seeds or Bt corn seeds from Defendants or their co-conspirators, who assert antitrust claims; and 2) United States farmers who are or have been engaged in farming non-GM corn and non-GM soybeans, who assert tort claims against Monsanto.
>
> With respect to the antitrust claims, plaintiffs sued Monsanto Company, Pioneer Hi-Bred International, Syngenta Seeds, and Aventis Crop-Science. Plaintiffs set forth the core of their antitrust claims as follows:
>
> ¶ 4. Beginning in the early 1990's, Monsanto began a scheme to transform the seed industry from a diverse market characterized by innovation and price competition into a tightly controlled club, dominated by a few large firms, that would jointly determine the prices to be charged to farmers on the types of new GM technologies.

With respect to the tort claims for public nuisance, negligence, and deceptive trade practices against Monsanto Company only, the plaintiffs' central claim, set forth in ¶ 5 of the complaint, was that Monsanto marketed transgenic soybeans and corn "without disclosing material facts as to the probable rejection of gene crops by international and domestic markets and the inevitable contamination of non-GM crops ..." with transgenic material.

The Honorable Rodney W. Sippel, United States District Judge, issued two opinions in September and October 2003 – one opinion relating to each distinct class and their claims – that resolved this complaint as a class action.

In the September 2003 opinion,[2] Judge Sippel addressed the class action tort claims. Judge Sippel began his opinion by noting that the plaintiff's counsel had abandoned allegations involving trespass and argued that the injury for which compensation was sought related to damages to international and domestic markets only. On this basis, Judge Sippel distinguished the decision in *In re Starlink Corn Prods. Liability Litig.*,[3] in which the plaintiffs alleged trespass by mixture of a transgenic crop not approved for food use with other crops, both transgenic and non-transgenic, approved and intended for food use. By such mixture, the *Starlink* court found that the mixed material became

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Farmer building farmworker housing exempted from county housing code

An owner of farm property who wanted to construct residential buildings on his property to house farmworkers brought an action in trial court seeking an order that would require the county to exempt him from the requirement that he comply with the building permit process while constructing the housing. *Trust v. County of Yuma*, 69 P.3d 510 (Ariz. Ct. App. 2003). The trial court ruled in favor of the farm property owner, and the county appealed to the Arizona Court of Appeals. *See id.* The Arizona Court of Appeals ruled that the farm property owner did not have to comply with the building permit process because free, on-site housing for farmworkers was "incidental to farming," as defined by Arizona law. *See id.* at 512-15. It also ruled that the county was precluded from asserting an equal protection claim and that the state statutes that exempted the property owner from complying with the building permit process did not violate equal protection under the Arizona Constitution or the United States Constitution. *See id.* at 515-16.

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adulterated and could not be used for its intended market.

Judge Sippel dismissed the public nuisance and negligence claims with prejudice on the basis that, in the absence of physical mixture, the plaintiffs were seeking damages for economic loss only. Judge Sippel quoted with approval language from the *Starlink* case which said that farmer's expectations of what they will receive for their crops are just that, expectations. Judge Sippel ruled that the economic loss doctrine means that economic expectations are not legally compensable damages. Judge Sippel held that the economic loss doctrine precluded recovery on either public nuisance or negligence liability.

In the October 2003 opinion,[4] Judge Sippel addressed the antitrust claims in a motion relating to whether certification should be granted for class action status for these antitrust claims. Federal Rule Civil Procedure 23 sets forth four requirements for certification: numerosity, commonality, adequacy of representation, and predominance of common issues.

Judge Sippel ruled that the plaintiffs had met the numerosity and commonality requirements.

Regarding the adequacy of representation, Judge Sippel ruled for the plaintiffs but only after stating that it was a close call as to whether the plaintiffs' attorneys had a disqualifying conflict of interest because they were attempting to represent two distinct classes that potentially had irreconcilable requests for relief.

As for the requirement of predominance, Judge Sippel ruled that the plaintiffs could not meet the requirement. Judge Sippel found that the evidence submitted indicated that the transgenic seed marked was not homogenous and that the various farmers paid different prices in different geographic markets. Consequently, Judge Sippel concluded that a common impact from alleged antitrust violations did not exist and that the impact, if any, would be individualized. If the legal impacts and the legal damages require individualized determinations, Judge Sippel ruled that the predominance requirement did not exist. Consequently, Judge Sippel dismissed the class action certification for the antitrust claims.

