



**MOLECULAR CIRCUITRY, INC.**

FDA  
Dockets Management Branch (HFA-305)  
5630 Fishers La.  
Rm. 1061  
Rockville, MD 20852

August 10, 2000

Re: Docket No. 00N-0504

Dear Sir or Madam:

Molecular Circuitry, Inc. (MCI) hereby respectfully submits these comments on the Food and Drug Administration's (FDA's) and Food Safety and Inspection Service's (FSIS') current thinking papers on national standards for egg safety. 65 Fed. Reg. 42707 (July 11, 2000). MCI submits these comments in triplicate to both the FDA and USDA dockets. If government staff reviewing these comments would prefer an electronic copy of these comments, MCI will be happy to provide one.

The comments contained herein are intended to support both the Egg Safety Action Plan and the current Thinking Papers. The comments focus principally on the Thinking Paper for On-Farm Standards.

MCI is dedicated to implementing high technology for improving food safety by detection of contaminating microorganisms. Introducing leading edge technology, automation, and data storage and retrieval, MCI manufactures and designs automated instruments and assay kits for the detection of pathogenic microorganisms. Therefore, MCI has an interest in the Draft Egg Safety Action Plan and associated Thinking Papers.

MCI appreciates the efforts of federal food safety staff across the federal agencies involved in developing and refining the Egg Safety Action Plan to reach the current iteration of the Plan. MCI commends FDA and FSIS and is supportive of the refined approach set forth in the Thinking Papers. MCI believes that the Thinking Papers are

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consistent with the government's goals and principles in food safety, and we commend the Agencies in that regard.

MCI appreciates the opportunities the Agencies have allowed to date for the public to provide input in the development of an effective and workable Egg Safety Action Plan that focuses on sources of significant food safety risk and opportunities for protecting public health. In addition, MCI would be glad to meet with staff from either agency to discuss any aspects of these comments or the underlying concepts or any recommendation the staff might have regarding our activities.

As the government has noted, current safety efforts are not providing the confidence in the food supply that U.S. consumers demand and deserve. An estimated 1 in 20,000 eggs in the U.S. supply will contain the *Salmonella enteritidis* bacteria and can cause illness if eaten raw in foods or not thoroughly cooked before consumption. The safety pressures on our food supply will continue to grow, yet without a concomitant or even relative increase in resources available to address them. Indeed, as a still-current Food and Drug Law Institute (FDLI) task force reported, food regulatory agencies will need to find new ways of meeting their responsibilities with fewer human and dollar resources. Thus, the Egg Safety Action Plan and associated Thinking Papers should, and we believe do, recognize the need to rely on available tools to prevent and identify the entry of contaminants into the U.S. egg supply.

One of the more readily available tools that can be used for this purpose is sophisticated pathogen detection technology. As the FDLI task force noted, the technological potential of the modern age – manifesting itself, for example, in more rapid pathogen detection methodologies – may offer tools for accomplishing the agencies' public health protection goals in an era of downsizing. The level of risk food products pose is directly related to the pathogens in these products. Any strategy the U.S. government employs that thus fails to embrace pathogen detection explicitly is limited by not making full use of the

tools at its disposal. With selective and proper application, these tools can be used cost-effectively to improve the safety of our food supply.

The draft Action Plan and Thinking Papers would provide a more refined and focused program to ensure safer eggs and egg products. Their reliance on science-based principles demonstrates in theory at least that the U.S. egg supply safety system can be moved quickly beyond where traditional food safety programs have led. The science-based approach would have food safety programs focus our collective efforts on the most significant and actual hazards.

Significantly reducing the risk of foodborne illnesses can be accomplished through regulations, inspections, enforcement, research, and education. MCI urges the Agency to acknowledge that the most significant gains in reduced risk and consumer confidence can be gained through a science-based and coordinated regulatory scheme that relies on food processing and inspection that proves eggs are dependable and safe through testing. A sharper focus on detection and prevention will: (1) reduce risk in the first instance; (2) promote greater accountability with food producers; and (3) instill greater public confidence in the egg safety system. Thus, a Plan that implements environmental/food testing is an appropriate component of an ultimate goal, because testing generates the necessary proof or evidence of safety.

