United Egg Producers
Leadership by Egg Farmers for Egg Farmers

February 22, 2021

UEP COMMENTS ON REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS PROPOSED RULE

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. FDA-2014-N-0053
RIN 0910-AI44

Dear Sir or Madam:

These comments are submitted on behalf of United Egg Producers (UEP). We appreciate the opportunity to provide our views on the Food and Drug Administration's (FDA) proposed rule entitled "Requirement for Additional Traceability Records for Certain Foods" (the "proposed rule" or the "traceability rule").

UEP is a farmer cooperative whose producer-members independently market more than 90% of all eggs sold in the United States. UEP serves as the voice of the egg industry and shares FDA's dedication to ensuring safe products throughout our food supply. We supported passage of the Food Safety Modernization Act (FSMA), which requires the present rulemaking. Our organization has a long history of working cooperatively with FDA, notably during the process that resulted in the final rule entitled "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation," which we also support.

General Comments

As a general matter, UEP believes the proposed rule is **unnecessarily complex** and will in some cases generate information that is superfluous and not easily used by the recipients. This is especially the case for the information required to be generated by farms when acting as shippers. More broadly, though, we would encourage the agency to reconsider its current approach and find ways to **simplify the recordkeeping requirements imposed by the rule and make them more flexible.**

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We are also concerned that FDA is overestimating the degree to which some farms – particularly small contract farms, which would have responsibilities as shippers under the proposed rule – have ready access to, and familiarity with, computer spreadsheet programs and similar electronic recordkeeping technology. Moreover, FDA is surely aware that in large areas of rural America, internet access is slow, unreliable or non-existent. **We fear FDA is designing a rule for urban areas and consumer packaged goods companies and then trying to apply it unchanged to small farms.**

Definition of "Farm"

The traceability rule is being promulgated pursuant to a mandate in Sec. 204(d) of FSMA. Through a series of rules, FDA has established a definition of "farm" that applies to entities potentially regulated under FSMA. Although this definition is somewhat complex, it takes into account various ownership and management structures that characterize different segments of the agricultural sector.

UEP does not understand why FDA proposes to apply this same definition of "farm" to all segments of agriculture *except* for the egg industry. Instead, FDA proposes to use the farm definition in the Egg Safety Rule, which has different purposes and scope than the traceability rule or the other FSMA rules.

The rationale cannot be that eggs, unlike other agricultural commodities, are covered by a separate rule (the Egg Safety Rule). While that is true, the same logic would suggest a separate farm definition for fresh produce, which likewise is covered by a separate rule designed specifically for fresh fruits and vegetables. The same could be said of seafood.
Nor can the logic be that egg farms have unique structures that differentiate them from all other agricultural commodities, necessitating a separate farm definition. The ownership and management structures found in the egg industry, from (relatively uncommon) contract production to the presence of packing facilities on farm sites, can be found in many other commodity sectors.

FDA has failed to explain why it has chosen the Egg Safety Rule definition. This definition works well for the administration of that rule, which solely focuses on the regulation of egg production in henhouses. The Egg Safety Rule does not regulate the washing, grading and packing that are an integral part of egg farms, and therefore the Egg Safety Rule farm definition does not focus on those activities but on "poultry houses," which are only one component of an egg farm.

Under the approach FDA is proposing, **some egg farms that are "farms" for purposes of all the other FSMA rules will not be "farms" for purposes of the traceability rule.** It seems nonsensical for the agency to consciously create a situation of such confusion, inconsistency and unnecessary complexity.

Instead, UEP urges FDA to **make the farm definition used in this rule consistent with the farm definition that applies to other FSMA rules**. That approach is simpler, more easily understandable and takes advantage of the agency's experience in refining the FSMA farm definition over several different rulemakings.

First Receiving

It is unclear, under the proposed rule, to what degree egg farms would be **first receivers**. A shell egg processing plant that is supplied by several contract farms located within a few miles of each other will be in an ambiguous position because the proposed farm definition refers to "grounds immediately surrounding the poultry houses …". This suggests that even though the laying hens on contract farms are typically under the same ownership as the shell egg processing plant, the owner of that plant and the birds may not be considered a "farm" under this rule. If so, the shell egg processing plant may be considered the first receiver.

As noted above, we think this is an anomalous result, since generally speaking, this same operation would in fact be a "farm" under the other FSMA rules. However, in the event that an egg farm that is a farm for every other regulatory purpose is deemed by the agency for this regulation, and this regulation only, *not* to be a farm, then we have the following questions.
It would be typical for such an operation to receive eggs from several different contract farms during a single day and wash, grade and carton the eggs during a single shift. The eggs might or might not be physically segregated from each other.

