SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

UNLIMITED JURISDICTION

CENTER FOR ENVIRONMENTAL HEALTH, Plaintiff, v. FOOD MARKET MANAGEMENT, INC., *et al.*, Defendants.	Case No. CGC-12-526395 **[PROPOSED] CONSENT JUDGMENT AS TO DEFENDANT MCCORMICK & COMPANY, INC.**

1. INTRODUCTION

1.1 The Parties to this Consent Judgment are the Center For Environmental Health, a California non-profit corporation ("CEH"), and Defendant McCormick & Company, Inc. ("Settling Defendant"). The Parties enter into this Consent Judgment to settle certain claims asserted by CEH against Settling Defendant as set forth in the operative complaint in this matter. This Consent Judgment covers the lead content of crystalized, uncrystalized and candied ginger baking ingredient products ("Covered Products") sold or offered for sale by Settling Defendant.

1.2 On January 15, 2013, CEH served Settling Defendant with a 60-day Notice of

Violation under Proposition 65, alleging that Settling Defendant violated Proposition 65 by exposing persons to lead and lead compounds ("Lead") contained in Covered Products without first providing a clear and reasonable Proposition 65 warning.

1.3 Settling Defendant is a corporation that distributes, sells, or offers for sale Covered Products that are offered for sale in the State of California.

1.4 On November 27, 2012, CEH filed the original complaint in this matter. On December 20, 2012, CEH filed the operative First Amended Complaint in this matter. The First Amended Complaint has since been amended to add additional named defendants, including Settling Defendant on April 4, 2013.

1.5 In late 2014 and early 2015, several discovery disputes arose between the Parties. On March 30, 2015, per the Parties' stipulation, the Court issued an order appointing the Honorable Charlotte Woolard (Ret.) as a Discovery Referee to offer recommendations for resolving these disputes. On April 23, 2015, the Discovery Referee issued an Amended and Corrected Recommendations and (Proposed) Order Re Various Discovery Issues and Defendant McCormick's Motion for Sanctions. The Discovery Referee recommended, in relevant part, that the Court award monetary sanctions to CEH in connection with a Motion to Strike McCormick's Motion for Protective Order and an Opposition to McCormick's Motion for Protective Order, and as the prevailing party on its Motion to Compel McCormick's further discovery responses. The Discovery Referee recommended that McCormick pay CEH $32,399 in monetary sanctions under Code of Civil Procedure §2023.030(a). On May 5, 2015, McCormick filed Objections to the Discovery Referee's Recommendations Regarding Plaintiff's Motion to Compel and Requests for Sanctions, to which CEH responded on May 13, 2015. The Court adopted the Discovery Referee's recommendations in their entirety on June 24, 2015 (the "Discovery Order"). McCormick filed its notice of appeal regarding the monetary sanctions in the Discovery Order on August 21, 2015. That appeal is pending.

1.6 For purposes of this Consent Judgment only, CEH and Settling Defendant stipulate that the Court has jurisdiction over the allegations of violations in the complaint and personal

jurisdiction over Settling Defendant as to the acts alleged in the complaint, that venue is proper in the County of San Francisco, and that the Court has jurisdiction to enter this Consent Judgment as a full and final resolution of all claims which were or could have been raised in the complaint based on the facts alleged therein with respect to Covered Products manufactured, distributed and/or sold by Settling Defendant.

1.7 Nothing in this Consent Judgment is or shall be construed as an admission by the Parties of any fact, conclusion of law, issue of law or violation of law, nor shall compliance with the Consent Judgment constitute or be construed as an admission by the Parties of any fact, conclusion of law, issue of law or violation of law. Nothing in this Consent Judgment shall prejudice, waive or impair any right, remedy, argument or defense the Parties may have in any other pending or future legal proceedings. This Consent Judgment is the product of negotiation and compromise and is accepted by the Parties solely for purposes of settling, compromising, and resolving issues disputed in this action.

2. DEFINITIONS

2.1 The "Effective Date" shall mean the date fifteen (15) days after entry of this Consent Judgment.

2.2 "Independent Food Processing Auditor" shall mean an independent auditing company, foreign or domestic, that: (i) has extensive knowledge of good manufacturing practices in the food processing industry; (ii) has sufficient experience in inspecting food processing facilities to ensure compliance with good manufacturing practices and with the Hazard Analysis and Critical Control Points ("HACCP") food safety management system; (iii) (1) is certified as an International HACCP Alliance Lead Instructor; (2) is certified as a SQF (Safe Quality Food) HACCP Lead Auditor or SQF Consultant; (3) holds an NEHA (National Environmental Health Association) Certified Professional - Food Safety (CP-FS) Credential; (4) is certified as a Food Scientist by the Institute of Food Technology; or (5) has equivalent qualifications; and (iv) has submitted a satisfactory resume of its qualifications to Settling Defendant.

