

1. What is the purpose of the proposal/amendment?

The proposed action would amend the hazelnut marketing order (Marketing Order No. 982) (order) by creating a new § 982.45(c), Quality Control, that would authorize the Board, with the approval of the Secretary, to establish minimum quality requirements for hazelnuts handled under the order. Under such authority, regulations could be established to help ensure the high product quality of hazelnuts handled under the order through the mandatory treatment of hazelnuts by processes that have been proven to reduce the level of foodborne pathogens (salmonella, listeria, and E. coli) in tree nuts.

The proposed amendment would also authorize establishing different quality control regulations for different markets. This would give the Board the flexibility to adapt regulations, as needed, to be more responsive to variations in the diverse markets for Northwest hazelnuts. Hazelnuts produced in the production area are marketed both domestically and internationally, and in both inshell and kernel forms to each of those outlets. Also, in addition to the nuts being consumed as a distinct commodity or in a mix with other nuts, hazelnuts may be marketed to manufacturers, who further process the nuts in conjunction with other products before consumption. Allowing the regulations to be adapted to specific market outlets could increase regulatory efficiency and minimize the overall regulatory impact on handlers.

Should quality control authority be established for the order, the hazelnut industry envisions implementing regulations similar to the mandatory treatment provisions specified within the almond marketing order that were implemented for that industry in 2007. Such provisions were established under the almond marketing order's quality control authority. The hazelnut industry believes that the mandatory treatment of almonds has been successful for the almond industry in managing its product quality challenges. In addition, quality control regulation is believed to have contributed to the industry's growth through greater assurance of product quality to consumers. The hazelnut industry further believes that quality control authority, along with the specific regulations that may be established under that authority, would benefit the industry by allowing it to better respond to the food quality and marketing challenges of the day.

Under the proposed quality control authority, the Board envisions the establishment of a Technical Review Committee (TRC) to coordinate the investigation and recommendation of kill step processes certified to reduce pathogen loads in outgoing hazelnut product. The almond industry has successfully utilized such a committee, calling it a Technical Expert Review Panel. Members of a TRC could bring much needed scientific expertise to the quality control regulatory process, and could be appointed by the Board, with the concurrence of USDA.

2. What problem is the proposal designed to address?

Under currently accepted hazelnut production practices, hazelnut producers harvest their crop by picking up nuts off the orchard floor after the nuts have fallen naturally from

the trees. Harvest methods employed by producers almost universally involve the nuts making contact with the soil. Salmonella, listeria, and E. coli pathogens are naturally present in the soil. Such pathogens, then, have the opportunity to transfer to harvested nuts under current harvesting processes. Most handlers have implemented procedures to reduce the potential pathogen load when they wash and dry the product prior to handling, but scientific research has shown these to have an inconsistent effect on pathogen reduction. In addition, many hazelnut handlers have implemented treatment processes to reduce contamination in finished merchantable product, but no industry-wide regulation exists to collectively address the potential hazard risk with proven technologies backed by scientific studies, and handlers employing such quality control steps are doing so voluntarily.

Tree nuts, including hazelnuts, have been implicated in a number of food safety incidents or recalls in recent years. There have been two hazelnut incidents. In 2009, FDA detected salmonella on equipment in an Oregon packing facility during a random inspection. Subsequent testing of product detected the pathogen on merchantable product stored in the facility. Certain lots of hazelnut kernels that had been shipped to customers were recalled out of caution. Thankfully, no illnesses were associated with the detection of the pathogen on merchantable product. Another food safety incident occurred in 2012, when a salmonella outbreak occurred in Canada with inshell hazelnuts that originated in Oregon. The outbreak caused several illnesses and a broad recall, however the origin of the pathogen was not determined.

Food safety incidents like what the hazelnut industry has experienced led Congress to enact the Food Safety Modernization Act (FSMA). Implementation of FSMA has led FDA to research and quantify the food safety risk assessment for all tree nuts, including hazelnuts. While not fully completed at this time, the hazelnut industry expects that the FDA risk assessment will result in nut industries being required to manage food safety risks by treatment processes found to achieve some level of reduction in pathogen load prior to final shipment of product. To date, the only method expected to be validated by FDA to reduce the pathogen load in hazelnuts is via a post-harvest treatment process applied by the handler prior to shipment of product to customers.

