

**M O L E C U L A R C I R C U I T R Y , I N C .**

February 11, 2000

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

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Re: Docket No. 97N-0074

Dear Sir or Madam:

Molecular Circuitry, Inc. (MCI) hereby respectfully submits these comments on the President's Council on Food Safety Draft Preliminary Food Safety Strategic Plan. 64 Fed. Reg. 70168 (December 15, 1999). 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.

MCI submitted comments on the President's Council on Food Safety draft Inter-Agency Food Safety Strategic Plan. 64 Fed. Reg. 32788 (June 17, 1999) on August 30, 1999. As was the case with that submittal, the comments contained herein are intended to strengthen both the Plan and its language. Where appropriate we provide proposed language in *italics*.

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 this Draft Preliminary Strategic Plan.

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MCI appreciates the efforts of federal food safety staff across the federal agencies involved in developing and refining the Strategic Plan to reach the current iteration of the Plan. MCI commends the Food Safety Council on the Strategic Plan and is supportive of the refined goals, intent, and approach set forth in the draft strategy. MCI believes that the Strategic Plan is consistent with the government's goals and principles in food safety, and we commend the Council in that regard.

MCI also appreciates the opportunities the Food Safety Council has allowed to date for the public to provide input in the development of an effective and workable Strategic 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 Council staff to discuss any aspects of these comments or the underlying concepts or any recommendation the staff might have regarding our activities.

The workgroups involved in refining the Strategic Plan have made great strides in providing focus to the Plan. Nonetheless, there are still areas in which we believe the Plan can be enhanced to address not only current food safety needs, but those yet to be uncovered. We believe the Plan lacks most an emphasis on the tools that can be used to be prepared for and to prevent future food safety concerns.

As the government has noted, current safety efforts are not providing the confidence in the food supply that U.S. consumers demand and deserve. 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 recent 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 Plan should recognize the need to rely on available tools to prevent and identify the entry of contaminants into the U.S. food 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 revised draft preliminary Strategic Plan provides a more refined and focused program that is to be the skeletal framework for programs to ensure safer food products. The Plan's reliance on science-based principles demonstrates in theory at least that the U.S. food 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. As MCI noted in our prior comment submittal, the Strategic Plan complements President Clinton's Food Safety Initiative, through which the Administration seeks to continue to increase the resources for research to develop tests that detect microbes that cause food-borne illness, expanded inspections to improve compliance, and educational programs to improve food handling at the home and at the retail level.

MCI wholeheartedly supports risk-based decision-making and is genuinely pleased about the support the President has directly shown for developing tests to detect pathogens. Both the decision-making process and appropriate pathogen testing mechanisms can be used to focus site-specific hazard assessments, identify vulnerable populations, and minimize the impact on facilities posing less or no risk.



**Overarching Goal: To protect public health by significantly reducing the prevalence of foodborne hazards, thereby reducing acute and chronic illnesses and injuries through science-based and coordinated regulation, inspection, enforcement, research, and education programs.**

MCI generally supports the overall purpose and goals of the Strategic Plan. The Plan is appropriately promoting dialogue among all stakeholders in a context broader than the federal food safety agencies' own regulatory scope. In terms of the Plan's Overarching Goal, MCI agrees that the government should expect that once implemented, the Plan should achieve a significant reduction in the prevalence of foodborne illnesses. However, in emphasizing a science-based approach to food safety, the Overarching Goal should state that it seeks significant reductions in the risk of foodborne illnesses occurring, rather than the prevalence of foodborne illnesses. At the public meeting held on January 19, 2000, a commenter noted the clear disconnect between the statement "reducing the prevalence of foodborne hazards" and the statement in the Plan's Vision Statement that "Consumers can be confident that food is safe." These statements need to be rephrased, and the simplest and most accurate way to do so is to alter the emphasis of the statements to respond to the impact that risk plays in the food safety equation. After all, the bases for the Strategic Plan, indeed its goals, are drawn specifically under the categories of science, risk assessment, risk management, and risk communication. The Council should not shy away from the Plan's emphasis and reliance on science and risk-related activities.

MCI recommends that the above-noted phrase in the Vision Statement should read:

*"Consumers should be confident that risks from food are minimized."*



In addition, the last sentence of the Vision Statement needs to be re-phrased. It currently states "Food is safe because everyone understands and fulfills their responsibilities." It should read:

*"Food can be made safe because everyone understands and fulfills their responsibilities,*

MCI here restates that significantly reducing the risk of foodborne illnesses can be accomplished through avenues the Council suggests, namely regulations, inspections, enforcement, research, and education. MCI urges the Council 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 prove food is 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 government's food system. Thus, a Plan that implements food testing is an appropriate component of an ultimate goal, because testing generates the necessary proof or evidence of safety.