2.3 "Internal Auditor" shall mean an employee or other agent of that manufacturer or supplier who has received training adequate to conduct and document the audits and who has assumed the Independent Food Processing Auditor's responsibility for certifications set forth in Exhibit A, Attachment 1. The Internal Auditor may assume such responsibility only after an Independent Food Quality Auditor has provided the initial certification required by Exhibit A, Attachment 1. When an Internal Auditor assumes responsibility for providing certifications pursuant to this Section, the first such annual certification must be reviewed and approved by the Independent Food Processing Auditor.

2.4 The "Reformulation Level" shall mean a concentration level of no more than sixty-one (61) parts per billion ("ppb") Lead by weight.

3. INJUNCTIVE RELIEF

3.1 **Reformulation of Covered Products.** After the Effective Date, Settling Defendant shall not purchase, manufacture, ship, sell, or offer for sale any Covered Product that will be offered for sale in California, unless such Covered Product complies with the Reformulation Level.

3.1.1 Compliance with the Reformulation Level shall be determined by use of a test performed by an accredited laboratory using inductively coupled plasma mass spectrometry (ICP-MS) equipment with a level of detection of at least ten (10) ppb that meets standard laboratory QA/QC requirements. If any Party seeks to enforce this Consent Judgment, that Party will bear its own costs related to such enforcement.

3.2 **Lead Reduction Measures.**

3.2.1 Commencing ninety (90) days after the Effective Date, Settling Defendant shall do the following prior to obtaining any Covered Product from any manufacturer or supplier that is not a party to one of the two Consent Judgments entered by the Court on October 25, 2016:

3.2.1.1 Provide that manufacturer or supplier with a copy of the Summary of Compliance Information for Suppliers/Manufacturers set forth in Exhibit A.

3.2.1.2 Obtain, for each Covered Product, an initial and subsequent annual certifications, as set forth in Attachment 1 to Exhibit A, from the Independent Food Quality Auditor or Internal Auditor selected by the supplier of that Covered Product.

3.2.1.3 Settling Defendant may, as an alternative to obtaining certifications from manufacturers and suppliers of Covered Products, obtain its own initial and annual certification, as set forth in Attachment 1 to Exhibit A, from an Independent Food Quality Auditor or Internal Auditor.

3.2.1.4 Settling Defendant shall provide the annual certifications set forth in Attachment 1 to Exhibit A pursuant to the following Schedule:

Audit	Due Date	Audit Conducted by
Initial Certifications from Suppliers.	Six months after the Effective Date	Independent Food Processing Auditor
Second Certification from suppliers	December 31, 2017	Independent Food Processing Auditor or Internal Auditor
Third Certification from Suppliers.	December 31, 2018	Independent Food Processing Auditor or Internal Auditor
Fourth Certification from Suppliers.	December 31, 2019	Independent Food Processing Auditor or Internal Auditor

These certifications shall be provided to CEH. After the completion of the Fourth Certification from Suppliers, Settling Defendant will provide certification with respect to subsequent annual audits on the request of CEH.

4. ENFORCEMENT

4.1 **Enforcement Procedures**. Prior to bringing any motion or order to show cause to enforce the terms of Section 3 of this Consent Judgment, a Party seeking to enforce shall provide the violating Party thirty (30) days advanced written notice of the alleged violation. The Parties shall meet and confer during such thirty (30) day period in an effort to try to reach agreement on an appropriate cure for the alleged violation. After such thirty (30) day period, the Party seeking to enforce may, by new action, motion or order to show cause before the Superior Court of San Francisco, seek to enforce the terms and conditions contained in this Consent Judgment.

5. INITIAL PAYMENTS

5.1 **Payments by Settling Defendant.** Within five (5) days of the entry of this Consent Judgment, Settling Defendant shall pay a total of $100,000.