In such a case, **is a different lot code required** for each shipment of eggs received from each contract farm each day? If so, does this not mean that FDA, instead of merely requiring recordkeeping, is imposing a new and costly **segregation requirement** that does not exist today? If that is the agency's intent, it should be clearly spelled out. However, if that is not the agency's intent, as we believe it likely is not, then it would be extremely helpful for FDA to make this clear in the preamble to the final rule. The basic concern is that farms be able to define the scope of lots for themselves.

Shipping

Under the proposed rule, it is clear that farms can be shippers. We have several questions about how the requirements for shippers would operate on a practical level.
In so-called "in-line" egg farms, both the henhouses and the shell egg processing plant are located on a single site. However, "off-line" farms feature a shell egg processing plant that receives eggs daily from other nearby but not necessarily adjacent farms. In some cases, the farms may be under common ownership with the plant, but in other cases the farm operating the shell egg processing plant owns the laying hens but not the land or buildings in which the hens are kept and the eggs are laid. This situation is normally referred to as contract production.

If FDA adopts our recommendation to use the FSMA farm definition, as we strongly believe it should, then the shell egg processing plant owning the birds as well as each contract farm will be "farms" for purposes of this rule. This means that the Key Data Elements (KDEs) required of shippers that are farms would apply to both categories of farm.

Now consider the farm operating the shell egg processing plant. It will be required to send certain information about each and every individual contract farm to the immediate subsequent recipient of the eggs, typically a retail grocery or food service company. This is because it appears from the definitions in the proposed rule that the eggs in question will be **"originated" on the contract farms**, since the originator is where the eggs are "harvested" and the proposed rule cites "collecting eggs" as an example of harvesting.

In turn, this means the shell egg processing plant must **supply information about all its contract farms to its customers with every single shipment.** We would submit that this is information the customer likely does not want, will not act on in any meaningful way and has no reason to receive.

We certainly are not saying the information (with a clarification as outlined below) should not be retained and available to FDA. Clearly, it should. However, simply passing along data to a customer who has no need for it seems unnecessary and burdensome. Again, the information will readily be available to the customer if it is ever needed for a traceback.

The KDEs to be tracked by the shipper include the "**date and time"** of harvesting, cooling and packing. The date is likely to be known, but the exact clock time may not be, since a single truck may collect eggs from several farms and the eggs may be collected over a range of times. We would therefore recommend that only the date be required.

In the requirements it imposes on shippers, the proposed rule appears to require egg farms to share **business-sensitive information** with customers, contractors or both. In the case where a producer is selling eggs to another producer, they must disclose the contact information of other farm entities they have established a contractional relationship with and a sole agreement to purchase eggs. This would allow competitors to have business sensitive information related to contract farms. UEP urges the agency to take a second look at these requirements, particularly as they apply to farms acting as shippers.

Another issue for the shipper – also applicable to first receivers – is the information required about the **name of the transporter** of the eggs. Does this refer to the corporate name of the trucking company that moved the eggs, or does it actually require the name of the individual truck driver? The former is likely to be much more readily available than the latter, and probably is more useful to FDA. However, a clarification in the final rule would be helpful.

Exemption for Commingled Raw Agricultural Commodities

It is unclear to us how the exemption for **"eggs from separate farms under different company management that are physically mixed before packing"** would operate in practical terms. In particular, consider the situation where a shell egg processing plant is washing, grading and packaging both its own eggs and eggs that enjoy the exemption above. In such a situation, the exempt eggs might sometimes be segregated from the farm's own eggs, but that is not the typical practice. In that case, how does the farm assign a lot code to the day's production? Is the production of the entire shift a single lot? This seems counter-intuitive since the farm would be required to track various Key Data Elements for some eggs in the lot but not others. But under the contrary assumption, namely that the farm's own eggs must be a separate lot that does not include exempt eggs, then the agency has imposed a *de facto* segregation requirement that does not presently exist. We assume that is not the agency's intent, but clarity is needed in the final rule.

Re-Proposed Rule

UEP believes that the structure and requirements of the proposed rule are unnecessarily complex, confusing and unclear. Instead of finalizing the present proposal, UEP encourages FDA to take into account all comments received, make significant adjustments in light of the comments, and **re-propose the rule for additional public comment**. In this way, the agency can make appropriate – and significant – modifications to its initial proposal but afford the public an opportunity to comment on those changes, in accord with the Administrative Procedures Act. We note that the agency took this approach on more than one major FSMA rule, to the ultimate benefit of both FDA and the regulated community.

Once again, UEP does not oppose, and in fact supports, appropriate traceability requirements. If done right, these requirements can help the agency move swiftly in cases of foodborne illness outbreaks. Unfortunately, the current proposal suffers from unnecessary complexity and the public interest would be better served by a re-proposal, which need not be a lengthy process but will ultimately lead to a more workable regulatory regime.

Thank you for your attention to these comments.

Sincerely,

Oscar Garrison
Sr. VP of Food Safety Regulatory Affairs