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and the party contributing funds towards the development of such patents, copyrights, inventions, trademarks, information, publications, or product formulations in a manner consistent with this paragraph.

§ 63.502 Personal liability.

No member or employee of the Board shall be held personally responsible, either individually or jointly, in any way whatsoever to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member or employee, except for acts of dishonesty or willful misconduct.

§ 63.503 Separability.

If any provision of the part is declared invalid or the applicability thereof to any person or circumstance is held invalid, the validity of the remainder of this subpart, or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 63.504 Amendments.

Amendments to this part may be proposed, from time to time, by the Board or by any interested persons affected by the provisions of the Act, including the Secretary.

§ 63.505 OMB control number.

The control number assigned to the information collection requirements of this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB control number 0505-new.

Subpart B [Reserved]

PART 65—COUNTRY OF ORIGIN LABELING OF LAMB, CHICKEN, AND GOAT MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADAMIA NUTS, PECANS, PEANUTS, AND GINSENG

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Subpart B [Reserved]

AUTHORITY: 7 U.S.C. 1621 *et seq.*

SOURCE: 74 FR 2704, Jan. 15, 2009, unless otherwise noted.

Subpart A—General Provisions

DEFINITIONS

§ 65.100 Act.

Act means the Agricultural Marketing Act of 1946, (7 U.S.C. 1621 *et seq.*).

§ 65.105 AMS.

AMS means the Agricultural Marketing Service, United States Department of Agriculture.

§ 65.115 Born.

Born in the case of chicken means hatched from the egg.

§ 65.120 Chicken.

Chicken has the meaning given the term in 9 CFR 381.170(a)(1).

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§ 65.125 **Commingled covered commodities.**

Commingled covered commodities means covered commodities (of the same type) presented for retail sale in a consumer package that have been prepared from raw material sources having different origins.

§ 65.130 **Consumer package.**

Consumer package means any container or wrapping in which a covered commodity is enclosed for the delivery and/or display of such commodity to retail purchasers.

§ 65.135 **Covered commodity.**

(a) *Covered commodity* means:

- (1) Muscle cuts of lamb, chicken, and goat;
- (2) Ground lamb, ground chicken, and ground goat;
- (3) Perishable agricultural commodities;
- (4) Peanuts;
- (5) Macadamia nuts;
- (6) Pecans; and
- (7) Ginseng.

(b) Covered commodities are excluded from this part if the commodity is an ingredient in a processed food item as defined in § 65.220.

[74 FR 2704, Jan. 15, 2009, as amended at 81 FR 10761, Mar. 2, 2016]

§ 65.140 **Food service establishment.**

Food service establishment means a restaurant, cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, or other similar facility operated as an enterprise engaged in the business of selling food to the public. Similar food service facilities include salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

§ 65.145 **Ginseng.**

Ginseng means ginseng root of the genus *Panax*.

§ 65.150 **Goat.**

Goat means meat produced from goats.

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§ 65.160 **Ground chicken.**

Ground chicken means comminuted chicken of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.165 **Ground goat.**

Ground goat means comminuted goat of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.170 **Ground lamb.**

Ground lamb means comminuted lamb of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

§ 65.180 **Imported for immediate slaughter.**

Imported for immediate slaughter means imported into the United States for “immediate slaughter” as that term is defined in 9 CFR 93.400, i.e., consignment directly from the port of entry to a recognized slaughtering establishment and slaughtered within 2 weeks from the date of entry.

§ 65.185 **Ingredient.**

Ingredient means a component either in part or in full, of a finished retail food product.

§ 65.190 **Lamb.**

Lamb means meat produced from sheep.

§ 65.195 **Legible.**

Legible means text that can be easily read.

§ 65.205 **Perishable agricultural commodity.**

Perishable agricultural commodity means fresh and frozen fruits and vegetables of every kind and character that have not been manufactured into articles of a different kind or character and includes cherries in brine as defined by the Secretary in accordance with trade usages.

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§ 65.210 Person.