5.2 **Allocation of Payments.** The total settlement amount paid by Settling Defendant shall be paid in four separate checks in the amounts set forth below and delivered as set forth below. Any failure by Settling Defendant to comply with the payment terms herein shall be subject to a stipulated late fee in the amount of $100 for each day after the delivery date the payment is received. The late fees required under this Section shall be recoverable, together with reasonable attorneys' fees, in an enforcement proceeding brought pursuant to Section 4 of this Consent Judgment. The funds paid by Settling Defendant shall be allocated as set forth below between the following categories and made payable as follows:

5.2.1 A civil penalty pursuant to Health & Safety Code §25249.7(b) in the amount of $12,800. The civil penalty payment shall be apportioned in accordance with Health & Safety Code §25249.12 (25% to CEH and 75% to the State of California's Office of Environmental Health Hazard Assessment ("OEHHA")). Accordingly, the OEHHA portion of the civil penalty payment in the amount of $9,600 shall be made payable to OEHHA and associated with taxpayer identification number 68-0284486. This payment shall be delivered as follows:

For United States Postal Service Delivery:
Attn: Mike Gyurics
Fiscal Operations Branch Chief
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS #19B
Sacramento, CA 95812-4010

For Non-United States Postal Service Delivery:
Attn: Mike Gyurics
Fiscal Operations Branch Chief
Office of Environmental Health Hazard Assessment
1001 I Street, MS #19B
Sacramento, CA 95814

The CEH portion of the civil penalty payment in the amount of $3,200 shall be made payable to the Center For Environmental Health and associated with taxpayer identification number 94-3251981. This payment shall be delivered to Lexington Law Group, 503 Divisadero

Street, San Francisco, CA 94117.

A payment in lieu of civil penalty to CEH pursuant to Health & Safety Code §25249.7(b) and 11 Cal. Code Regs. §3203(b) in the amount of $19,200. CEH shall use such funds to continue its work educating and protecting people from exposures to toxic chemicals, including heavy metals. In addition, as part of its Community Environmental Action and Justice Fund, CEH will use four percent of such funds to award grants to grassroots environmental justice groups working to educate and protect people from exposures to toxic chemicals. The method of selection of such groups can be found at the CEH web site at www.ceh.org/justicefund. The payment pursuant to this Section shall be made payable to the Center For Environmental Health and associated with taxpayer identification number 94-3251981. This payment shall be delivered to Lexington Law Group, 503 Divisadero Street, San Francisco, CA 94117.

5.2.2 A reimbursement of a portion of CEH's reasonable attorneys' fees and costs in the amount of $68,000. The attorneys' fees and cost reimbursement check shall be made payable to the Lexington Law Group and associated with taxpayer identification number 94-3317175. This payment shall be delivered to Lexington Law Group, 503 Divisadero Street, San Francisco, CA 94117.

6. APPEAL

6.1 **Reservation of Rights on Appeal.** The Parties reserve all rights related to the appeal currently pending between the Parties and this Consent Judgment shall not impact or effect any Party's right to pursue the appeal until such time as the issues raised in the appeal are finally resolved and the Discovery Order becomes final and non-appealable (the "Final Appeal Date").

6.2 **Payment to Settling Defendant.** CEH was awarded $32,399 in monetary discovery sanctions on June 24, 2015. Settling Defendant paid $32,999 to CEH on July 24, 2015. If, upon the Final Appeal Date, Settling Defendant is ruled to owe to CEH a sum less than the initially awarded $32,399, then Settling Defendant shall be deemed the "Prevailing Party" on the appeal and CEH shall pay to Settling Defendant the following:

6.2.1 Any difference between the $32,399 initially awarded on June 24, 2015 and the amount Settling Defendant is ultimately ruled to owe to CEH in monetary discovery sanctions; and

6.2.2 Any reasonable attorneys' fees and costs incurred by Settling Defendant on appeal, including any related remands or further appeals.

6.3 **Payment to CEH.** If, upon the Final Appeal Date, Settling Defendant is ruled to owe to CEH a sum equal to or greater than the $32,399 already awarded in monetary discovery sanctions, then CEH shall be deemed the "Prevailing Party" on the appeal and Settling Defendant shall pay to CEH the following:

6.3.1 Any difference between the $32,399 awarded on June 24, 2015 and the amount Settling Defendant is ultimately ruled to owe to CEH in monetary discovery sanctions; and

6.3.2 Any reasonable attorneys' fees and costs incurred by CEH on appeal, including any related remands or further appeals.

6.4 **Timing of Payment; Dispute Resolution.** Within thirty (30) days of the Final Appeal Date, the non-Prevailing Party shall pay to the Prevailing Party the amount set forth in Section 6.2.1 or 6.3.1 as applicable. At the same time, the Prevailing Party shall also submit to the non-Prevailing Party documentation supporting its claim as to the amount of reasonable attorneys' fees and costs incurred by the Prevailing Party on appeal and any related remands or further appeals.

