Direct-reading and Rapid-test Methods Used to Evaluate Food Safety Controls in Maryland High-priority Firms

D’Ann L. Williams, DrPH, MS, LEHS
Chief, Center for Food Emergency Response and Defense
Maryland Department of Health
International Food Protection Training Institute (IFPTI)
Fellowship in Food Protection

Author Note
D’Ann L. Williams, Chief
Maryland Department of Health, Office of Food Protection
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Correspondence concerning this article should be addressed to:
D’Ann L. Williams, DrPH, MS, LEHS
Maryland Department of Health, Office of Food Protection,
6 St. Paul St., Suite 1301, Baltimore, MD 21202
dann.williams@maryland.gov

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Abstract

This article describes the results of a survey that was developed at the Maryland Department of Health Office of Food of Protection (MDHOFP) and administered to food safety professionals at Maryland high-priority food manufacturing firms. The survey focuses on the use of direct-reading and rapid-test methods (DRI/RT) for monitoring good manufacturing practices (GMPs), sanitary standard operation procedures (sSOPs) and/or preventive controls (PC). Of the 17 firms surveyed, 14 identify that they are subject to the FSMA Preventive Controls Rule, 15 have at least one preventive controls qualified individual (PCQI), 14 have a Food Safety Plan, 12 have corrective action plans and 12 reported using DRI/RT within their firms. Of particular note is that only three of the PCQIs were aware of the limitations of the instrumentation they employed to assess the food safety environment in their firms. Review of the manuals of the instruments that were reported to be used by the firms revealed that only one of six manufacturer manuals mentions a limitation of the method when subject to sanitizer solutions, conditions often occurring in food manufacturing firms and as part of a corrective action plan. One other instrument manual reports limitations associated with electromagnetic interference. This research provides valuable information for food regulators to evaluate the use of DRI/RT instruments and opportunities to educate and reduce potential food safety risks during corrective action procedures in food manufacturing firms that employ these technologies.

Keywords: ATP, direct-reading instruments, rapid-test methods, preventive controls, GMPs, sSOPs, food manufacturing, corrective actions, allergens, contaminants, sanitizer, food production, food safety, instrument limitations
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**Background**

The Food Safety Modernization Act requires food firms to identify and reduce food safety hazards via the Preventive Controls Rule (Taylor, 2011). Many firms use direct-reading instruments and rapid test methods (DRI/RT) for hazard monitoring and good manufacturing practices (GMPs) verification.

Direct-reading instruments, such as monitors that measure adenosine triphosphate (ATP), a component of all living cells, have been used for over 20 years for the validation of sanitary conditions in the food industry (Velazquez & Feirtag, 1997). Multiple DRI/RT instruments are commercially available to evaluate environmental sanitation and allergen control measurements. These instruments are produced by companies such as 3M™, BioControl, Charm Sciences, Hygiena, Kikkoman and Neogen. Publicly available research was reviewed that describes the use of these instruments, generally in the dairy, meat, and brewing industries (Sala, Decun, Morar, & Morvay, 2009; Osimani, Garofalo, Clementi, Tavoletti, & Aquilanti, 2014). However, exactly how these instruments are currently being used by the food manufacturing industry in Maryland high-priority firms is unclear.

ATP monitors employ the oxidation reaction of luciferase with ATP to produce photons of light that are then read and reported as relative light units (RLU) by a luminometer, a light detector. Surfaces within a facility are swabbed, an enzyme is added to the swab and then the swab is placed into the instrument that reports a numeric RLU reading or a text and/or colorimetric judgement indicator (e.g., green, good; yellow,
caution; red, fail). The detection of ATP on a surface indicates the presence of living cells or organisms. High RLU measurements are interpreted as an indicator of an unclean surface or a surface with living cells present. ATP monitors are also used as a rapid test method indicating the presence of proteins for general allergen detection.

While the instruments are used to verify GMPs, sSOPs and other hazard control measures in food manufacturing firms, there are limitations to the method and practices and/or conditions within food manufacturing firms that can influence the measurements reported by these instruments (Velazquez & Feirtag, 1997; Green, Russell, & Fletcher, 1999; Bakke & Suzuki, 2018). If these limitations are not understood by the operator, the measurements can be “quenched or enhanced” giving false negative or false positive readings. The use of erroneous readings to make production decisions may have unintended food safety consequences.