Newspaper articles about these two rulings by Judge Sippel indicate that the plaintiffs are likely to appeal.[5]

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[1] The complaint is available at www.cmht.com under Antitrust Actions, Genetically Engineered Seeds, Important Documents.

[2] *Sample v. Monsanto Co.*, Case No. 4: 01CV65 RWS, (September 19, 2003) (opinion of 13 pages), available at www.moed.uscourts.gov

[3] 212 F. Supp.2d 828 (N.D. Ill. 2002).

[4] *Sample v. Monsanto Co.*, Case No. 4: 01CV65 RWS, (October 1, 2003) (opinion of 17 pages), available at www.moed.uscourts.gov

[5] David Barboza, Judge Rejects Class Action Lawsuit Against Gene Giants, New York Times (October 2, 2003); David Barboza, Anti-Trust Case Against Monsanto & Gene Giants Moves Forward, New York Times (September 20, 2003).

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Farmworker housing/Cont. from p. 1

Braden Trust owned a 7,500-acre farm located in Yuma County, Arizona ("County"). *See id.* He planned to construct housing on his farm property to house farmworkers. *See id.* Trust believed that under Arizona state law he was not required to obtain building permits from the County for the construction project. *See id.* Defining agricultural buildings "as structures for such uses as farm implements and grain storage, not for human occupancy," the County asserted that Trust's proposed construction project was residential in nature, rather than agricultural and Trust therefore was required to comply with the building permit process. *Id.*

Trust filed a complaint in trial court "for special action, mandamus, and declaratory judgment, and sought an order directing the County to exempt ... [him] from complying with the building permit process and building code with regard to existing and planned residential buildings." *Id.* The trial court ruled that Trust was exempt from the County's building and zoning codes and that his proposal to build farmworker housing "constituted construction incidental to farming and agriculture and thus was not subject to the County building and zoning codes." *Id.* It also issued a declaratory judgment "ordering the County to allow ... Trust to construct farmworker housing free from interference and from any requirements to comply with the County building or zoning codes." *Id.*

On appeal, the Arizona Court of Appeals court first examined whether the trial court had correctly interpreted Ariz. Rev. Stat. §§ 11-830 and 11-865 "to mean that residential structures built on a farm to house farm workers are exempt from county zoning and building codes." *Id.* at 511-12. Section 11-830 provides, in relevant part, that "[n]othing contained in any ordinance authorized by this chapter shall: ... [p]revent, restrict or otherwise regulate the use or occupation of land or improvements for railroad, mining, metallurgical, grazing or general agricultural purposes, if the tract concerned is five or more contiguous commercial acres." *Id.* at 512 (quoting Ariz. Rev. Stat. § 11-830(A)(2)). Section 11-865 provides, in relevant part, that "[t]he provisions of this article shall not be construed to apply to: ... [c]onstruction or operation incidental to ... farming, dairying, agriculture, viti-culture, horticulture or stock or poultry raising ...." *Id.* (quoting Ariz. Rev. Stat. § 11-865(A)(1)).

The County argued that the plain meanings of the phrases "'use or occupation of land or improvements for ... general agricultural purposes' and '[c]onstruction or operation incidental to . . . agriculture' do not encompass multifamily residential dwellings." *Id.* It asserted that the statutory language only exempted "structures that house such things as agricultural products, farm implements, or tools–not people."

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BAP affirms that party with right of first refusal must receive notice of sale

In an action brought by a corporation that submitted the highest bid at the auction of a debtor's assets alleging that the bankruptcy court abused its discretion by ordering the reopening of the bidding process and by approving a compromise and a settlement that governed the procedures for the final auction, the Bankruptcy Appellate Panel (BAP) for the Eighth Circuit has ruled that the bankruptcy court did not err in finding that the party with the right of first refusal had not received sufficient notice of the proposed sale and that it did not abuse its discretion in continuing the auction and in approving the compromise regarding the terms to govern the continued auction. *In re Farmland Industries, Inc.*, 289 B.R. 122, 124, 128 (B.A.P 8th Cir. 2003).