6.4.1 Should the non-Prevailing Party assent to the proffer described in Section 6.3, then the non-Prevailing Party shall, within fifteen (15) days of receiving the proffer, remit the payment described in Section 6.2.1 or 6.3.1 to the Prevailing Party.

6.4.2 Should the non-Prevailing Party dispute the proffer described in Section 6.3, then the non-Prevailing Party shall so notify the Prevailing Party in writing within ten (10) days of receiving the proffer. In such event, the Parties shall attempt in good faith to meet and confer over the next thirty (30) days to reach an agreement as to the amount of reasonable

attorneys' fees and costs incurred by the Prevailing Party on appeal. Upon the expiration of this 30-day meet-and-confer period, the non-Prevailing Party shall either (a) remit the agreed-upon sum to the Prevailing Party or (b) notify the Prevailing Party that an agreement as to the amount of reasonable attorneys' fees and costs cannot be reached.

6.4.3 In the event that an agreement cannot be reached as to the amount of reasonable attorneys' fees and costs incurred on appeal, the Parties shall each select a neutral within fifteen (15) days of the expiration of the meet-and-confer period described in Section 6.3.2. Each Party will bear the cost of its neutral. These two neutrals will select a third neutral ("Fee Arbitrator"), who will determine the amount of reasonable attorneys' fees and costs to award to the Prevailing Party. Upon selection of the Fee Arbitrator, the Prevailing Party shall, within thirty (30) days of the date that the Fee Arbitrator is appointed, submit to that arbitrator a written brief, not to exceed five (5) pages in length, setting forth the basis for its entitlement to the amount sought. The Prevailing Party's submission to the Fee Arbitrator shall include documentation supporting its claim as to the amount of reasonable attorneys' fees and costs it incurred on appeal. Within fifteen (15) days of receiving the Prevailing Party's submission to the Fee Arbitrator, the non-Prevailing Party shall submit to the Fee Arbitrator a written brief, not to exceed five (5) pages in length, setting forth the basis for its opposition to the amount sought. The Fee Arbitrator shall set a hearing, not to exceed one-half day in length, at which each Party may present argumentation in support of its contention as to the amount of reasonable attorneys' fees and costs incurred by the Prevailing Party on appeal. The Parties will equally share the Fee Arbitrator's costs for resolving this dispute absent an order granting those costs to either Party.

6.4.4 After the hearing, the Fee Arbitrator shall issue a written order setting forth the amount of reasonable attorneys' fees and costs incurred by the Prevailing Party on appeal and any related remands or further appeals. As part of this order, the Fee Arbitrator shall order that the non-prevailing party is to reimburse the prevailing party in this Dispute Resolution process for its share of the Fee Arbitrator's costs and the reasonable attorneys' fees incurred by the prevailing party in this Dispute Resolution process.

6.4.4.1 Within ten (10) days of receiving the Fee Arbitrator's order, the non-Prevailing Party shall pay to the Prevailing Party the amount in the order, adjusted upward or downward by any amount in additional attorneys' fees or other litigation costs awarded by the Fee Arbitrator relating to this Dispute Resolution process.

7. MODIFICATION AND DISPUTE RESOLUTION

7.1 **Modification.** This Consent Judgment may be modified from time to time by express written agreement of the Parties, with the approval of the Court, or by an order of the Court on motion and in accordance with law.

7.2 **Notice; Meet and Confer.** Any Party seeking to modify this Consent Judgment shall attempt in good faith to meet and confer with all affected Parties prior to filing a motion to modify the Consent Judgment.

8. CLAIMS COVERED AND RELEASE

8.1 This Consent Judgment is a full, final, and binding resolution between CEH on behalf of itself and the public interest and Settling Defendant, and Settling Defendant's parents, subsidiaries, affiliated entities that are under common ownership, directors, officers, employees, and attorneys ("Defendant Releasees"), and all entities to which Settling Defendant distributes or sells Covered Products, including but not limited to distributors, wholesalers, customers, retailers such as Wal-Mart Stores, Inc., Walmart.com USA LLC, Safeway Inc., The Vons Companies, Inc., Albertsons LLC and their respective subsidiaries and parents, franchisees, licensors, and licensees ("Downstream Defendant Releasees"), of any violation of Proposition 65 based on failure to warn about alleged exposure to Lead contained in Covered Products that were sold by Settling Defendant prior to the Effective Date.

8.2 CEH, for itself releases, waives, and forever discharges any and all claims against Settling Defendant, Defendant Releasees, and Downstream Defendant Releasees arising from any violation of Proposition 65 or any other statutory or common law claims that have been or could have been asserted in the public interest regarding the failure to warn about exposure to Lead arising in connection with Covered Products manufactured, distributed, or sold by Settling

Defendant prior to the Effective Date.

