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TO: FDA, Docket No. 98N-1230
FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852
"Fdadockets@oc.fda.gov"

FROM: Danny R. Hughes, President
National Egg Regulatory Officials
#1 Natural Resources Drive
Little Rock, AR 72215

The following comments are submitted on the behalf of the National Egg Regulatory Officials (NERO). The membership of NERO consists of 35 State Department of Agriculture officials involved in shell egg and egg product regulations and programs. Examples of areas regulated by members include refrigeration of shell eggs, enforcement of quality standards, egg container labeling, record keeping for handlers of shell eggs, sanitation standards for shell egg processing plants and third party monitoring of Egg Quality Assurance Plans. Many members have cooperative agreements with USDA/AMS and USDA/FSIS for inspections conducted under the Egg Products Inspection Act and for the voluntary grading of shell eggs. The primary goal of the NERO organization is to promote uniform state, local and federal regulations concerning shell eggs and egg products that provide effective consumer protection in the areas of egg safety, quality and labeling.

Four members represented NERO at the August 26, 1999 public meeting on shell egg safety. The format for the meeting was excellent. The opening session gave participants a clear outline of the current status of action items and the issues that still need to be addressed. The breakout sessions afforded everyone the opportunity for open discussion of the potential impact and results of any proposed actions. The majority of the public meetings attended by NERO members are formatted to allow all interested parties five to ten minutes to present their views. In our experience, that format does not facilitate the necessary consensus building that will produce effective actions concerning egg safety. The facilitators provided by the federal government did an excellent job of ensuring all participants had an opportunity to express their opinions while keeping the discussions on track. Our organization would highly recommend the same

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meeting format for
future meetings.

In response to the question raised at the meeting concerning the most i
mportant problem that
needs to be overcome to achieve the overarching goal, we do not believe
there is a single egg
safety problem in the farm to table spectrum that is most important. T
he single most important
problem is a lack of coordination in egg safety activities, not only be
tween federal agencies, but
between federal and state agencies. Many State Departments of Agricult
ure are already actively
involved in enforcement and educational programs that have been proven
effective in addressing
many of the problems the federal government is currently developing a s
trategic plan to address.
Better coordination between federal agencies and state agencies involve
d in egg safety activities
would reduce the barriers to a comprehensive plan for egg safety. Both
FDA and FSIS have
indicated that any program will be a partnership between the federal go
vernment and state
governments. The most important action to achieve this partnership is
the inclusion of State
representatives such as NERO, State Veterinarians and State Health Dep
artments in the planning
process.

Although we know of no single action in the farm to table continuum tha
t would significantly
reduce Salmonella enteritidis, we do think a combination of risk reduct
ion actions would increase
egg safety. Based on our knowledge of current regulations and program
s, enforcement actions
and the prevention, control and education discussions at the meeting, w
e have outlined the actions
we feel would reduce the risk of human illness from bacteria in shell e
ggs.

Labeling

NERO strongly supports safe handling requirements for shell eggs, howev
er, we feel both FDA's
proposed rule and FSIS's rule could be more effective. FSIS's rule req
uires refrigeration labeling
for eggs packed into containers destined for the ultimate consumer. T
his labeling is not required
on the primary master container used to ship cartons of eggs destined f
or the ultimate consumer.
Members of our organization are very experienced in conducting inspecti
ons of shell eggs at retail

and wholesale locations. Based on our observations during these inspec tions, we think the primary master container used to ship cartons of eggs should also bear refrigeration labeling. Wholesale and retail receivers of shell eggs are not always trained in food safety and a notice on the case to refrigerate eggs would serve as a reminder of the importanc e of refrigerating eggs promptly.

We feel the labeling statement FDA has proposed is too lengthy with the most important information at the end of the statement. We are concerned about the le ngth for two reasons. One is the probability of consumers reading the entire statement. The seco nd is the amount of room available on a carton to display the information. We would recommend a statement such as "Keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly". This statement contains all of the information necessary to inform consumers how to avoid food borne illness, is easier for consumers to read and would take considerably less room on the carton. The FDA proposed rule also indicates eggs destined for food service could have the safe handling instructions on invoices or bills of lading. In our experience, invoices and bills of lading are not in the possession of the persons handling the receivi ng and preparation of the eggs. Additionally, the majority of salmonella enteritidis outbreaks h ave been traced back to a combination of egg contamination and mishandling of the product at the food service level. The majority of the eggs shipped to food service establishments are in 15 d ozen or 30 dozen cases that have ample room for additional labeling. As there is adequate room on these cases, inclusion of the food service safe handling instructions developed by the American E gg Board along with a warning statement that failure to follow these guidelines could result in food borne illness would be more effective in reducing the mishandling of eggs at food service e stablishments. These instructions include guidelines for refrigeration, handling and prepara tion and would be readily visible to the food handlers if they were on the container.