Farmland Industries, Inc. (Farmland), debtor, "filed a motion to establish bid procedures and to approve the sale of a fertilizer warehouse to ConAgra Trade Group, Inc. (ConAgra) ...." *Id.* at 124. The bankruptcy court "approved [the] auction and [the] bid procedures, pursuant to which the Debtor was to solicit additional bids and conduct an auction on September 9, 2002, if necessary." *Id.* It also "scheduled a hearing for September 10, 2002, to determine whether to approve a sale pursuant to the highest bid." *Id.*

Farmland conducted an auction and American Plant Food Corporation (American) submitted the highest bid. *See id.* However, at the September 10, 2002, hearing United Agri Products, Inc. d/b/a UAP-MidSouth (UAP) "appeared ... and asserted a right of first refusal with respect to the fertilizer warehouse" alleging that it did not have notice of the sale. *Id.* Farmland "had not served a copy of the motion or notice of the sale or bid procedures on UAP." *Id.* at 125. Thus, the bankruptcy court concluded that "UAP had not received notice of the proposed sale" and entered an order on September 17, 2002, "reopening the bidding, scheduling an auction in court on September 24, 2002, and authorizing American to submit higher bids and UAP to match any such bids at such final auction." *Id.*

At the September 24, 2002, hearing, "all parties except American reached a settlement pursuant to which UAP agreed to waive its right of first refusal, ConAgra agreed to waive its right to a break-up fee, and American, UAP, and Equalizer, Inc. would be allowed to participate in a reopened auction." *Id.* The bankruptcy court found the settlement reasonable and entered an order on September 25, 2002, approving the settlement. *See id.* American appealed the September 17, 2002, and the September 25, 2002, bankruptcy court orders reopening the bidding and approving the compromise, arguing that bankruptcy court had abused its discretion. *See id.*

The BAP first examined the nature of the orders entered by the bankruptcy court and noted that "[t]he orders at issue schedule a judicial auction" and that "[t]he bankruptcy court has not effectively resolved the controversy and its remaining tasks are more than mechanical or ministerial." *Id.* at 125-26. It concluded that the orders are interlocutory, stating that "[t]his court has discretion to consider interlocutory appeals" and chose to exercise this discretion. *Id.* at 126 (citation omitted).

Next, the BAP considered the issue of UAP's right of first refusal and noted that "[t]he evidence that UAP had not received a copy of the motion or notice was undisputed." *Id.* It concluded that "[e]vidence supports the conclusion that UAP was not given notice of the proposed sale as required by the terms of the right of first refusal," therefore upholding the bankruptcy's court finding. *Id.*

Next, the BAP examined the order of the bankruptcy court that reopened the bidding process and noted that "[a] bankruptcy court has considerable discretion in approving assets sales and is granted ample latitude to strike a balance between fairness, finality, integrity, and maximization of assets." *Id.* (citing *In re Wintz Co.*, 219 F.3d 807, 812 (8th Cir. 2000) and *In re Food Barn, Inc.*, 107 F.3d 558, 565-66 (8th Cir. 1997)). It added that "the [bankruptcy] court must be mindful of the interests of unsecured creditors and the goal of maximizing the value of the bankruptcy estate." *Id.* (citation omitted).

The BAP stated that "[h]ere, the bankruptcy court carefully considered the countervailing interests of the bidders, including the expectations of American, and those of the Debtor and the creditors in maximizing price." *Id.* Concerning the expectations of American, the BAP noted that American "knew that the sale could not be final until approved by the bankruptcy court" and that "its justifiable expectations as a purchaser could not have crystalized to the point of certainty prior to the entry of an order approving the sale." *Id.* at 127. Concerning the interests of the creditors, the BAP noted that "[t]he court addressed the interests of the creditors in maximizing estate value by continuing the auction to provide the possibility of greater recovery as a result of the sale of this asset." *Id.* With respect to the interests of UAP, the BAP stated that "[t]he bankruptcy court struck a reasonable balance, honoring UAP's right of first refusal while granting American the right to increase its bid in light of this new development." *Id.* It concluded that "[t]he [bankruptcy] court did not abuse its discretion and its decision must be affirmed." *Id.*

Finally, the BAP examined the order of the bankruptcy court approving the compromise and stated that "American [was] unhappy because the price of the fertilizer warehouse may increase as a result of the continued auction, resulting in American either paying more than its existing bid or deciding not to increase its bid to exceed another bidder's higher offer." *Id.* It added that "American's unhappiness [was] not sufficient legal ground to reject the compromise" and that "[t]he bankruptcy court did not abuse its discretion in approving the compromise which itself furthered the goals underlying bankruptcy sales: fairness, finality, integrity, and maximization of assets." *Id.* at 127-28.