The cornerstone of any Egg Safety Action Plan is mandatory environmental testing. The *Salmonella enteritidis* risk assessment demonstrated the need for testing, especially on large farms. The risk assessment found that by flock size strata, the largest stratum, flock sizes of 100,000 per flock, contributed almost two-thirds of *Salmonella enteritidis*-positive eggs.

MCI strongly supports the use of environmental testing, followed by egg testing in the event of a positive result, with diversion if that subsequent testing is positive.

Environmental tests provide a more accurate picture of whether or not the process is contaminated. MCI recognizes that testing batches of eggs will not provide sufficient evidence to determine whether, for example, the flock house is contaminated by *Salmonella enteritidis*. Yet because infected hens will shed *Salmonella enteritidis*, environmental samples provide greater certainty as to whether *Salmonella enteritidis* is present in the hens. Infected hens do not produce contaminated eggs all the time, and not all hens at a flock house are infected by *Salmonella enteritidis* at the same time.

Environmental testing provides verification. Verification is necessary to provide assurance that the components of the control program are actually effectively reducing *Salmonella enteritidis*. In the absence of such testing, the producer cannot know if its production process has gone awry at the pathogen level. For example, the need to disinfect and clean is clearly critical to safe egg production, and MCI would like to see *Salmonella enteritidis* testing as a means to ensure that the cleaning and disinfection are actually successful. Thus, testing educates producers by verifying that a problem exists and that it is appropriate to go forward and address the problem. Without the testing there is no understanding that a problem exists. The environmental testing is extremely useful for producers implementing best-management practices or another form of a hazard analysis and critical control point (HACCP) program.

Testing verifies the management practices that have been implemented on the farms. MCI believes that sustainable long-term egg safety is achieved through the management practices that are implemented on the farms. As a consequence of a positive test result, the main emphasis should be on viewing the management strategies and correcting management problems that can be refined and improved. Positive tests are in this way a tool to identify those needed improvements that at this time may not be thoroughly understood.

In addition, research indicates that environmental testing is an appropriate means of verification of the effectiveness of a *Salmonella enteritidis* program. Such testing allows for appropriate reaction to a flock house that has a positive environmental test. Based on a positive test, producers would review their program to make certain all of the best-management practices really are in place and if any of them need to be improved.

MCI also recommends that the Agency employ the HACCP principles to the whole development of a farm-to-table egg safety program. The goal should be to use HACCP principles in the industry to develop producer programs to make them meet the needs that the consumer wants and deserves.

MCI understands the need for less expensive yet more sensitive and rapid tests with which to validate the effectiveness of such programs and practices. MCI supports and is working to develop and improve testing methodologies and assays for *Salmonella enteritidis* that can be used on farms and in eggs.

The Agency should be clear that whatever processes are implemented they should be efficient and provide the desired results in a timely fashion without becoming mired in administrative process issues. This requires having measurable results. Results that demonstrate whether eggs are contaminated and if so the level of contamination are important in terms of reducing public health outcomes we seek to avoid. If the Agency is serious about reducing the figures that end up in the public health surveillance column tally sheets, the most effective way to do so is to identify the contaminated food before it is consumed.

Pathogen detection testing is a critical link in the farm-to-table chain that comprises the Agency's comprehensive Egg Safety Action Plan. Performance-based standards in food safety are part of a fundamental shift in regulatory philosophy and strategy that have taken hold for some segments of the federal food safety system. Having such standards

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in place would be a good start. Implementation of such standards should be the next important step for those agencies to espouse.

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MCI recognizes the perception of its self-interest in promoting testing. At the same time, MCI knows full well that the existence of deadly pathogens and incidents of contamination occur in the United States supports the need for continued surveillance and pathogen testing. The farm-to-table approach dictates that testing should be used to validate the entire egg production system, and this in turn calls for a stronger, more consistent regulatory stance regarding testing standards and types of testing and equipment. MCI also recommends that the agencies ensure that regulatory changes be made palatable to industry by enacting such changes in phases, or allowing for staged entry of such changes. Although increased standards, inspection, and testing should be embraced by all stakeholders, drastic and sudden change is not acceptable. Phasing in such changes can help make such changes palatable.

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Thank you for the opportunity to provide comments on the Thinking Papers associated with the Egg Safety Action Plan. If you have any questions, please call me at (610) 313-9900.

Sincerely,



Herbert Lotman

Chairman and CEO

Molecular Circuitry, Inc.