8.3 This Consent Judgment does not cover, and CEH does not release, waive, or discharge, on behalf of itself or any other enforcers, any claims arising from any violation of Proposition 65 or any other statutory or common law claims that have been or could have been asserted in the public interest regarding the failure to warn about exposure to lead arising in connection with ginger or plum baking ingredients other than Covered Products.

8.4 Compliance with the terms of this Consent Judgment by Settling Defendant and Defendant Releasees shall constitute compliance with Proposition 65 by Settling Defendant, Defendant Releasees, and Downstream Defendant Releasees with respect to any alleged failure to warn about Lead in Covered Products manufactured, distributed, or sold by Settling Defendant after the Effective Date.

9. PROVISION OF NOTICE

9.1 When CEH is entitled to receive any notice under this Consent Judgment, the notice shall be sent by first class and electronic mail to:

Eric S. Somers
Lexington Law Group
503 Divisadero Street
San Francisco, CA 94117
esomers@lexlawgroup.com

9.2 When Settling Defendant is entitled to receive any notice under this Consent Judgment, the notice shall be sent by first class and electronic mail to:

Mark C. Goodman
Hogan Lovells US LLP
3 Embarcadero Center, Suite 1500
San Francisco, CA 94111
mark.goodman@hoganlovells.com

9.3 Any Party may modify the person and address to whom the notice is to be sent by sending the other Party notice by first class and electronic mail.

10. COURT APPROVAL

10.1 This Consent Judgment shall become effective on the Effective Date, provided however, that CEH shall prepare and file a Motion for Approval of this Consent Judgment and

Settling Defendant shall support approval of such motion. CEH and Settling Defendant will use best efforts to ensure that the Consent Judgment is approved and entered by the Court and will work together in good faith address any issues raised by the Court with respect to approval of this Consent Judgment.

10.2 If this Consent Judgment is not entered by the Court, it shall be of no force or effect and shall not be introduced into evidence or otherwise used in any proceeding for any purpose.

11. GOVERNING LAW AND CONSTRUCTION

11.1 The terms of this Consent Judgment shall be governed by the laws of the State of California.

12. ATTORNEYS' FEES

12.1 A Party who unsuccessfully brings or contests an action arising out of this Consent Judgment shall be required to pay the prevailing Party's reasonable attorneys' fees and costs unless the unsuccessful Party has acted with substantial justification. For purposes of this Consent Judgment, the term substantial justification shall carry the same meaning as used in the Civil Discovery Act of 1986, Code of Civil Procedure §§2016.010, *et seq.*

12.2 Notwithstanding Section 12.1, a Party who prevails in a contested enforcement action brought pursuant to Section 3 may seek an award of attorneys' fees pursuant to Code of Civil Procedure §1021.5 against a Party that acted with substantial justification. The Party seeking such an award shall bear the burden of meeting all of the elements of §1021.5, and this provision shall not be construed as altering any procedural or substantive requirements for obtaining such an award.

12.3 Nothing in this Section 12 shall preclude a Party from seeking an award of sanctions pursuant to law.

13. ENTIRE AGREEMENT

13.1 This Consent Judgment contains the sole and entire agreement and understanding of the Parties with respect to the entire subject matter hereof, and any and all prior discussions, negotiations, commitments, or understandings related thereto, if any, are hereby merged herein

and therein. There are no warranties, representations, or other agreements between the Parties except as expressly set forth herein. No representations, oral or otherwise, express or implied, other than those specifically referred to in this Consent Judgment have been made by any Party hereto. No other agreements not specifically contained or referenced herein, oral or otherwise, shall be deemed to exist or to bind any of the Parties hereto. Any agreements specifically contained or referenced herein, oral or otherwise, shall be deemed to exist or to bind any of the Parties hereto only to the extent that they are expressly incorporated herein. No supplementation, modification, waiver, or termination of this Consent Judgment shall be binding unless executed in writing by the Party to be bound thereby. No waiver of any of the provisions of this Consent Judgment shall be deemed or shall constitute a waiver of any of the other provisions hereof whether or not similar, nor shall such waiver constitute a continuing waiver.

14. RETENTION OF JURISDICTION

14.1 This Court shall retain jurisdiction of this matter to enforce, implement or modify the Consent Judgment, and to any address issues remanded to it that are related to the Appeal.

15. AUTHORITY TO STIPULATE TO CONSENT JUDGMENT

15.1 Each signatory to this Consent Judgment certifies that he or she is fully authorized by the Party he or she represents to stipulate to this Consent Judgment and to enter into and execute the Consent Judgment on behalf of the Party represented and legally to bind that Party.