The BAP concluded that "[t]he bankruptcy court did not err in finding that UAP had not received sufficient notice of the proposed sale as required by the right of first refusal" and that it "did not abuse its discretion in continuing the auction nor in approving the compromise regarding terms to govern the continued auction." *Id.* at 128

–Gaby R. Jabbour, National AgLaw Center Research Assistant

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Farmworker/Cont. from page 2

Id. It also asserted that "farm-worker housing has its own function independent of agricultural purposes and is not intended to serve agricultural purposes, as distinguished, for example, from a barn." *Id.*

Trust argued that the farmworker housing served both "'general agricultural purposes'" and was "'incidental to agriculture.'" *Id.* He reasoned that the occupants of the apartments would be employed full-time on the farm and that providing on-site housing would relieve them of the burden of having to drive long distances to work. *See id.* He noted that courts in other jurisdictions have examined the application of similar statutes to farmworker housing and "have all concluded that such dwellings are exempt from zoning and/or building codes." *Id.*

The court explained that the primary goal of statutory interpretation is to ascertain the legislative intent behind the statute. *See id.* (citation omitted). It also explained that it would interpret a statute

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The EU's traceability and labeling and food and feed proposals for products of transgenic origin

By Mark Mansour and Sarah Key

The European Parliament has formally adopted the following European Commission proposals:

• *Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organism*

• *Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed.*

These proposals address the approval process for genetically modified (GM) food and feed, as well as establishment of a traceability system for genetically modified organisms (GMOs) and foods produced from GMOs. In addition, both proposals address labeling for GMOs, as well as GM food and feed.

Now that the proposals have been adopted, they will have to be formally published in the Official Journal, which is expected to occur sometime in the very near future. The proposals will go into effect twenty days after publication, although there will be a three-month transition period for labeling and traceability, and a six-month period for food and feed to give producers time to achieve compliance with the new rules before they are fully enforced.

Changes to the existing regulatory framework

Several regulations currently govern the approval and labeling of GMOs and GM food and feed marketed in the EU. Below is a discussion of the regulatory regime currently in place in the EU, as well as how the proposed regulations affect that existing regulatory framework.

Existing regulatory framework

In addition to requiring pre-market authorization for bioengineered food products, the Novel Foods Regulation[1] (Regulation No. 258/97) governs food safety assessments and labeling for most bioengineered foods. This regulation requires that the consumer be informed of any property that makes a novel food or ingredient "no longer equivalent" to its conventional counterpart with respect to composition, nutritional value, or intended use. The product must bear labeling informing the consumer of (1) "the presence of an organism genetically modified by techniques of genetic modification;" or (2) "the presence in the novel food or food ingredients of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population."

Council Directive 2001/18/EC,[2] which revised Council Directive 90/220/EEC, governs approval of "living" GMOs prior to their environmental release and commercialization. Although Directive 2001/18/EC went into effect on October 17, 2002, many Member States have yet to transform this directive into national law.

Regulation No. 1139/98[3] was adopted to govern the labeling of the bioengineered corn and soybeans already approved for marketing in the EU prior to the adoption of the Novel Foods Regulation. This regulation was amended by Regulation No. 49/2000,[4] which establishes a 1% threshold for the labeling of bioengineered corn and soybeans to accommodate adventitious contamination of "identity-preserved" (non-bioengineered) crops with the bioengineered varieties. In addition, Regulation No. 50/2000[5] extends the bioengineered labeling requirements to any food product that contains "the presence of an additive or flavouring that is or contains an organism genetically modified by techniques of genetic modification." This labeling requirement is also triggered if the additive or flavoring contains protein or DNA resulting from the bioengineering process. There is no established de minimis threshold or required sensitivity for this analysis, nor is there a 1% threshold to accommodate adventitious contamination.

How the proposals affect the existing regulatory framework

Once they become effective, the proposals will replace three of the four laws currently governing the regulatory review and commercialization of GMOs and foods containing or produced with GMOs in the EU. The regulations being replaced are 1139/98, 49/2000, and 50/2000. Although some provisions of the Novel Food Law (Regulation 258/97) will be amended by the proposal on Food and Feed, it will remain in place for novel foods that are not genetically modified. Finally, both proposals will amend 2001/18 on the deliberate release of GMOs into the environment.

Specifics of the traceability and labeling proposal

Objective

According to the explanatory memorandum, the Traceability and Labeling proposal (T&L proposal) was needed because the existing regulatory framework fails to directly address the traceability and labeling of products produced from GMOs, does not provide a definition of traceability for GMOs, does not set forth the objectives of traceability, and does not provide a complete approach for implementation of a traceability system. The T&L proposal thus seeks to build upon the foundation of requirements set forth in 2001/18/EC and establish a harmonized framework for the traceability of products derived from GMOs.