Refrigeration

FDA's proposed rule that would require shell eggs to be held at 45øF is an excellent step towards

creating a uniform national standard that will reduce the risk of bacte rial growth in shell eggs. The
inclusion of food banks and flea markets under this rule will close exi sting gaps. To facilitate
enforcement of this rule, FDA should explore the possibility of agreeme nts with State
Departments of Agriculture who are already visiting the retail and food service establishments to
enforce egg regulations.

NERO is concerned about the proposal to destroy or divert to pasteuriza tion any eggs found held
at temperatures above 45øF. One of our concerns is the inconsistency be tween FSIS' regulations
and FDA's proposed rule. If eggs are found to be held at temperatures above 45øF in locations
covered by FSIS' regulations, it is a facility violation and the produc t is not retained. Under
FDA's rule, the product would be destroyed or diverted to pasteurizatio n. There is a limited
number of egg products plants in the United States. The direct shipmen t of eggs from retailers
and food service facilitates to egg products plants is not feasible. R etailers and food service
facilities would not be able to divert product for pasteurization witho ut returning it to the
processor. This means the eggs would almost have to be destroyed. We would recommend the
use of civil penalties to encourage compliance by retailers and food se rvice establishments to
minimize the destruction of eggs.

FSIS' rule for refrigeration still has enforcement gaps. Although FSIS has delegated authority to
AMS representatives to verify cooler temperatures at processing plants during surveillance visits,
there has been no provision made for verifying temperatures of transpor t trailers on these same
premises. The most efficient and cost effective way to enforce the tra nsportation temperature
requirements would be for AMS representatives to verify the trailer tem peratures during the
surveillance visit. Additionally, FSIS has indicated they will check t he temperatures of transport
vehicles when FSIS program employees are present at warehouses or other in-distribution
locations. Many State Departments of Agriculture already have personn el inspecting warehouses
or other in-distribution locations. The costs associated with determin ing and documenting these
temperatures could be reduced by FSIS entering into agreements with the States to perform these

functions on a cost share basis.

The lack of a requirement for nest run eggs is a gap in the refrigerati on of shell eggs from farm to table. FSIS and/or FDA should consider a national requirement for the refrigeration of shell eggs prior to processing and packaging.

Education

Food handler certification for persons preparing and serving food espec ially to highly susceptible populations was discussed. All participants felt this was an extremely important part of egg safety. FDA should consider proposing a rule requiring this certificat ion rather than delaying by waiting for each State to adopt this requirement.

Materials related to educating consumers, retailers, food service, prod ucers and processors of shell eggs, warehouses, etc. on egg safety should be made readily avail able to States. State Departments of Agriculture could utilize these materials in responding to the numerous inquiries they receive concerning egg safety. Also, many State Departments of Ag riculture participate in events that educate the public on food safety such as state fairs, ag i n the classroom activities and meetings of many types of organizations. Rather than each State develo ping their own literature and materials, FDA and/or FSIS could develop and provide the materials to the States. This would be a cost effective method of increasing public awareness of the risks and methods of reducing that risk.

Mandatory National Standards for the production and processing of shell eggs

The discussions at the August 26,1999 meeting indicated there is a cons ensus among consumer groups, industry groups and state regulators that mandatory national st andards for all producers and processors are necessary. There are standards for many aspects of the production and processing of shell eggs that could contribute to the reduction of risk . For each of these we have offered our opinion on both the effectiveness and costs involved both i n compliance and enforcement.

1. HACCP like requirements for production that include cleaning

and disinfecting of houses,
rodent and pest control programs, biosecurity, environmental testi ng and government
monitoring for compliance. The PEQAP program is evidence that the se requirements can
significantly reduce salmonella enteritidis in laying houses. The implementation of these
requirements would involve appreciable costs both to the industry for testing and
government for monitoring for compliance. Consumers would probabl y see increased
costs in purchasing shell eggs. To reduce the costs involved in g overnment monitoring,
the feasibility of providing resources to State Departments of Agr iculture to perform the
monitoring should be explored.