Currently, there is no authority within the hazelnut marketing order to regulate the minimum quality of hazelnuts handled. As such, there is no ability to require the treatment of hazelnuts to reduce pathogen load prior to outgoing shipment. The Northwest hazelnut industry believes that all product sold to customers, except product that will be subject to further processing prior to its distribution and consumption or product that will be exported, should be treated by a process proven to achieve a specified log reduction of salmonella, E.coli, and listeria pathogens on the surface of both inshell hazelnuts and hazelnut kernels (including whole kernels and kernel products).

The Board believes that requiring an approved treatment process under the marketing order would help eliminate food safety incidents for hazelnuts that could result in public health issues. Food safety issues often result in long-term negative economic impacts.

The direct economic impact of past food safety incidents have been the cost of recalling the affected product, transportation charges to ship all suspect product in the handler's inventory out of the production area for PPO treatment, lost production time from the plant while it was closed for sanitizing and FDA recertification to open, and lost sales over the bad press. Handlers affected by the discovery of pathogens on their product have not disclosed the level of their expenses related to those incidents, but the dollar amount is estimated to be in the hundreds of thousands. The indirect costs of a food safety incident are much harder to quantify. Lost customers, reduction in market share, and changes in consumer preference would be incredibly hard to quantify, but industry members consider the cost to be substantial.

While hazelnuts produced in Oregon and Washington are shipped to many markets throughout the world, the proposed amendment is primarily intentioned to regulate hazelnuts shipped to North America. Almost all inshell hazelnuts and a smaller percentage of kernels, shipped to the domestic market (including Canada) are destined for retail sales in a raw form. The majority of these hazelnuts are already treated to reduce the pathogen load by handlers on a voluntary basis. In addition, the hazelnut industry's food safety committee has provided handlers with sample documents to use when untreated product is shipped domestically to a receiver who will subject such product to further treatment or manufacturing prior to consumption. However, there could be instances where potential buyers of untreated product, who have no plan for further treatment or manufacturing, have pressured handlers to sell product without attesting to a treatment step. Mandatory regulation of domestic shipments would resolve that issue.

Buyers of product shipped to export destinations may have different food safety requirements or may further manufacture or treat the product with kill-step processes such as roasting, baking, or pasteurizing, so mandatory treatment of such hazelnuts may not be necessary. However, should a buyer of export product request that the hazelnuts be treated before leaving the US, assuredly a handler could voluntarily accommodate that request, even if the product was not covered by marketing order regulations. With the ability to differentiate between markets in the application of regulation, the Board would be able to recommend the most appropriate and efficient requirements to effectuate the intent of this proposal without creating an additional, unnecessary burden on handlers.

3. What are the current requirements or industry practices relative to the proposal?

Northwest hazelnut handlers are not currently subject to any mandatory quality control requirements under the order or any other regulation. Handlers are only subject to size and grade requirements. In addition, all product handled under the order must be inspected. In light of the recent food safety events in the hazelnut industry, and the general consumer movement prioritizing safe food, the hazelnut industry does not believe that the current order provisions are sufficient to address the industry's concerns with regard to product quality.

The Northwest hazelnut industry's Food Safety Steering Committee (FSSC), an industry wide committee formed in conjunction with the Board (but not a Board subcommittee), has issued recommendations to the industry with regards to the treatment of hazelnuts to reduce foodborne pathogens. The FSSC continues to research best practices for the industry and intends to issue findings as soon as substantiated. Many handlers, in response to food safety concerns, are voluntarily treating their hazelnuts prior to shipment to North American destinations and/or are requiring customers to provide documentation attesting that the product will be subject to a treatment step within their own manufacturing process. Such handlers have employed various treatments intended to achieve the level of pathogen reduction recommended by the FSSC. However, as the treatment of outgoing product is not required by the order, there could be some handlers who have chosen not to respond to the perceived food safety risks present in hazelnuts and ship product without regard to the recommended eradication measures.

The FSSC has been instrumental in addressing the hazelnut industry's food quality challenges since its inception in 2010. Through that body, the industry is currently conducting a prevalence study to analyze the pathogen load present in field run hazelnuts to assist in the development of base load levels. The Committee is also actively seeking to identify specific processes that have been determined to effectuate a 5-log reduction in pathogen population (a "5-log reduction" means lowering the number of microorganisms by 100,000-fold). Such processes, often referred to as a "kill step", may include, but are not limited to, fumigation with propylene oxide gas (PPO), steam pasteurization, or heat treatment. Validation studies to determine the minimum time and temperature for effective heat or steam treatments, and the minimum dosage of PPO, are currently in process. While several different technologies have undergone successful testing by hazelnut handlers to date, only a steam pasteurizer has been validated by the Food and Drug Administration (FDA) as a kill step for hazelnuts. Some of the other processes are currently being employed by the hazelnut industry on a voluntarily basis. Requiring the entire industry to employ a kill step prior to the shipment of hazelnuts outside the production area (with the proviso that different regulations may be applied to different markets) would help ensure that only hazelnuts of the highest quality are released to the market.