Scope

The proposal applies to the following at all stages of marketing:

• products consisting of or containing GMOs;

• foods and food ingredients, including food additives and flavorings, produced from GMOs; and

• feed materials, compound feedingstuffs, and feed additives produced from GMOs.

General traceability requirements

The regulation defines "traceability" as "the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market throughout the production and distribution chains." Tracking of the movement of GMOs and products derived from GMOs through the production and distribution chains will be accomplished by traceability requirements based on the transmission and retention of all relevant information regarding such products through all stages of marketing. The intent is for the traceability system to facilitate the withdrawal of products when a risk to human health or the environment is established, allow for targeted monitoring of the potential effects of products on human health and the environment, and the control and verification of labeling claims.

To ensure a harmonized system for tracing products through all stages of marketing, operators[6] must enact procedures to carry out the following:

• establish and maintain systems and procedures to identify to whom and from whom products are made available;

• transmit specified information concerning the identity of a product in terms of the individual GMOs it contains or whether it is derived from GMOs;

• retain all specified information for a period of five years and make it available to the competent authorities on demand.

Because many producers already have in place traceability systems, the proposal does not specify the means by which this information must be transmitted and retained. Thus, to the extent existing systems are in place to transmit and retain the required information, those existing systems

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theoretically are sufficient, and may be used.

The proposal draws a distinction between GMOs and products produced from GMOs, noting that the objectives for the traceability of each group are not identical, and that the specified information required to be transmitted and retained for each group differs. In this regard, the proposal provides for the traceability of individual GMOs within a product on the basis of its authorized transformation event while the traceability of products produced from GMOs do not require identification of the GMOs from which they are produced.

Traceability and labeling for GMOs

Specific requirements for traceability

Existing Commission law requires the implementation of measures to ensure the traceability of GMOs at all stages of marketing.[7] However, this requirement does not differentiate between uses of GMOs. In addition, Directive 2001/18/EC requires the implementation of monitoring plans to trace and identify any direct, indirect, immediate, delayed, or unforeseen effects on human health or the environment. Because possible effects from GMOs are dependent upon the inherent nature of the GMO or the specific transformation event, the T&L proposal calls for the specific identification of each GMO and its associated traits and characteristics in order to facilitate targeted withdrawals and environmental monitoring. As a result, according to the proposals, a unique means of identifying each GMO is necessary. To facilitate this identification, operators must transmit the following specified information to the operator receiving the products: 1) that the product contains/consists of GMOs; and 2) the unique codes relating to the GMOs.

Unique codes

The proposal takes the authorized "transformation event"[8] from which the GMO is developed as its point of departure. Directive 2001/18 requires specification of the identity of the GMOs and their unique identifier, which must reflect the authorized transformation event. The T&L proposal requires that the Commission establish a system to develop and assign unique codes[9] to the GMOs. In furtherance of this requirement, the proposal recommends the establishment of a Committee to develop a system for the development and assignment of the unique GMO codes.

The unique codes must be transmitted and retained from the time the GMOs are first placed on the market through to their final and ultimate use as a food or feed or for processing. The purpose of this requirement is to enable the traceback of GMOs through the production and distribution chains. In addition, the unique code information will facilitate labeling, and, in the case of an unforeseen event, post-market withdrawals.

Sampling and testing

The proposal acknowledges that, particularly in the case of imports from third countries, *e.g.*, bulk shipments of commodity crops, analytical testing and sampling may be needed if the exporter fails or is unable to supply the importer with information regarding the identity of the products, in particular the GMOs they contain. The proposal does not require mandatory testing at each stage of marketing. However, the proposal does direct the Commission to develop technical guidance on sampling and testing methodologies prior to enactment of the regulation in order to facilitate a coordinated approach for inspection and control by Member States.

Labeling

Currently, pursuant to Directive 2001/18/EC, the labeling of GMOs is required at all stages of marketing. The T&L proposal places a legal obligation on operators to label prepackaged products in accordance with 2001/18. Specifically, the proposal requires that operators ensure that products are labeled "this product contains genetically modified organisms." Where labeling is not possible, *e.g.*, bulk commodities that are not packaged, operators must ensure the appropriate information is transmitted with the product to allow for labeling at a later time.

Traceability for products produced from GMOs

The proposal builds on existing traceability systems required by other EC laws[10] with the objective of extending those requirements to include information regarding whether a product is produced from GMOs. In particular, the following information must be transmitted to operators receiving products produced from GMOs:

- an indication of each of the food ingredients, including additives and flavorings, derived from GMOs;
- an indication of each of the feed materials or additives produced from GMOs;
- where products do not have an ingredient list, an indication that the product is produced from GMOs.