Person means any individual, partnership, corporation, association, or other legal entity.

§ 65.218 Pre-labeled.

Pre-labeled means a covered commodity that has the commodity's country of origin and the name and place of business of the manufacturer, packer, or distributor on the covered commodity itself, on the package in which it is sold to the consumer, or on the master shipping container. The place of business information must include at a minimum the city and state or other acceptable locale designation.

§ 65.220 Processed food item.

Processed food item means a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one other covered commodity or other substantive food component (*e.g.*, chocolate, breading, tomato sauce), except that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item. Specific processing that results in a change in the character of the covered commodity includes cooking (*e.g.*, frying, broiling, grilling, boiling, steaming, baking, roasting), curing (*e.g.*, salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (*e.g.*, emulsifying and extruding). Examples of items excluded include roasted peanuts, breaded chicken tenders, and fruit medley.

[81 FR 10761, Mar. 2, 2016]

§ 65.225 Produced.

Produced in the case of a perishable agricultural commodity, peanuts, ginseng, pecans, and macadamia nuts means harvested.

§ 65.230 Production step.

Production step means, in the case of beef, pork, goat, chicken, and lamb, born, raised, or slaughtered.

§ 65.235 Raised.

Raised means, in the case of beef, pork, chicken, goat, and lamb, the period of time from birth until slaughter or in the case of animals imported for immediate slaughter as defined in § 65.180, the period of time from birth until date of entry into the United States.

§ 65.240 Retailer.

Retailer means any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(b)).

[78 FR 31385, May 24, 2013]

§ 65.245 Secretary.

Secretary means the Secretary of Agriculture of the United States or any person to whom the Secretary's authority has been delegated.

§ 65.250 Slaughter.

Slaughter means the point in which a livestock animal (including chicken) is prepared into meat products (covered commodities) for human consumption. For purposes of labeling under this part, the word harvested may be used in lieu of slaughtered.

§ 65.255 United States.

United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, the Northern Mariana Islands, and any other Commonwealth, territory, or possession of the United States.

§ 65.260 United States country of origin.

United States country of origin means in the case of:

(a) Beef, pork, lamb, chicken, and goat:

(1) From animals exclusively born, raised, and slaughtered in the United States;

(2) From animals born and raised in Alaska or Hawaii and transported for a period of not more than 60 days through Canada to the United States and slaughtered in the United States; or

(3) From animals present in the United States on or before July 15, 2008,

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and once present in the United States, remained continuously in the United States.

(b) Perishable agricultural commodities, peanuts, ginseng, pecans, and macadamia nuts: from products produced in the United States.

§ 65.265 USDA.

USDA means the United States Department of Agriculture.

COUNTRY OF ORIGIN NOTIFICATION

§ 65.300 Country of origin notification.

In providing notice of the country of origin as required by the Act, the following requirements shall be followed by retailers:

(a) *General.* Labeling of covered commodities offered for sale whether individually, in a bulk bin, carton, crate, barrel, cluster, or consumer package must contain country of origin as set forth in this regulation.

(b) *Exemptions.* Food service establishments as defined in § 65.135 are exempt from labeling under this subpart.

(c) *Exclusions.* A covered commodity is excluded from this subpart if it is an ingredient in a processed food item as defined in § 65.220.

(d) *Labeling Covered Commodities of United States Origin.* A covered commodity may bear a declaration that identifies the United States as the sole country of origin at retail only if it meets the definition of United States country of origin as defined in § 65.260. The United States country of origin designation for muscle cut covered commodities shall include all of the production steps (i.e., “Born, Raised, and Slaughtered in the United States”).