The Maryland Department of Health Office of Food Protection (MDHOFP) Center for Food Processing regulates 482 high-priority food (HPF) manufacturing firms. High-priority firms are determined by their use of food products or processes that may increase the potential for food safety issues related to bacterial, chemical or physical contamination. The number of Maryland high-priority facilities employing DRI/RT instruments is currently unknown and a questionnaire was designed to explore the use of these instruments.

**Problem Statement**

The extent of the use of DRI/RT instruments by manufacturing firms in Maryland is largely unknown by the Maryland Department of Health.
Research Questions

This research project employed a survey questionnaire to evaluate the use of DRI/RT to monitor food safety, sanitation or allergen control programs in high-priority facilities in Maryland.

1. What DRI methodologies are currently being used in Maryland high-priority firms?
2. For what purposes are high-priority firms employing these instruments?
3. What training methods are used by firms for personnel using their specific equipment?
4. Are firms aware of the methodological limitations that are associated with these instruments?

Methodology

The survey was developed based on questions that MDHOFP regulators had discussed pertaining to the use and validity of DRI/RT methods. The survey language was refined by reviewing peer-reviewed journal articles and other industry articles that discuss the use of DRI in the food industry. The survey was tested in house by MDHOFP regulators and selected industry partners. There are no other surveys of this type for comparison, so there is a need for future studies to assess the reliability of this methodology.

The survey consisted of yes/no, and open-ended questions to investigate the use of rapid testing methods within firms designated as high-priority by the MDHOFP. The survey included questions about firm size, production methods, food products, type of DRI/RT used, training procedures, how these instruments are used to verify firm sanitary
protocols and understanding of the instrument limitations (Figure 1.). The survey was administered by this author via telephone interview with the designated Quality Assurance/Food Safety representative for the firm. Data was entered into an Excel spreadsheet and was reported using descriptive statistics.

**Results**

Fifty firms listed as high-priority in the Maryland Food Inspection database were contacted via email invitation to participate in the DRI survey questionnaire that was developed for this research. All 50 firms also had at least one follow-up phone call if there was no response to the email. Of the 20 firms that responded, two firms refused to participate, five firms reported that they did not use DRI/RT (Table 1a.) and 13 firms reported using DRI/RT (Table 1b and Figure 1). One DRI/RT facility was dropped due to the inability to complete Section 2 and 3 of the survey. Twelve DRI/RT firms were included in the final DRI/RT analysis.

*Figure 1. Recruitment, Participation, and Survey Section Content*

Eighteen Maryland HPFs were surveyed. Of the 17 firms included in the analysis, 14 reported having a food safety plan and 15 reported having a PCQI on site. Twelve
firms reported using an instrument that measures ATP, nine firms reported using a rapid test for allergen detection and two reported using a microbial rapid test. Of those firms using DRI/RT, all reported having training programs that address the use of DRI/RT in the firm. Training programs consisted of internal training with no evaluation of user understanding, to program assessment with practical and written tests, and direct observation of performance. Third party yearly instruction provided by instrument manufacturing technical support or other food safety programs was reported by four firms. One firm reported using DRI/RT for GMPs and one for PC only. Ten firms reported using DRI/RT for both GMPs and PC.

When asked about conducting positive and negative controls, blank or duplicate analysis, four firms reported that they conducted these quality assurance checks. Yearly calibration of instruments was reported by eight firms. Only three PCQI interviewed reported being aware of the limitations of the ATP technology. Results from the survey are presented in Table 1.