Finally, the proposal envisages that the traceability requirements will provide the basis for extending current labeling requirements for foods produced from GMOs to cover all foods and food ingredients produced from GMOs.

Specifics of the food and feed proposal

Objectives

The Food and Feed Proposal has three objectives:

- to ensure the protection of human life and health, animal health and welfare, environment, and consumers' interest in relation to GM food and feed, while ensuring the effective functioning of the internal market;
- to establish Community procedures for the assessment, authorization, and supervision of genetically modified food and feed; and
- to establish provisions for the labeling of GM food and feed.

Scope

The proposal covers food and feed containing, consisting of, or produced from GMOs. In addition, the proposal extends the scope of existing Community legislation on GMOs to also cover feed produced from GMOs, and a specific evaluation of the genetic modification relating to substances such as food additives, flavorings, or feed additives, where they have been produced from GMOs.

Significantly, the proposal applies to products produced *from* a GMO, but does not apply to products produced *with* a GMO. The proposal defines "produced from GMOs" as "derived in whole or in part, from GMOs, but not containing or consisting of GMOs" while "produced with GMOs" refers to a product that is produced with the assistance of a GMO, but no material derived from the GMO is present in the end product. As a result, cheese produced with GM enzymes that are not present in the end product would not be subject to the regulation. The final product obtained from animals fed with GM feed or treated with GM medicinal products would also not be subject to the regulations.

The proposal is based on the "one door–one key" principle, whereby it will be possible to file a single application to obtain authorization for both the (1) deliberate release of a GMO into the environment, pursuant to the criteria set forth in Directive 2001/18/EC, and (2) the use of that GMO in food and/or feed, pursuant to the criteria set forth in this proposal. Authorizations will be granted subject to a single risk assessment process, addressing both the environmental risk and risks to human and animal health, to be conducted by the European Food Authority (EFA), as well as a single risk management process involving the Commission and Member States through a regulatory committee procedure.

Principles of the authorization procedure

The proposal sets out the procedures for submitting an application for the approval of GM food and feed. Applications must be made to the EFA, which will then conduct risk assessments in order to streamline and improve the current authorization procedure for GM foods. In addition, in an attempt to ensure a harmonized approach to the scientific assessment of GM foods and feed, the EFA will conduct risk assessments for GM feed. Ostensibly to ensure clarity, transparency, and a harmonized framework for authorizing GM food and feed, the proposal does not provide for a notification procedure as similar to the one

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set forth in Regulation 258/97 on novel foods. However, the proposal does provide for public involvement in the authorization process whereby a summary of the application and opinion of the EFA will be made available to the public, which may then comment on the opinion for 30 days.

Products approved under the proposed regulation will be listed in a registry of GM food and feed–the Community Register of Genetically Modified Food and Feed–which includes product specific information, studies demonstrating the safety of the product, and detection methods that must be provided by the applicant to facilitate control. The initial authorization will be granted for a period of ten years, subject, where appropriate, to a post-market monitoring plan.[11] The need for such a plan will be assessed on a case-by-case basis during the risk assessment. Authorizations would be renewable for subsequent ten-year periods.

Authorizations granted under existing Community law[12] would remain in place under the proposal, provided that additional information concerning the risk assessment, methods for sampling and detection, including samples of the food and feed, are submitted to the EFA within six months of the enactment date of this regulation. The consequence of failing to comply with this requirement is that food or feed currently approved for marketing in the EU will no longer be viewed as approved.

Labeling

As discussed previously, labeling requirements for GM food are currently set forth in several pieces of Community legislation. In addition, labeling is currently required for GM feed pursuant to 2001/18/EC. However, this Directive applies only to "live" GMOs, and thus there is no current labeling requirement for feed produced from GMOs, but no longer containing GMOs.[13]

Labeling is currently triggered by the presence of DNA or protein resulting from genetic modification. However, the proposal extends the current labeling provisions to all GM food and feed *regardless of the detectability of DNA or protein*. As a result, food that consists of, contains, or is produced from GMOs would have to be labeled as such. This is a significant change from the current regulatory regime that will result in the required labeling of numerous products that do not currently require labeling, *e.g.*, highly refined oils of GMO origin. The T&L proposal is intended to facilitate the labeling required under this proposal.