4. What are the expected impacts on producers, handlers and consumers?

The proposed amendment is expected to have an overall positive economic impact. Under the order, only handlers are regulated, so only handlers would incur any increased direct costs that may be associated with regulations established under a new quality control authority. In addition, it is not expected that the cost of any regulation under the new authority would be passed on to producers in the form of lower producer prices. Rather, producers and handlers are expected to both benefit from the increased market stability that should result from assuring the market that only hazelnuts of high quality (i.e., reasonably free from food borne pathogens) are shipped from the

production area. In addition to the expected positive impacts relative to the amendment, it is expected that the domestic hazelnut market would be less susceptible to the negative impacts of a food safety issue.

The addition of quality regulation authority to the order, if mandatory treatment regulations are ultimately established under the authority for some or all hazelnut markets, would have a direct operational and financial impact on handlers, as they would be required to bear the cost of such treatment. If the treatment costs were to be passed along to buyers, as would be expected, this amendment could result in higher prices for end product consumers. However, any potential price increase would be mitigated by the fact that a percentage of hazelnut shipments are already being treated under current market conditions, and the cost of such treatment has already been incorporated into the market price. In addition, the industry believes that the potential savings from a reduction in foodborne illnesses and/or product recalls would more than offset any of the additional handling costs.

Mandatory treatment, if established, would also address the current "free rider" situation in hazelnuts. Many handlers are employing some level of treatment to their product prior to shipment out of the production area. The handlers that are doing so are building a quality reputation for hazelnuts by seeking to reduce the risk of food safety incidents. Those handlers who treat their product absorb all of the cost of such treatment. Conversely, handlers who may not treat product incur food safety risks that, in part, would negatively impact the industry at large should a food safety event in untreated hazelnuts occur.

The cost associated with the treatment of hazelnuts by chemical process or heat pasteurization is estimated to be \$0.10/pound. This cost, as detailed below, would include the cost of the treatment and transportation charges to and from a contract treatment facility. Many of the hazelnuts currently being shipped from the production area are treated by some process. There would be no additional cost associated with establishing mandatory treatment requirements for those nuts. Only if the Board chooses to recommend mandatory treatment for a certain market, and only if a handler shipping to that market does not currently treat their product, would this proposal represent a potential additional cost over and above the handler's current cost structure.

The biggest potential positive impact on the industry would be that hazelnut consumers could have confidence in the high degree of product quality that would be consistently and uniformly available in the market. As recent food quality incidents in nuts have begun to erode the positive reputation that has been carefully cultivated by marketing efforts for hazelnuts over the past two decades, a concerted effort by the hazelnut industry to address those challenges is expected to resonate with consumers. If product were to be guaranteed to be treated to reduce levels of harmful pathogens, consumers could continue to include hazelnuts as part of their balanced diet without the fear of a food quality incident.

5. How would the proposal tend to improve returns to producers? Quantify.

Adding the authority to regulate quality would assist the Board in addressing challenges of pathogen control in merchantable product. Adding the authority to establish regulations for food quality, up to and including mandatory treatment of hazelnuts destined for certain markets, could facilitate buyer confidence as to the quality of domestically produced hazelnuts amongst food manufacturers and retailers. Buyer confidence in the quality of hazelnuts from the production area could translate to a market preference for such nuts and/or a willingness to pay higher market prices. Both increased market share and an increase in commodity price should lead to improved returns to producers.

The proposed action could result in significantly increased distribution and usage of hazelnuts, offering greater marketing opportunities for handlers and, ultimately, more outlets for producers to sell their hazelnuts. Regulations that are similar to this proposed action have been implemented under the almond marketing order and have reportedly been very successful. The mandatory treatment for pathogens in almonds has resulted in improved market demand and increased producers' returns.