16. NO EFFECT ON OTHER SETTLEMENTS

16.1 Nothing in this Consent Judgment shall preclude CEH from resolving any claim against an entity that is not a Settling Defendant on terms that are different than those contained in this Consent Judgment.

17. EXECUTION IN COUNTERPARTS

17.1 The stipulations to this Consent Judgment may be executed in counterparts and by means of facsimile or portable document format (pdf), which taken together shall be deemed to constitute one document.

IT IS SO ORDERED, ADJUDGED, AND DECREED

Dated: _____

_____
Judge of the Superior Court of the State of California

IT IS SO STIPULATED:

Dated: 14 Dec, 2016	**CENTER FOR ENVIRONMENTAL HEALTH** _____ Carmelita Pizarro Printed Name Associate Director Title
Dated: _____, 2016	**MCCORMICK & COMPANY, INC.** _____ _____ Printed Name _____ Title

IT IS SO ORDERED, ADJUDGED, AND DECREED

Dated: _____

_____
Judge of the Superior Court of the State of California

IT IS SO STIPULATED:

Dated: _____, 2016	**CENTER FOR ENVIRONMENTAL HEALTH** _____ _____ Printed Name _____ Title
Dated: 12/13, 2016	**MCCORMICK & COMPANY, INC.** _____ JASON E. WYNN Printed Name ASSOCIATE GENERAL COUNSEL Title

EXHIBIT A

SUMMARY OF COMPLIANCE INFORMATION FOR THE SUPPLIER/MANUFACTURER OF COVERED PRODUCTS

Dear [Insert Name of Supplier/Manufacturer]:

We plan to offer the following products for sale in California:

[Insert Names of Specific Covered Products]

Prior to doing so, we will need certification from you that the following steps have been taken under the supervision of an Independent Food Processing Auditor, to minimize the lead levels in each of these products during the manufacturing process.

The Independent Food Processing Auditor must:

1. Have extensive knowledge of good manufacturing practices in the food processing industry;

2. Have sufficient experience in inspecting food processing facilities to ensure compliance with good manufacturing practices and with the Hazard Analysis and Critical Control Points ("HACCP") food safety management system;

3. Hold one of the following certifications: (1) certification as International HACCP Alliance lead Instructor; (2) certification as a SQF (Safe Quality Food) HACCP Lead Auditor or SQF Consultant, (3) hold an NEHA (National Environmental Health Association) Certified Professional - Food Safety (CP-FS) Credential; (4) certification as a Food Scientist by Institute of Food Technology; or (5) equivalent qualifications.

4. Supply us with a resume demonstrating the qualifications listed above.

The Independent Food Processing Auditor must provide the initial signed Certification attached as Attachment 1 for each type of Covered Product sold. Thereafter, the Independent Food Processing Auditor or a qualified Internal Auditor may provide the Certification, but the Internal Auditor's first annual Certification must be reviewed and approved by the Independent Food Processing Auditor.

For the purposes of that Certification, the following definitions are applicable:

- "Covered Products" shall mean crystalized, uncrystalized and candied ginger baking ingredient products supplied to us by you.

- The "Reformulation Level" shall mean a concentration level of no more than sixty-one (61) parts per billion ("ppb") lead by weight.

- A "Qualified Laboratory" is a laboratory that has demonstrated proficiency to conduct lead analysis on the Covered Products using Inductively Coupled Plasma Mass

Spectrometry ("ICP-MS"). For analysis of the Packaging Materials, a "Qualified Laboratory" shall mean a laboratory that has demonstrated proficiency to conduct lead analysis on packaging materials using ICP-MS. A Qualified Laboratory must meet the specifications set forth in Title 27 California Code of Regulations section 25900(b) and must at all times satisfy the Laboratory Standards set forth in Attachment 2.

- "Periodic Testing" means annual testing of Representative Product Samples of the Covered Products at a Qualified Laboratory, unless a product fails to satisfy the Reformulation Level in which case the testing frequency will be increased to reflect the severity of the failure.