Adventitious contamination

To provide for situations where minute traces of GM material may be present in food and feed as a result of adventitious or technically unavoidable contamination, the proposal establishes a threshold of 0.9% for approved GMOs. For unapproved GMOs, the threshold is 0.5% for three years after the enactment date of the regulations, after which time it will drop to 0%.

Conclusion

The proposals, in what is presumably their final form, have the potential to exacerbate the already growing distortions and disruptions in trade in commodities and finished food products between the United States and the EU Member States. In addition, a template is now in place for developing countries to take essentially the same action, or some variant. The proposals, subject of a protracted dispute between the EU and the U.S. for several years, since the revision of Directive 90/220, send an unmistakable signal that the EU is abandoning all traces of substantial equivalence and content-based labeling, in favor of process-based labeling, based at least in part on the Precautionary Principle.

The documents also rely on so-called "other" non-scientific factors, and the provisions of the Convention on Biological Diversity's Biosafety Protocol, which was never intended to apply to food products, but is in fact the basis for the entire EU revision process, including the initial changes to Directive 90/220 that set these directives into motion several years ago.

The readily predictable effects of implementation of these proposals will be several:

• There will be increased costs to U.S. manufacturers related to securing, collating, transmitting and maintaining records for each and every product and ingredient which contains or which may be derived from biotechnology, regardless of whether protein or DNA is detectable. It is important to remember that the "adventitious contamination" threshold loophole, for labeling purposes, is now closed. Unless a manufacturer knows to a certainty that its product or ingredient has only been subjected to adventitious "contamination" (and is prepared to document that fact), rather than having been produced in part or in whole as a result of genetic recombination, labeling is a requirement. Ultimately, the result will be increases in production costs and, inevitably, consumer prices. Any manufacturer that is dependent on transgenically-sourced materials loses competitive advantage in proportion to that dependence as long as consumer choice is denied.

• The legal penalties for failure to comply are not yet clear, but the commercial penalties will be far more severe. Given the degree of attention this initiative has received, and the lack of acceptance accorded to the old regulatory system, EU member state officials will have little choice but to enforce compliance if they are to maintain their credibility with the public. In any event, activist groups will be watching closely, and taking their own action, in concert with some sectors of the media, to ensure compliance. The consequences of failure to comply are just as, if not more serious, in their effect on relations with distributors and consumers as are the expected fines. The margin for error in the production process will approach zero, and each and every U.S. brand (and eventually some European brands as well) will be placed under a microscope.

• The implementation of these proposals will give additional momentum to activist groups and like-minded regulators in a number of developing markets. Many countries are in the process of developing labeling regulations, and the EU proposals already have been copied by other countries anxious to avoid seeming to be lax in managing this issue. The results, if carried to their logical conclusion, would create large "biotech free zones" throughout the world, in an environment in which U.S. farmers, grain handlers, and ingredient suppliers are powerless to provide adequate and legally merchantable product. The resulting demand for "GM free" soy, corn and canola, among other products, will also result in increased raw material prices, such increases proportionate to the number and size of the countries adopting similar provisions.

In sum, all concerned face a protracted period of uncertainty and dislocation as these regulations are promulgated, and as the race to comply begins in earnest. Within a year, we should know definitively whether the EU is correct in its conviction that these proposals are needed to guarantee acceptance of biotechnology, or its opponents are correct in their argument that the proposals will cause a regulatory and economic mess that may take years to resolve, while further demonizing the technology.

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[1] Regulation (EC) No. 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients.

[2] Council Directive 2001/18 was previously Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

[3] Council Regulation (EC) No. 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

[4] Commission Regulation (EC) No. 49/2000 of 10 January 2000 amending Council regulation (EC) No. 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive

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79/112/EEC.

[5] Commission Regulation (EC) No. 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms.

[6] The T&L proposal defines "operator" as "a person who places product on the market and also a person who receives a product that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer."

[7] *See* 2001/18/EC.

[8] A "transformation event" is where a conventional organism is "transform," through the introduction of modified DNA sequences, resulting in formation of a GMO. The introduction of these sequences ultimately determines the modified characteristics of the GMO, *e.g.*, insect resistance or herbicide tolerance.

[9] The proposal defines "unique code" as a "simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO."

[10] *See* Regulation (EC) 1726/2000 which requires a traceability system for beef products, Directive 95/96/EC which provides for certain traceability requirements in the animal feed sector, and Directive 89/396/EEC requiring labeling to identify the particular lot to which a food product belongs., as well as the Commission Proposal for a Council and Parliament Regulation which establishes the principle of traceability at all stages of the production and distribution chain in the food and feed sectors.