Finally regarding the Overarching Goal, while MCI agrees with the goal of seeking an overall Strategic Plan, MCI asks that the Council emphasize results over process. The government 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. These results can come in the form of heightened surveillance of health outcomes, which is really beyond the point at which the public seeks an understanding of food safety, as well as increase scrutiny of the food itself, before it is consumed. Results that demonstrate whether food is contaminated and if so the level of contamination are important in terms of reducing public health outcomes we seek to avoid. If the Council is serious about



reducing the figures that end up in the surveillance column tally sheets, the most effective way to do so is to identify the contaminated food before it is consumed.

### **Science and Risk Assessment Goal**

**The United States' food safety system is based on sound science and risk assessment.**

MCI wholeheartedly supports the science-based foundation on which the government is continuing to develop the current food safety system. MCI provides the following comments with regard the specified objectives and action items.

#### **Objective 4: Identify emerging and potential high-risk food safety threats.**

MCI commends the Council for identifying this objective. We urge the Council to revise the Objective 4 to read:

*"Identify and quantify existing, emerging, and potential high risk food safety threats."*

As written, and with the limited action items set forth under this Objective, the Council appears to be overlooking the need to stay on top of *existing* food safety threats. It may seem that the insertion of the word "existing" is more appropriate in the realm of risk management, rather than risk assessment – the category or goal under which this objective is listed -- however, none of the action items under the risk management goal address the implementation of new or enhanced technologies or identification systems for purposes of generating data to be used in risk assessments on existing food safety threats.

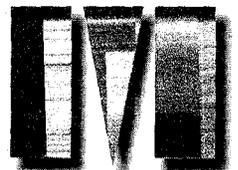


Although objective 2 under the risk assessment goal addresses the use of data in risk assessments, the data referred to is "surveys, surveillance and other tools and data from public and private sources to identify adverse health outcomes." Any complete risk assessment of food should not look only at health outcomes, but prevalence and quantity of pathogens in food as well.

The use of such pathogen monitoring data is mentioned under Objective 6, but this is in the context of examining "trends over time in foodborne illnesses, pathogens and chemicals," whereas it should be used also in the development of risk assessments. This need might be implicitly acknowledged under the third action item under Objective 4, which discusses new risk assessment methods for determining aggregate exposures and cumulative risks. Indeed, to complete such risk assessments, pathogen monitoring data would be needed, yet the collection of such data is not explicitly included as an action item under this Goal. MCI recommends the addition of the following action item under Objective 4 to ensure appropriate pathogen monitoring data is collected for purposes of risk assessments for existing high risk food safety threats:

*"Expand data collection capabilities for pathogens that employ enhanced identification and testing systems."*

Efforts to gather and review pathogen monitoring data can be enhanced through the development of improved data collection, storage, and retrieval mechanisms. MCI urges the Council to include this action item, which can work to build a pathogen database of information needed to support the risk assessment objectives subsequently listed in the Plan. The information generated would be from those very same enhanced identification, microbial evaluation methods, and rapid tests specifically mentioned as action items



under Objective 4. MCI also recommends the following action item to further Objective 4:

*“Develop enhanced and automated data and information storage and retrieval capabilities that allow for the rapid sharing of data to respond to food safety hazards.”*

Finally under Objective 4, MCI applauds the Council’s action item regarding the facilitation of the development of rapid tests for pathogenic microorganisms and chemical agents in food. MCI urges, however, that the Council more specifically identify the need for tests that meet the needs of those implementing food safety programs in the field – inspectors and regulated entities. Thus MCI recommends the following revision to this action item.

*“Develop new and existing analytical methods and technologies for detecting pathogenic microorganisms and chemical agents in food and clinical specimens that support the specific needs of the regulatory and inspection components of the food safety system.”*

**Objective 6: Evaluate research, risk assessment, and surveillance programs for their effectiveness in providing the scientific knowledge needed to develop and implement programs that assure maximum public health.**

Regarding Objective 6, MCI recommends that the wording of the objective itself be changed. The listing of “research, risk assessment, and surveillance programs” is limiting, to the extent that surveillance is undefined. Typically, surveillance in the food safety context pertains to review or monitoring of foodborne illnesses. By setting forth an exclusive list of programs on which to rely, regulators are limiting their resources. For example, also included in that list should be monitoring (pathogen) programs. Thus, either a fuller list of programs should be fleshed out, or those listed should be removed from Objective 6.



