November 15, 2013

Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: FDA Desk Officer

Re: Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food (Docket No. FDA–2011–N–0920; RIN 0910–AG36) – GMA Comments on PRA Information Collection Burden

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) in the Food and Drug Administration’s (FDA’s) proposed rule regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (78 Fed. Reg. 3646 (Jan. 16, 2013)).

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation's economy.

GMA appreciates the considerable resources FDA has dedicated to developing a proposed rule to implement the preventive controls provisions of the Food Safety Modernization Act (FSMA). The PRA requirements are an important element of the rulemaking process, and serve to ensure that required records are useful, practical, and no more burdensome than necessary to achieve their intended purpose. GMA has significant concerns about the accuracy of FDA’s estimate of the recordkeeping burden of the proposed information collection, including the validity of the methodology and assumptions used. As these comments explain, our members’ experience shows that the PRA assessment appears to substantially underestimate the recordkeeping burden.
of the proposed rule. We urge the Office of Management and Budget (OMB) to submit comments to FDA regarding this issue and to ask the Agency to revise and justify its information collection burden estimates.

Of note, the PRA assessment for this proposed rule does not explain the basis for the estimates provided, including the scope of the activities considered as part of the estimates and the reasoning behind the Agency’s conclusions. Without this information, it is not possible to adequately assess the accuracy of the recordkeeping burden estimates. Equally important, information collection needs will depend substantially on the form and approach of the final rule, which is difficult to assess at this early stage. It is clear, however, based on consideration of current industry practices that the PRA assessment appears to significantly underestimate the burden of this information collection.

In our comments below, we address each of the six issues identified by FDA as triggering an information collection recordkeeping burden. Our comments are based on our members’ current experiences with Hazard Analysis and Critical Control Points (HACCP) programs. Although there are material differences between HACCP and preventive controls under FSMA as proposed by FDA, we expect that our current experience will be a useful guide in assessing the burdens because FDA’s preliminary regulatory impact analysis generally assumes that companies operating under voluntary HACCP programs will already comply with the proposed rule without need for additional recordkeeping.

1. Food Safety Plan

The PRA assessment estimates that creation of a single food safety plan will require 110 hours and that one plan will be required per facility, but the assessment provides no explanation of the basis for this estimate. In our members’ experience, it takes considerably longer to develop a HACCP plan and under FDA’s proposed framework, food safety plans would be broader than HACCP plans. Our members reported a range of quantitative estimates, with a median of over 200 hours per facility. We understand that the estimate was based on a company that is starting from scratch, with no existing procedures. In our experience it can take over 200 hours to initially develop a HACCP plan, even for a small plant with low complexity. This assumes reliance on existing corporate procedures for prerequisite programs and recall plans. It can take considerably longer to develop a plan for new products and facilities, depending on product and process characteristics.

Additionally, many of our members’ plants currently have more than one HACCP plan in place. Large plants have multiple products, raw materials, processes, and equipment. One member

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1 To facilitate preparation of these comments, GMA conducted an informal survey of seven member companies that operate both large and small facilities that produce a wide range of foods, including finished products and ingredients.

2 We also question the assessment’s estimate of the number of facilities that will be subject to new or increased recordkeeping obligations as a result of the proposed rule. The estimates are from a baseline of current industry practices that assumes most large companies are already in compliance with the proposed rule’s requirements. As will be explained further in our future comments on the proposed rule and FDA’s Preliminary Regulatory Impact Analysis, we are concerned with a conclusion that this proposed rule will not impose considerable additional costs on our members.
reported that one large plant has 34 plans in place that took approximately 860 hours to develop and another large plant has 25 plans in place that took approximately 1385 hours to develop.

The assessment appears not to take into consideration the time requirements for large facilities with complex food safety plans, nor for individual facilities with multiple food safety plans. Although facilities with a large number of food safety plans may take less time per plan on average, the total time for the facility far exceeds the time estimate stated in the Federal Register notice.

It also is not clear if the assessment includes the considerable pre-work time that is required as an input to development of a HACCP plan. Pre-work includes activities such as employee training, assembling the food safety plan team (which may require outside experts, and specific company experts like microbiologists, procurement, research and development, etc.), creating the processing and product profile, and creating a flow diagram. Some members estimated that approximately 150-300 hours of pre-work are needed per facility before the actual HACCP plan is prepared.

Furthermore, a robust food safety plan is developed by a multidisciplinary group of professionals with a broad skill set. It is unclear what wage rate FDA used in its estimate of the operating and maintenance costs associated with implementing and maintaining a food safety plan or if those estimates consider the range of wages applicable to the broad team involved in plan development.

2. Monitoring Records

The assessment estimates that facilities will keep records of 730 monitoring activities and that each record can be made in about three minutes (36.5 hours total per year per facility), which severely underestimates both the number of activities and the time required based upon our member’s current practices. We note that it is premature to comment on the accuracy of the estimate that only 16,668 facilities will need to keep additional records of monitoring. Further analysis of the substance of FDA’s proposed rule will be necessary to understand whether it imposes new monitoring requirements on companies that currently implement voluntary HACCP programs and the extent of those requirements (e.g., which controls require monitoring and the rigor and frequency of that monitoring).