(e) *Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin from Animals Slaughtered in the United States.* If an animal was born and/or raised in Country X and/or (as applicable) Country Y, and slaughtered in the United States, the resulting muscle cut covered commodities shall be labeled to specifically identify the production steps occurring in each country (e.g., “Born and Raised in Country X, Slaughtered in the United States”). If an animal is raised in the United States as well as another country (or

multiple countries), the raising occurring in the other country (or countries) may be omitted from the origin designation except if the animal was imported for immediate slaughter as defined in § 65.180 or where by doing so the muscle cut covered commodity would be designated as having a United States country of origin (e.g., “Born in Country X, Raised and Slaughtered in the United States” in lieu of “Born and Raised in Country X, Raised in Country Y, Raised and Slaughtered in the United States”).

(f) *Labeling Imported Covered Commodities.* (1) Perishable agricultural commodities, peanuts, pecans, ginseng, macadamia nuts and ground meat covered commodities that have been produced in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale.

(2) Muscle cut covered commodities derived from an animal that was slaughtered in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale (e.g., “Product of Country X”), including muscle cut covered commodities derived from an animal that was born and/or raised in the United States and slaughtered in another country. In addition, the origin declaration may include more specific location information related to production steps (i.e., born, raised, and slaughtered) provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

(g) *Labeling Commingled Covered Commodities.* In the case of perishable agricultural commodities; peanuts; pecans; ginseng; and macadamia nuts: For imported covered commodities that have not subsequently been substantially transformed in the United States that are commingled with covered commodities sourced from a different origin that have not been substantially transformed (as established by CBP) in the United States, and/or covered commodities of United States origin, the declaration shall indicate the countries of

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origin in accordance with existing Federal legal requirements.

(h) *Labeling ground lamb, ground goat, and ground chicken.* The declaration for ground lamb, ground goat, and ground chicken covered commodities shall list all countries of origin contained therein or that may be reasonably contained therein. In determining what is considered reasonable, when a raw material from a specific origin is not in a processor's inventory for more than 60 days, that country shall no longer be included as a possible country of origin.

(i) *Remotely Purchased Products.* For sales of a covered commodity in which the customer purchases a covered commodity prior to having an opportunity to observe the final package (e.g., Internet sales, home delivery sales, etc.), the retailer may provide the country of origin notification either on the sales vehicle or at the time the product is delivered to the consumer.

[74 FR 2704, Jan. 15, 2009, as amended at 78 FR 31385, May 24, 2013; 81 FR 10761, Mar. 2, 2016]

§ 65.400 Labeling.

(a) Country of origin declarations can either be in the form of a placard, sign, label, sticker, band, twist tie, pin tag, or other format that allows consumers to identify the country of origin. The declaration of the country of origin of a product may be in the form of a statement such as "Product of USA," "Produce of the USA", or "Grown in Mexico," may only contain the name of the country such as "USA" or "Mexico," or may be in the form of a check box provided it is in conformance with other Federal labeling laws.

(b) The declaration of the country of origin (e.g., placard, sign, label, sticker, band, twist tie, pin tag, or other display) must be legible and placed in a conspicuous location, so as to render it likely to be read and understood by a customer under normal conditions of purchase.

(c) The declaration of country of origin may be typed, printed, or handwritten provided it is in conformance with other Federal labeling laws and does not obscure other labeling information required by other Federal regulations.

(d) A bulk container (e.g., display case, shipper, bin, carton, and barrel) used at the retail level to present product to consumers, may contain a covered commodity from more than one country of origin provided all possible origins are listed.

(e) In general, country abbreviations are not acceptable. Only those abbreviations approved for use under Customs and Border Protection rules, regulations, and policies, such as "U.K." for "The United Kingdom of Great Britain and Northern Ireland", "Luxemb" for Luxembourg, and "U.S. or USA" for the "United States of America" are acceptable. The adjectival form of the name of a country may be used as proper notification of the country of origin of imported commodities provided the adjectival form of the name does not appear with other words so as to refer to a kind or species of product. Symbols or flags alone may not be used to denote country of origin.

(f) Domestic and imported perishable agricultural commodities, peanuts, pecans, macadamia nuts, and ginseng may use State, regional, or locality label designations in lieu of country of origin labeling. Abbreviations may be used for state, regional, or locality label designations for these commodities whether domestically harvested or imported using official United States Postal Service abbreviations or other abbreviations approved by CBP.