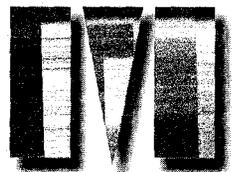
**Risk Management Goal**

MCI supports the Council's development of more focused objectives and action items to address the risk management segment of the Strategic Plan. There remain, however, some inconsistencies and gaps in this segment of the Plan as drafted.

**Objective 2: Promote development and implementation of preventive techniques and controls using risk-based approaches and establishment of national standards, including performance standards, where appropriate.**

Regarding Objective 2, MCI is concerned that the Council is exhibiting a clear preference for performance standards over all other regulatory mechanisms. It is not clear why the phrase "including performance standards" is listed. Certainly they would be included, but if listed, should the Council not also list voluntary standards, mandatory standards, and any other form of national standard? By stating this form of standard specifically, the Council intimates this is the preferred form of standard. This form of standard, however, should not be preferentially selected or applied to a given situation until the specific threat being addressed is identified and the stakeholders involved can gain a complete understanding of how that threat should be addressed. MCI fears that the Council is leaning too far to automatic acceptance of performance standards, when in fact such standards may not be appropriate for a given, future and unknown threat. MCI recommends deleting the phrase "including performance standards."

Pathogen detection testing is a critical link in the farm-to-table chain that comprises the Agency's comprehensive Strategic Plan. And it is critical not just for domestically produced foods, but imported foods as well. More and more food is coming from outside the United States, and the safety of this food is less certain than that which is produced,

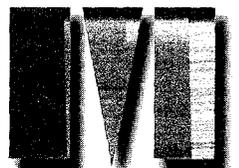


tested, and inspected in the United States. Performance-based standards in food safety are part of a fundamental shift in regulatory philosophy and strategy that have taken hold for some segments of the federal food safety system. Having such standards in place is a good start. Developing improved and sophisticated technology to implement the standards should be the next important step for those agencies to espouse, and a first important step for agencies without such standards.

Regarding the first action item under Objective 2 – “facilitate industry adoption of preventive controls, as appropriate based on risk, throughout the farm-to-table continuum” -- MCI suggests the following insertion: “Facilitate industry adoption of preventive controls *and diagnostic procedures . . . .*” Diagnosing, or identifying, the need for preventive controls is a necessary pre-cursor to the controls themselves. Indeed, this is especially true when the preventive controls are not necessary continuously but are to be implemented in response to the identification of a temporary upset condition.

Finally regarding Objective 2, MCI believes that the objective does not address a critical but unmentioned component of the risk management goal – data management (on information technology and data storage and retrieval systems) for regulatory purposes. There is no doubt that data management is a critical component of the food safety infrastructure and thus must be mentioned. In support of regulations that already require inspection of foods, MCI recommends that the Council include as an action item in support of Objective 2 the following:

*“Develop and improve data generation, storage, and retrieval mechanisms related to food safety [compliance].”*



**Objective 3: Expand and enhance effective monitoring, surveys, inspections and surveillance of foodborne illness and other health effects resulting from food safety hazards.**

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MCI believes that Objective 3 suffers from a lack of both specificity and focus on prevention. First, as in other instances in the Strategic Plan, it is not clear how the Council is defining surveillance – whether it is referring solely to foodborne illness, or to general surveillance of food processing and its attendant elements. The Council should clarify its use of the term. Second, as drafted, the Objective would seek effective monitoring of illness, surveys of illness, inspections of illness, and surveillance of illness. The Council can cure this drafting oversight by specifying “monitoring of microorganisms in food, surveys of food safety prevention and operating practices, inspections of food processing, and surveillance of foodborne illness.” If the Council believes each action word in the phrase is self-explanatory in terms of its associated activity, than simply changing the Objective to read “effective monitoring, surveys, *and* inspections, and surveillance of foodborne illness . . .” could suffice. Simply put, as drafted Objective 3 focuses on health outcomes and not prevention – and prevention is integral to risk management.

A third oversight related to Objective 3 and its associated action items is that it is not forward looking. For example, the efforts undertaken per this Objective will work to identify existing food safety threats. MCI believes the items under this Objective are best served by altering its first action item. That action items, which reads “Monitor hazards and prevention practices” should read “Monitor *for the presence of defined hazards and future threats to the food supply; monitor employed* prevention practices.”