[11] Note that the post-market monitoring plan proposed under this regulation would address use of GM foods and feeds by humans and animals. Post-market environmental monitoring of GMOs is already required by 2001/18/EC.

[12] In particular, authorizations granted under Regulation No. 258/97 on novel foods and novel food ingredients and existing authorizations of GM food and feed granted under Directives 90/220/EEC and 2001/18/EC, Directive 82/471/EEC or Directive 70/524/EEC, will continue to remain in force.

[13] The issue of labeling requirements for GM feed is further complicated by the fact that until the second revision of Directive 90/220/EEC, which was the predecessor to 2001/18/EC, there was no requirement for the labeling of GM feed. As a result, currently four authorizations for GM feed require labeling, while four other authorizations do not.

contrary to its plain meaning "'only if necessary to effectuate the legislature's clearly expressed contrary intent or to avoid an absurd result that the legislature could not in any event have intended.'" *Id*. (citation omitted). It further explained that it assumed that the legislature accorded words their "natural and obvious meanings unless otherwise stated." *Id*. (citations omitted).

The court noted that the terms used in Ariz. Rev. Stat. §§ 11-830 and 11-865 were "quite broad in their scope and application." *Id*. It explained that although the phrase "general agricultural purposes" in § 11-830(A)(2) was not defined in the planning and zoning statutes, other statutes had illustrated the broad scope of the phrase "general agricultural purposes." *Id.* The court noted, for example, that in the valuation of "'agricultural property' for taxation purposes, 'residential dwellings that are maintained for occupancy by agricultural employees as a condition of employment or as a convenience to the employer' are valued as agricultural land." *Id.* (citation omitted).

The court found the language in § 11-865(A)(1) to be quite broad. *See id.* It stated that the term "incidental" "is generally defined as '[s]ubordinate to something of greater importance; having a minor role." *Id.* (citing Black's Law Dictionary 765 (7th ed. 1990)). It also stated that "'construction or operation' that is 'incidental' to farming or agriculture does not necessarily involve the primary functions of the farm but, instead, may concern functions that are tangentially related to the principal activity of the farm." *Id*. at 513. It further stated that "[o]n-site housing for full-time farm workers can be said to be 'incidental' to farming because housing the workers on the farm is a subordinate accommodation to their primary role as employees and because free, on-site housing arguably benefits both the employer and the workers in terms of safety and productivity." *Id*.

The court concluded that

> [b]ecause the statutory language is broad enough to include farm-worker housing and the statutes at issue do not preclude residential dwellings from the exemption from county zoning and building codes, we conclude that on-site dwellings for farm workers, like those proposed by Braden Trust, fall within the provisions of §§ 11-830(A)(2) and 11-865(A)(1). Our conclusion is consistent with decisions by courts from other states that have determined that farm housing is incidental to farming or agriculture and/or that it serves an agricultural purpose."

Id.

The court also examined whether "treating farm workers differently from other workers whose employers provide housing violates the equal protection clauses of both the Arizona and United States Constitutions." *Id*. at 515 (*see* Ariz. Const. art. 2, § 13; U.S. Const. amend. XIV, § 1). The court explained that the guarantee of equal protection under the Arizona and United States Constitutions "'require that all persons subject to state legislation shall be treated alike under similar circumstances.'" *Id.* (citation omitted). It also explained that considerations of equal protection "do not prohibit unequal treatment between people of different classes as long as the classification is reasonable." *Id.* (citations omitted).

The County argued that the relevant class for purposes of the equal protection analysis was all workers whose employers provided housing and who resided in counties that have adopted building codes. *See id.* It argued that § 11-865(A)(1) "discriminates against the subclass of workers employed in agriculture because the statute deprives them of 'the minimum life, safety and health requirements and inspections provided by the building codes.'" *Id*. Trust argued that the County was not entitled to attack the constitutionality of the statute on equal protection grounds. *See id*.

The court agreed with Trust's assertion, stating that because the County was neither a "'citizen'" under the Arizona Constitution nor a "'person'" within the meaning of the Fourteenth Amendment to the United States Constitution, it was not entitled to assert an equal protection claim. *Id*. (citations omitted). The court added that :

> [f]urthermore, neither § 11-830(A)(2) nor § 11-865(A)(1) denies farm workers equal protection because these statutes, which exempt a broad array of entities that collectively comprise the agricultural industry from complying with zoning and building code requirements, are not directed at farm workers per se, let alone farm workers of any particular racial or ethnic background.

Id. (citation omitted).

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