RECORDKEEPING

§ 65.500 Recordkeeping requirements.

(a) *General.* (1) All records must be legible and may be maintained in either electronic or hard copy formats. Due to the variation in inventory and accounting documentary systems, various forms of documentation and records will be acceptable.

(2) Upon request by USDA representatives, suppliers and retailers subject to this subpart shall make available to USDA representatives, records maintained in the normal course of business that verify an origin claim. Such records shall be provided within 5 business days of the request and may be maintained in any location.

(b) *Responsibilities of suppliers.* (1) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must make available information to the buyer about the country(ies) of origin of the covered commodity. This information may be provided either on the product itself, on the master shipping container, or in a document that accompanies the product through retail sale. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of lamb, chicken, and goat, is the slaughter facility, must possess records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. For that purpose, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking (i.e., “CAN” or “M”) may use that information as a basis for a U.S. origin claim. Packers that slaughter animals that are part of another country’s recognized official system (e.g. Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. Producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction.

(2) Any intermediary supplier handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the intermediary supplier relied on the designation provided by the initiating supplier or other intermediary supplier, unless the intermediary supplier willfully disregarded information establishing that the country of origin declaration was false.

(3) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly (i.e., including but not limited to growers, distributors, handlers,

packers, and processors), must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of a covered commodity for a period of 1 year from the date of the transaction.

(4) For an imported covered commodity (as defined in §65.300(f)), the importer of record as determined by CBP, must ensure that records: provide clear product tracking from the port of entry into the United States to the immediate subsequent recipient and accurately reflect the country of origin of the item as identified in relevant CBP entry documents and information systems; and must maintain such records for a period of 1 year from the date of the transaction.

(c) *Responsibilities of retailers.* (1) In providing the country of origin notification for a covered commodity, in general, retailers are to convey the origin information provided by their suppliers. Only if the retailer physically commingles a covered commodity of different origins in preparation for retail sale, whether in a consumer-ready package or in a bulk display (and not discretely packaged) (i.e., full service meat case), can the retailer initiate a multiple country of origin designation that reflects the actual countries of origin for the resulting covered commodity.

(2) Records and other documentary evidence relied upon at the point of sale to establish a covered commodity’s country(ies) of origin must either be maintained at the retail facility or at another location for as long as the product is on hand and provided to any duly authorized representative of USDA in accordance with §65.500(a)(2). For pre-labeled products, the label itself is sufficient information on which the retailer may rely to establish the product’s origin and no additional records documenting origin information are necessary.

(3) Any retailer handling a covered commodity that is found to be designated incorrectly as to the country of origin shall not be held liable for a violation of the Act by reason of the conduct of another if the retailer relied

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on the designation provided by the supplier, unless the retailer willfully disregarded information establishing that the country of origin declaration was false.

(4) Records that identify the covered commodity, the retail supplier, and for products that are not pre-labeled, the country of origin information must be maintained for a period of 1 year from the date the origin declaration is made at retail.

[74 FR 2704, Jan. 15, 2009, as amended at 81 FR 10761, Mar. 2, 2016]

Subpart B [Reserved]

PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD

Subpart A—General Provisions

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AUTHORITY: 7 U.S.C. 1621 *et seq.*

SOURCE: 83 FR 65871, Dec. 21, 2018, unless otherwise noted.

Subpart A—General Provisions

§ 66.1 Definitions.

Act means the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*), as amended to include Subtitle E—National Bioengineered Food Disclosure Standard and Subtitle F—Labeling of Certain Food.

Administrator means the Administrator of the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

AMS means the Agricultural Marketing Service of the United States Department of Agriculture.

Bioengineered food means—

(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition:

(i) A food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; *provided that*

(ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.

(2) A food that meets one of the following factors and conditions is not a bioengineered food.

(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3).

(ii) [Reserved]

Bioengineered substance means substance that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be