MCI recommends the addition of an action item under Objective 3 that is needed to prompt and ensure the development of improved inspection procedures and practices. Advances in technology will no doubt in short order facilitate inspections and improve

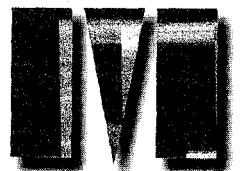


inspectors' ability to detect problems. Thus, MCI recommends that the Council incorporate an action item that allows for and indeed acknowledges such potential advances:

*"Improve inspection procedures and practices through increased knowledge, experience, and the use of advanced technology as it develops and is proven."*

**Objective 7: Promote the development and transfer of new technologies and approaches to risk management directed at improving food safety.**

MCI points out that none of the action items associated with Objective 7 address technology advances in the area of pathogen detection. Pathogen detection is integral to risk management, and the technology and science supporting new and improved pathogen detection mechanisms and devices demand the attention of the Council and regulatory agencies. Such science and technology should be put to use for risk management, and the Plan should explicitly allow for this by including references in the action items to pathogen detection systems that serve to reduce food safety risks by identifying for removal from the food production cycle foods contaminated with microbes at unacceptable levels.



### **Risk Communication Goal**

Under the Plan's third goal, which addresses risk communication, MCI's comments are regarding Objective 3.

#### **Objective 3: Provide rapid access to information about food safety surveillance, hazards, outbreak actions, enforcement and other food safety emergency activities through active outreach efforts.**

In what many refer to as the "information age," it is short-sighted not to imagine the variable uses of information and the inevitable request for more data, or more information, by regulators for governmental purposes, and by regulators at the behest of consumers. It is not a far reach to envision the availability of information not just about food safety emergencies, but about food processing from farm to table, and by that MCI means "good news." Consumers more and more are seeking information about which products are best or safest. MCI believes consumers will be willing to make that decision for themselves (not rely on some governmental standard or edict), and that they will want information regarding, for example, the safety of their foods, or at least of the companies producing their foods. While the database MCI foresees may not be driven by regulatory edict, it would nonetheless be a component of our U.S. food safety system and as such a placeholder for such information should be allowed for in the Plan. MCI believes that in the future food consumers will seek not just information about food safety emergencies, but confirmatory information about the food they are buying, a tracking sheet if you will. The Council's Plan should acknowledge a future need for information not just about emergencies (the existence of risk), but also about safe food. Risk communication is not solely about the communication of unacceptable risks, but also acceptable or even non-existent risks.



MCI believes that as food safety system regulatory schemes develop further, much of the ability of food production entities and inspection personnel to make the necessary demonstrations to prove the safety of food will be a function of there being not only accurate and sensitive detection technology and methods, but simple and easy access to data that makes these demonstrations. Thus, MCI recommends that the Council more definitively establish within the objectives and action items associated with the risk communication goal the development and incorporation of an information management system, at the facility level even, that allows for quick inspection of compliance with performance-based and risk-based food safety standards and ultimate verification of food safety. Simplification of food safety surveillance activities at the facility level, for example, should help the Agency maintain much more comprehensive data on a variety of food safety activities. This information is critical to developing scientifically defensible risk assessments and risk management strategies and to monitoring implementation and success of these strategies. Specifically, the Plan should contain as an objective the promotion of opportunities and technologies that facilitate the storage and retrieval of compliance information and records. These technologies exist in the food safety arena. The easier it is to access such information, the easier and more quickly responsible parties and officials can respond at critical times, at critical junctures, and with appropriate resources. To clarify, the objective of such an action item is not outreach to alert the public, but the development of information pathways that will facilitate any schemes, regulatory or otherwise, that might be developed to gather information before an emergency occurs.

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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 issue *is* significant enough to be included explicitly in the Strategic Plan. The farm-to-table approach dictates that testing should be used to validate the entire production system, and this in turn calls for a stronger, more consistent regulatory stance regarding testing standards and types of testing and equipment. Moreover, explicitly noting the significance and importance of pathogen testing in the Strategic Plan is appropriate for a world leader in the food safety arena. The food production industry is now global. The United States should be setting the pace regarding the establishment of a standardized approach to method certification and validation. More stringent country regulatory guidelines are being established, and the United States should clearly state it is leading the way to ensure the appropriate methods are accepted around the world.

MCI also recommends that the Council 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.

In summary, MCI commends the Council for the steps it has taken to date to improve the nation's food safety system. This iteration of the Strategic Plan provides an overarching view of food safety and better focus. While MCI agrees with the overall approach of the Strategic Plan, it appears to be focused principally on existing risks and still needs to address future threats and the significant advantages that technology, particular pathogen detection technology, can provide in the development of a safer food supply.

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Thank you for the opportunity to provide comments on the draft Strategic Plan. If you have any questions, please call me at (610) 313-9900.



February 11, 2000

Page 16

Sincerely,

Handwritten signature of H. Lotman in cursive script.

Herbert Lotman <sup>EDS</sup>

Chairman and CEO

Molecular Circuitry, Inc.