The assessment appears to severely underestimate the number of monitoring records generated by food companies. Several of our members reported over 50,000 monitoring events in their facilities annually. For example, if one line has two metal detectors and one barcode scanner, there would be three records per shift, with three shifts per day. Assuming 300 days of operation per year, this one line would have 2700 records per year. Most plants have multiple lines and conduct monitoring beyond metal detectors and bar code scanners. A large plant may have well over 730 monitoring events per day – not per year as FDA estimates.

Again, it is unclear what activities are included in the time estimate. The amount of time required to produce a record will vary depending on whether the estimate only includes documenting time to create the record or also includes the underlying task of monitoring and follow-up tasks like filing. Furthermore, the number of monitoring events could be significantly
higher than the estimate if all preventive controls are subject to similar monitoring requirements as critical control points. Thus, although some tasks may take only three minutes to monitor, our members suggest that six minutes per monitoring event may be a more accurate estimate of the information collection burden.

3. Corrective Action Records

The estimated burden for corrective action records assumes that 18,291 facilities subject to preventive controls will have two corrective actions to document, which will take one hour each to record. The assessment does not explain the basis for estimating that only 18,291 facilities will engage in corrective actions. Because occasional deviations from expected values are an unavoidable part of any manufacturing environment, it should be expected that all facilities subject to preventive controls regulations will have corrective actions to document annually. Any auditing organization could substantiate this fact. Thus this burden estimate should apply to all facilities, not just a subset of facilities.

Our members report that their facilities typically engage in between 10 and 60 corrective actions per year for critical control point deviations, which is considerably higher than the proposed estimate of two actions per year. The time estimate also appears to be low. Although it may take only one hour to manage the record involved with the corrective action, additional time would be required to investigate the underlying issue and implement the corrective action. We expect it can take between two and four hours to investigate a single corrective action and come up with a solution. Of course, the time required to implement appropriate corrective actions, to track the status of each corrective action until completion, to verify effectiveness over time, and to record the required information will vary depending on the nature and complexity of the corrective action.

4. Verification Records

The estimate for keeping verification records assumes facilities will keep records of 244 verification events and that each record can be made in about three minutes (12.2 hours total per year per facility). The assessment does not explain whether this estimate considers the broad scope of activities included in the definition of “verification” in the proposed rule (proposed 21 CFR § 117.150), but it should. The proposed regulatory definition of verification not only includes verification of monitoring, corrective actions, and implementation and effectiveness (e.g., calibration), but also includes validation and reanalysis. Validation and reanalysis of a food safety plan are extensive activities that take tens, if not hundreds, of hours to conduct. The estimate does not appear to account for these activities. Furthermore, depending on the scope of the final rule, FDA’s proposed activity of records review also may impose a time and information collection burden on companies that does not appear to have been taken into account.

Even considering just the traditional activities considered as verification under HACCP, our members’ experience shows that the current verification estimate is too low. We received a wide

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3 The time required for a corrective action depends on the nature of the underlying deviation that needs correcting. If the definition of corrective action under the proposed rule is broader than the current use of the term, such as if it includes all corrections made in the facility, the time burden would increase.
range of estimates of the number of verification events conducted annually—from about 200 to over 14,000 events per year. Facilities have many different ways of engaging in verification, based on their unique circumstances, and there is no easily developed one-size-fits-all burden estimate. Similarly, our members report that it takes them between eight minutes and two hours per verification event. It is unclear whether the estimate includes only the time to handle the record or also the time to conduct the verification. This missing information in the estimate may explain the range of responses in our survey. The time to conduct the verification should be included.

5. Qualified Individual Training Records

FDA estimates that 47,484 food manufacturers will need to document the training of their qualified individual, which will take 15 minutes per facility. It is unclear why the Agency’s estimate is limited to only 47,484 food manufacturers, as all registered facilities subject to preventive controls would be required to have a qualified individual and to document that person’s training. Our members found that FDA is more accurate in this assumption, although documentation may take 30 minutes in some situations. In addition, many facilities may need to document more than one qualified individual. For example, the thermal process authority outside of the plant may be a qualified individual in terms of confirming the process has a validated kill step. In addition, the same facility will likely have a qualified individual responsible for approving the food safety plan. This situation would obviously increase the time burden beyond the Agency’s estimate.

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Finally, we note that these estimates only address the Paperwork Reduction Act issues in the proposed rule. FDA has requested comment on several potential regulatory requirements that would result in major additional information collection burdens on industry, such as mandatory food facility profiles, supplier verification, and testing. These important provisions were discussed, but not proposed. Depending on the approach FDA takes on these key issues, among others, in the final rule, the associated recordkeeping burden may be significantly higher. Separately from these comments on the information collection, GMA is preparing comprehensive comments addressing all aspects of the rulemaking, including these other activities that would trigger the additional recordkeeping burdens.\(^4\)

In conclusion, our members’ experience shows that FDA’s recordkeeping burden estimate significantly underestimates the time (and corresponding expense) imposed by the preventive controls proposed rule. We urge OMB to take a close look at the PRA analysis in the proposal.

\(^4\) Our separate comments are being submitted to Docket No. FDA–2011–N–0920 on November 15, 2013.
and to file its own comments with the Agency regarding the accuracy of these estimates. We ask that the information collection estimates be revised to more precisely and accurately reflect the actual conditions anticipated in the proposed rule before receiving OMB approval.

If we can provide further information that would assist you in assessing this issue, do not hesitate to contact me.

Sincerely,

Leon Bruner, DVM, Ph.D
Senior Vice President Scientific and Regulatory Affairs & Chief Science Officer

cc: FDA Division of Dockets Management