The distribution and sales of hazelnuts have been limited recently by lack of supply. Demand has grown tremendously over the past seven years for U.S.-produced hazelnuts, and growers have responded by planting additional acreage. The Board estimates that over 15,000 acres of new hazelnut orchards (which represents more than a 50 percent increase) have been established as of 2014. Some industry associations have reported that potentially a total of 60,000 acres have been established as of early 2016 (a 100 percent increase over 2008), with no sign that plantings are slowing down. As these new plantings come into production, broader distribution is expected within the U.S. This larger supply could increase the risk of foodborne illness if the hazelnuts are not treated to reduce the incidence of pathogens prior to shipment.

6. What are the expected impacts on small businesses?

The Small Business Administration (SBA) defines small agricultural producers as those having annual receipts of less than \$750,000, and defines small agricultural service firms as those whose annual receipts are less than \$7,500,000. There are approximately 800 producers in the production area. Most of those hazelnut producers would be classified as small businesses under the SBA definition. There would be little or no impact on producers as a result of the proposed change. In addition, there are 17 registered handlers of hazelnuts in the production area. Most of those handlers could be classified as small businesses under the SBA definition.

The impact of this proposed change on handlers classified as small businesses would be moderate, since almost all handlers are already treating hazelnuts as a result of the recent food safety incidents and based on FSSC recommendations. Most of the

hazelnut industry relies on contracted treatment services from large hazelnut handlers and other nut processing facilities outside of the production area. The cost of equipment to treat nuts is considerable, ranging from hundreds of thousands of dollars for steam and heat treatment to several million dollars for chemical fumigation, depending on the type and volume capacity of the equipment. While it is not financially feasible for most handlers to purchase, lease, or install treatment equipment within their own facilities, there are many such operations in California, and one in Oregon, that treat, or are capable of treating hazelnuts, as a fee-based service. Small handlers are already working together to pool loads to ship to treatment facilities and would be encouraged to continue doing so should quality control authority be added to the order and mandatory treatment regulations be implemented.

7. Would the proposal increase or decrease costs to producers, handlers, committees and/or the USDA? Explain/quantify.

The proposed order amendment, if established, is expected to be cost neutral to producers. As any regulations that may be implemented under the new authority would only be applicable to handlers, this action would not burden producers with any additional or increased direct costs. In addition, it is not expected that handlers would seek to pass any additional regulatory expenses that may result from the proposal on to the producers.

The proposed amendment is expected to increase handler costs, if regulations are established under the amendment to make treatment of outgoing hazelnuts mandatory. Handlers would bear the direct costs associated with installing and operating treatment equipment, or would be required to contract out the treatment of product by a third party. The cost of third-party treatment would also include transportation charges to ship product from the originating handler to the authorized treatment facility.

The cost of installing treatment equipment is high relative to the size of most hazelnut handling operations. It is expected that only a handful of handlers will incur such an expense should mandatory treatment of product be established under this proposal. One handler has already installed product treatment equipment, and one or two others are currently considering it. The remaining hazelnut handlers are unlikely to do so until on-site treatment processes become more scalable and affordable, and such systems have been validated by FDA. Pasteurization equipment costs vary greatly depending on the method, size and capacity. However, there are many treatment facilities located in California capable of treating hazelnuts that are already servicing the almond, walnut and pistachio industries.

Systems can range in cost from as much as \$5 million for a PPO chamber and \$3 million for a negative pressure steam blancher, to as little as \$100,000 for a used, low-volume, ambient pressure steam pasteurizer. In lower cost systems, however, decreased product quality and shelf-life become issues. Generally speaking, the amount of product expected to be treated by most handlers moving forward under

mandatory treatment regulations would not justify the cost of building high-volume facilities like PPO chambers and negative pressure steam blanchers that would be used for only a brief period each year for relatively low volumes of product.

The actual PPO treatment process costs approximately \$.075 per pound, and the transportation cost to ship product from within the production region to a PPO treatment facility in California amounts to approximately \$.025 per pound, for a total of approximately \$.10 per pound (assuming a full container load for throughput volume and transportation). Once treated, product is typically sent to the customer from the treatment facility rather than shipped back to the handler in Oregon.