- "Representative Product Samples" of a type of Covered Product shall mean six to ten samples randomly drawn from the following lots ("Representative Lots") of that Product which are intended for sale or distribution in California:

  - For purposes of the initial certification of the Reformulation Level: (a) the first six consecutive lots of the product that were produced after the implementation of the Lead Contribution Exercise and (b) the square root, rounded to the nearest whole number, of the additional number of lots sold in the preceding calendar year.[1] For new products for which no prior sales information is available, the number of lots used to calculate the number of tests for subpart (b) is to be based upon sales of similar products in the prior calendar year.
  - For subsequent certifications of the Reformulation Level: the square root, rounded to the nearest whole number, of the number of lots sold or distributed for sale in California in the preceding calendar year, unless a lot fails to satisfy the Reformulation Level. In the event of such a failure, the company that manufactures the Covered Product must re-evaluate its controls, and then show that six consecutive lots satisfy the Reformulation Level before reverting to testing the square root of the number of lots sold.

- "Representative Ingredient Samples" of ingredients for a Covered Product shall mean: the average of six or more samples taken from:

  - the square root, rounded to the nearest whole number, of the number of lots of the ingredient used in the Covered Product in the preceding calendar year;

  - a statistically representative number of the lots of that ingredient, as determined by the supplier of that ingredient; or

  - each lot of the ingredient.

- If a lot fails to satisfy the applicable maximum lead level for the ingredient, then:

  - If all lots of that ingredient are routinely tested before use, the lot may be rejected without additional action;

[1] If there are fewer than six production lots, samples shall be taken from each lot.

- Otherwise, the lot must be rejected and the company that supplies the ingredient must re-evaluate its controls, and then show that up to six consecutive lots of the ingredient satisfy the applicable maximum lead levels before the ingredient can be used in a Covered Product.

EXHIBIT A – ATTACHMENT 1

REQUIRED CERTIFICATION FROM INDEPENDENT FOOD QUALITY AUDITOR RETAINED BY THE MANUFACTURER OR SUPPLIER OF THE COVERED PRODUCTS

[Letterhead of Independent Food Processing Auditor.]

I, _____[Name]____, certify as follows with respect to the following Covered Products:

[Insert Names of specific Covered Products]

1. [Name of Company] (the "Company") has implemented a Hazard Analysis and Critical Control Points ("HACCP") program that identifies lead as a hazard and implements the prevention steps to minimize the presence of lead in the Covered Products.

2. Ginger. The Company has received adequate certification pursuant to paragraph 9 below that the raw ginger used as an ingredient in the Covered Products does not contain lead in excess of the higher of (a) 35 ppb or (b) the maximum concentration established in the Lead Contribution Exercise conducted pursuant to section 8 below.

   During the first calendar year following the Effective Date, if the ingredient ginger for a Covered Product has already been brined, the Company may obtain this certification for this brined ginger rather than raw ginger with the lead concentration in the brined ginger not in excess of 35 pbb.

4. Sugar. The sugar used as an ingredient in the Covered Products is food grade, and the Company has received adequate certification pursuant to paragraph 9 below that it does not contain lead in excess of the maximum concentration established in the Lead Contribution Exercise conducted pursuant to section 8 below.

5. Salt. If salt is more than 2% of the finished product, the salt used as an ingredient in the Covered Product is food grade, and the Company has received adequate certification pursuant to paragraph 10 below that that it does not contain lead in excess of the concentration established in the Lead Contribution Exercise conducted pursuant to section 9 below.

6. Brining Salt. [If the Covered Products are subject to a brining process:] The salt used in the brining of the ginger ingredient is food grade and the Company has received adequate certification pursuant to paragraph 10 below that it does not contain lead in excess of either (i) 50 ppb, or (ii) the maximum concentration established in the Lead Contribution Exercise conducted pursuant to section 9 below.

7. Other Ingredients/Aids. All other ingredients and processing aids are food grade and the Company has received adequate certification pursuant to paragraph 9 below that any ingredients that may contribute lead in excess of 5 ppb to the finished product do not contain lead in excess of the maximum concentration established in the Lead Contribution Exercise conducted pursuant to section 9 below.

8. Annual Audit. The Company undergoes an annual audit by an approved third party auditor to verify that their GMP and HACCP programs adequately prevent or minimize the presence of lead in their finished products.

9. Lead Contribution Exercise. The Company has evaluated all ingredients in, and the processing aids used in the production of, the Covered Products. Based on this evaluation, the Company has determined which ingredients and processing aids have the potential to cause the product to exceed the Reformulation Level or to contribute more than 5 ppb lead to the final product. The company has established maximum lead concentrations for the ingredients and processing aids identified as a result of this evaluation. The lead concentrations that the Company has established as part of this process are designed to result in finished Covered Products that have a lead concentration of no more than the Reformulation Level.