2. HACCP like requirements for processing that include plant san itation, proper washing,
interior quality of eggs as it relates to the mechanical and chemi cal defenses of the
albumen being reduced, rodent and pest control programs, processor verification of
HACCP plan compliance and effectiveness and government monitoring for compliance.
These requirements would not reduce the risk as significantly as p roduction requirements.
Production requirements have the potential for eliminating salmone lla enteritidis while the
best processing requirements can do is prevent cross contamination and minimize growth.
Processing requirements would not be as costly to implement as tho se for production.
The majority of processors are already following processing guidel ines so increased costs
to industry would be minimal. Government monitoring could be cos t effectively
implemented by including these requirements as part of the surveil lance visits conducted
by AMS representatives.

Quality Standards

The practice of repackaging and older eggs in the marketplace have been an area of concern for
consumers, industry and regulators. Research has indicated the breakdo wn in albumen quality
caused by time and temperature allows bacteria to penetrate the yolk an d multiply. USDA
standards for egg quality include a tolerance for eggs that have albume n breakdown. They are
classified as B quality based on the thinning of the albumen. The cur

rent USDA standards allows
13% B quality at origin and 18% B quality at destination. These standa rds have not been revised
since 1984. As changes in technology have reduced the amount of time be tween production and
delivery to the consumer, the need for 13% and 18% tolerances for B int erior quality eggs is no
longer valid. A reduction in the tolerance would be effective in remov ing older and/or repackaged
eggs from the market. Enforcement of the new tolerance would not incur any additional
expenses. The majority of the States are actively enforcing USDA toler ances as part of their
State egg law. The Egg Products Inspection Act prohibits the States fr om adopting tolerances or
standards that are different from USDA's. A change in the USDA standar ds would automatically
change the standards used in the enforcement of State egg laws.

Another method of enforcement would be to revise the requirements of th e Egg Products
Inspection Act. AMS representatives currently check all consumer label ed product to ensure it
does not exceed the tolerances established for Grade B even if the prod uct is labeled Grade A or
Grade AA. This requirement was established to prevent the sale of rest ricted (dirty, cracked,
inedible) eggs to consumers. AMS representatives could verify that the product met Grade A or
Grade AA standards in the same amount of time during the quarterly surv eillance visits. This
would prevent the sale of older eggs without incurring any additional i nspection costs.

Repackaging

NERO strongly supports the prohibition of repackaging of store returns and any type of
repackaging at the store level. Although we support the prohibition of these practices, we believe
it will be difficult to enforce. The changes we recommended to the qua lity standards would be an
effective enforcement tool to prevent repackaging. Persons that engage in repackaging can meet
the current tolerances allowed for B interior eggs in Grade A labeled p roduct by intermingling the
eggs with current production. If the amount of B interior eggs allowed in Grade A and Grade AA
labeled product was reduced, they would no longer be able to meet the s tandard.

Expiration Dates

Meaningful expiration dates would be beneficial to consumers, distributors, retailers and food service operations. An expiration date based on the date of lay would be the most meaningful, however, determining the accuracy of the expiration date would be impossible. The current interpretation of expiration dates is how long the eggs will still meet the tolerances for the labeled grade. The changes we recommend for the quality standards would also be effective in making the expiration date more meaningful. Current practice is to include expiration dates on consumer cartons but not on eggs packed for food service. A requirement for expiration dates on all eggs would assist distributors, retailers, and food service operations in rotating stock and disposing of old eggs.

Pasteurized Egg Use for Highly Susceptible Populations

Although the use of pasteurized eggs for highly susceptible populations is included in the model food code, the adoption by States is a lengthy process. Given the importance of this action, FDA should consider mandating it as federal law.

One Agency Responsible for Egg Safety

The NERO representatives attending the August 26, 1999 meeting felt there was consensus for consolidating egg safety responsibility in one agency. Although we support this concept, we recommend the federal agencies and the President's Food Safety Council carefully consider the options before delegating the authority to one agency. Since USDA's reorganization that changed the authority for the Egg Products Inspection Act from AMS to FSIS, our membership has experienced many difficulties. Although FSIS has expertise in food safety for meat and poultry, they have very little experience in egg products. This has created problems for States that have cooperative agreements for the provision of egg products inspection. We recognize USDA reorganized to avoid the appearance of conflict of interest, however, the expertise of the people performing the day to day work needs to be considered in any reorganization.

We appreciate the opportunity to provide input on the federal governmen

t's proposals for egg
safety and look forward to contributing the success of the strategic pl
an for achieving egg safety.

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

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See Docket Number/Item Code:	97P-0197/C532 96P-0418/C531