A total of 6.5 million pounds of shelled Oregon hazelnut kernels were shipped to the domestic market in 2014-15 (which is the first market that is expected to be covered by quality regulations under the proposed amendment). The cost to have all of those hazelnuts PPO treated would have been approximately \$650,000. Kernel shipments to Canada for 2014-15, 9.5 million pounds, were almost exclusively destined for further treatment by the customer, which would have required no additional cost to handlers for treatment under proposed regulation. Lastly, inshell sales to North America in 2014-15, 3.5 million pounds, would have been treated at an approximate cost to handlers of \$350,000. It is expected that costs related to steam pasteurization at facilities in California are typically slightly less than PPO treatment, while shipping costs are identical. Therefore, the estimated cost to the industry, if regulations were in place for the 2014-15 crop year, would have been approximately \$800,000 to \$1,000,000, depending on the type of treatment and the transportation required.

Small handlers that are currently treating product are either pooling product for shipping and treatment, or including their product in with other tree nuts at treatment facilities to maximize treatment chamber efficiency and to keep costs low. Those smaller handlers will continue to be encouraged to pool loads in the future. The 2009 food safety recall of hazelnuts involved one large handler that shelled product for many of the other smaller handlers. The cost to the smaller handlers to recall all product that had been shelled at the affected facility far eclipsed the modest amount that the handlers would have expended for treatment to kill pathogens.

There should be relatively little additional cost to the Board or USDA relative to this proposal other than industry staff time in administering the program. Product already must conform to mandatory inspection and minimum grade and size requirements. The Board would have negligible additional expense in adding administration of additional requirements. There may be additional reporting requirements and the evaluation of an annual verification plan for Board staff to administer, but it is expected that this could be accomplished within current staffing levels.

8. How would the proposal be implemented?

Should quality control regulation authority be added to the order, the Board would begin to evaluate if regulation is necessary to promote orderly marketing of hazelnuts and

what specific requirements would be appropriate under the new authority. As an example, if it is found that product quality continues to be adversely affected by the presence of pathogens in merchantable hazelnuts, the Board could pursue implementation of quality regulation, up to and including mandatory product treatment. The Board, as a body and through designated subcommittees, would review all available scientific data on the prevalence of pathogens in hazelnuts and the certified eradication methods that have been proven to reduce pathogens in merchantable product. As appropriate, the order's regulations could be amended, via informal rulemaking, to effectuate such mandatory eradication protocols. The regulations could be crafted to regulate quality for all markets or for specific market outlets only, as the Board determined which actions would be appropriate within the context of the costs and benefits to the handlers.

If the mandatory treatment of hazelnuts to reduce the pathogen load is determined to be in the best interest of the industry, the Board would develop policies and procedures for the certification of acceptable processes, facilities, and record-keeping. It is anticipated that subcommittees would be established to serve as reviewers of such processes, treatment facilities, and handlers' treatment plans. The Board envisions that much of the organization and implementation of mandatory treatment regulations would be modeled after the almond marketing order's current mandatory treatment requirements.

9. How would compliance with the proposal be effected? Explain/quantify.

If treatment of product is mandated, handlers would be required to submit treatment plans each year, including treatment processes, facilities, and documentation. The Board and relevant subcommittees would review and approve or reject submitted plans on an annual basis with regular submission of documentation. The Almond Board of California, which administers the almond marketing order, has developed a very good working model that could be used as a basis for the hazelnut industry to follow.

The Board staff would be charged with monitoring compliance with any new regulations established under the proposed quality control authority. If implemented, the mandatory treatment regulations would include compliance and verification provisions to ensure that the regulations are being followed by handlers. Those provisions would require handlers to submit verification plans to the Board and maintain records to substantiate compliance with the regulations.

Additional costs to the Board to effectuate compliance with any new regulations enacted under the proposed order amendment should be minimal. The primary additional compliance task assigned to the Board staff would be to receive, document, and approve verification plans from the 17 handlers each year. That task should require less than 20 additional personnel hours per year and could be incorporated into the duties of existing staff.

To ensure all handlers operate under an approved verification plan, existing regulation safeguards could be modified to include mandatory treatment of outgoing product. All outgoing product is already subject to inspection under the order by the Federal-State Inspection Service. The scope of duties for inspectors working inside a handler's facility could be expanded to certify handler compliance with such handler's approved verification plan. Like all cases of suspected compliance violations, the Board staff would prepare violation evidence and turn the case over to MOAD. Violations are very time consuming for Board staff to investigate and document, however compliance enforcement activities regarding mandatory treatment requirements should be few. As such, the cost of originating a compliance case against a handler for a violation of any mandatory treatment requirements that may be established as a result of this proposal cannot easily be estimated in terms of administrative expense and staff time allocation. However, the Board believes that the potential benefits of regulating quality outweigh any of the potential costs of ensuring compliance with such regulations.