10. Certification from Suppliers.

    a. The Company has either:

    (1) Requested from its suppliers and maintained a certificate of analysis specific to lead for each raw ingredient and for each manufacturing aid that may, based on the Lead Contribution Exercise, contribute more than 5 ppb of lead to the finished product. These certificates of analysis indicate that the lead levels in Representative Ingredient Samples of each such major ingredient and manufacturing aid do not exceed the maximum lead concentrations set forth in paragraphs 2 through 6, above. These certificates show that the ingredient or processing aid has been analyzed by a Qualified Laboratory.

    or

    (2) Has implemented a system to pre-approve each supplier. Such a pre-approved supplier must show that it has process controls and lead prevention programs in place to ensure that the lead levels in its products do not exceed the maximum lead concentrations that are set in paragraphs 2 through 6, above. The supplier must also show that it has a program in place to test Representative Ingredient Samples and that this testing shows that the maximum lead concentrations have not been exceeded. This testing must be conducted at a Qualified Laboratory.

    b. If the final product has failed to satisfy the Reformulation Level, any ingredients responsible for any failure to satisfy the Reformulation Level have undergone independent testing.

11. Potable Water Supply. The potable water supply is monitored for lead levels. The internal distribution system is not a source of lead contamination as verified by point of use testing versus influent lead level. The lead levels in potable water used in processing contains no more than 10 ppb.

12. Food Contact Surfaces. All food contact equipment utensils, containers are constructed from lead-free materials. No brass or bronze components may come in contact with ingredients or the final product.

13. Lubricants/Sealants, Etc. Lubricants, sealants and similar materials used in direct food contact areas, as well as in areas that have the potential to contaminate product, are food grade. This included storage areas in addition to processing and packing areas.

14. Packaging materials. Packaging materials, inks, and pigments with any contact to the product meet the requirements of California Health and Safety Code section 25214.13. Other packing materials do not result in lead migration into the final product.

15. Process control. Process control is validated through an audit program whereby processes and finished product is subjected to Periodic Testing for total lead content. The Limit of Quantification (LOQ) for the finished products and major ingredients must be equal to or less than 0.01 mg/kg.

16. Lot identification/Traceability. Lot identification and traceability is maintained for major and minor ingredients and processing aids. The manufacturer is able to document the major and minor ingredients lots used to produce specific finished product lots and to trace finished product shipments one level forward to the customer.

17. Testing Program for Final Product The company has a program in place to test Representative Samples of the product annually, unless a product fails to satisfy the Reformulation Level in which case the Company has in place a program whereby sampling frequency will be increased to reflect the lead level found in excess of what is permitted under the Consent Judgment.

18. Standard GMPs. The Company has in place Good Manufacturing Practices for the Covered Products, that include the following, which are continuously in place:

    a. Specifications are established for controlled manufacturing steps.

    b. Master manufacturing records and batch production records are prepared and maintained.

    c. Standard Operating Procedures (SOPs) are prepared to cover the quality control operations, including the calibration and control of equipment and instruments used in manufacturing.

19. Certification of Reformulation Level. I have reviewed testing of Representative Samples of the Covered Products listed above. This testing was conducted at Qualified Laboratory that met the standards set forth in Title 27 California Code of Regulations section 25900(b) or set forth in Attachment 2. This testing showed that none of the Representative Lots of Covered Products exceeded the Reformulation Level.

Dated: _____ _____

SIGNATURE OF INDEPENDENT FOOD QUALITY AUDITOR [OR INTERNAL AUDITOR IF APPLICABLE].

EXHIBIT A - ATTACHMENT 2

QUALIFIED LABORATORIES

Analytical guidance for Laboratories:

Analyses must utilize a method that employs ICP-MS. Laboratories must have the capability of controlling lead contamination throughout the analytical process, including sample compositing, sample digestion, and the lead determination steps. In order to meet the analytical objectives, the use of high purity acids will be required as well the use of closed-vessel type sample digestion procedures. The conditions and procedures needed to successfully meet the analyses are described in the FDA Elemental Analysis Manual.

http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006954.htm. See method EAM 4.7.

http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM377005.pdf

Particular attention must be given to recovery information offered to attribute accuracy to these analyses. The levels of lead used to fortify products and ingredients for analyte recovery must be in the range of 50-200% of the lead level found in the product, if the level of lead in the product is in a quantifiable range. As a measure of accuracy, laboratories are also encouraged to provide recovery information on certified reference materials with lead levels similar to these products or ingredients.

Participating laboratories must be accredited, preferably under ISO 17025 to conduct low level lead analyses in foods by ICP-MS.

The analytical objective for lead analysis, i.e., the Limit of Quantification (LOQ), for finished products and for the major ingredients is 0.010 mg/kg.