Table 1

Results of Survey Criteria for HPF

<table>
<thead>
<tr>
<th>1a. Survey Criteria Those Who Do Not Use DRI/RT</th>
<th>%* Firms (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject to Process PC</td>
<td>40</td>
</tr>
<tr>
<td>Subject to Sanitation PC</td>
<td>40</td>
</tr>
<tr>
<td>Subject to Supply-Chain PC</td>
<td>40</td>
</tr>
<tr>
<td>Subject to Allergen PC</td>
<td>40</td>
</tr>
<tr>
<td>PCQI In-House</td>
<td>60</td>
</tr>
<tr>
<td>Food Safety Plan in Place</td>
<td>60</td>
</tr>
<tr>
<td>Corrective Action Plans in Place</td>
<td>60</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1b. Survey Criteria Those Who Use DRI/RT</th>
<th>%* Firms (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject to Process PC</td>
<td>92</td>
</tr>
</tbody>
</table>

Section 1. General Business Characteristics
During this research, manuals for the instruments used by the firms were reviewed to determine if the limitations of the methods were discussed within the document. Of the six instrument manuals reviewed, only one discussed limitations of the method due to potential interference with sanitizing chemicals. One other manual discussed potential electromagnetic interference associated with instrument use around specific electronic equipment used in food processing facilities. Phone discussion about instruments/method limitations with technical experts from the instrument manufacturing firms revealed that they discuss the need for each firm to evaluate the use of the instrument for their own particular use and within their firms.
Of the 17 Maryland firms surveyed, all but three firms reported having a food safety plan and corrective action plans. DRI/RT instrument values that triggered corrective actions were non-uniform, based on specific process requirements, instrument reporting methodology, facility/product baselines and 3rd party requirements, acceptable numeric values ranged from zero to 10,000 RLU. Seven of the firms are also audited or certified by external food safety program entities. Larger firms, as assessed by production volume, indicated a clear understanding of FSMA and the requirements and the policies and procedures within their firms. Smaller firms expressed uncertainty of FSMA requirements or how those requirements might affect their operations.

**Conclusions**

This research was used to explore the usage of DRI/RT instruments in HPFs in Maryland. The DRI/RT instruments were used for monitoring GMPs, sSOPs and PC verification. The thresholds chosen by firms for triggering corrective actions were different based on the instrument used, specific acceptable levels within the food product and 3rd party audit requirements.

All firms using DRI/RT reported conducting in-house training by a PCQI. Four firms have a yearly 3rd party auditor or instrument manufacturer training event. Effectiveness of training programs was assessed by various methods, pre-post quizzes, field tests as well as direct observation indicating no standardization of training methodologies or assessment.

When PCQI personnel were questioned about their interactions with the manufacturer manuals and technical support of these DRI/RT technologies, firm PCQIs suggested that the limitations related to the use of these technologies for verification or
validation of sanitary conditions are not adequately explained. These limitations were discussed with the firms at the time of the interview.

When discussing the limitations of the DRI/RT methods, 75% of firms were not aware of the limitations of the instruments that they were using. Due to the lack of understanding about the limitations of DRI/RT, a concern is raised about the reliance on these instruments as a method for hazard control or PC verification. The misinterpretation or improper use of these technologies to designate a “clean or safe” environment for food production, especially if used to verify PCs, could adversely impact the actual safety of the food produced by these industries and impact public health.

**Recommendations**

Maryland regulators should gain a better understanding of the type of DRI/RT used by Maryland food manufacturing firms to monitor and verify sSOPs, GMPs and PCs. A more comprehensive understanding of the DRI/RT technologies as they apply to hazard controls and how they are used in Maryland firms can provide information and encourage open discussion about the limitations of these methods with firm food safety personnel.

The following recommendations are based on discussions with members of the MDHOFP and Maryland firm food safety individuals that were interviewed.

1. During field inspections, food safety regulators should include a discussion of the use of these methods and the limitations of the instruments during document and procedural review of sSOPs and HACCP controls, as well as for the PC Inspection.

2. Instrument manufacturing firms should be encouraged by food safety regulators to provide guidance for training and use of their instruments including discussion of
the instrument/method limitation in the user manual that is provided with the purchase of the instrument.

3. Instrument manufacturing firms should provide training and technical support for purchasers to evaluate the use of their instruments in the firm and identify inappropriate use or misinterpretation of results.

4. The questionnaire used in this study should be used by other regulatory agencies to evaluate the use of direct reading instruments and user understanding adding to the body of knowledge.

5. Further research is critically needed to assess firm understanding as well as inspector and regulator understanding of the use of DRI/RT in food production firms.

**Acknowledgments**

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