



December 19, 2012

**From:** Biologist, Regulatory Team 2, Division of Biotechnology and GRAS Notice Review (HFS-255)

**Through:** Annette M. McCarthy, Ph.D, Senior Science and Policy Staff\_\_\_\_\_

**To:** Division of Food Contact Notifications (HFS-275)

**Attention:**

**Subject:** FALP 003 – Request for an exemption from the Section 403(w)(1) labeling requirements as described in Section 403(w)(6) for soy lecithin products produced by Solae, LLC., when used as release agents applied to food-contact surfaces.

**Notifier:** Solae, LLC.

Attached is the Finding of No Significant Impact (FONSI) for FALP 003. After this petition is approved, copies of this FONSI and the environmental assessment, dated December 11, 2012, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the subject products.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt

File: FALP 003

## FINDING OF NO SIGNIFICANT IMPACT

A Food Allergen Labeling Petition (FALP No. 003), submitted by Solae, LLC., requesting an exemption from the Section 403(w)(1) labeling requirements as described in Section 403(w)(6) for soy lecithin products

The Office of Food Additive Safety has determined that approval of this petition will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on an environmental assessment, dated December 11, 2012, as discussed below.

Lecithin is authorized for use in food with no limitation other than current good manufacturing practice under 21 CFR 184.1400(a)<sup>1</sup> which states that “Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils.” Furthermore, the regulations state in 21 CFR 184.1400(b) that food grade soy lecithin must meet the specifications of the Food Chemicals Codex, 8th Edition (2012), pages 634-634.

No new uses of lecithin are authorized as a result of the requested labeling exemption. Furthermore, although the requested action may result in increased production of lecithin sourced from soy, we do not anticipate an increase in overall lecithin production, as soy, safflower, and corn are considered interchangeable sources, and an increase in demand and production from one source is expected to result in a decrease in one or both of the other sources, depending on market conditions and availability of finite land area. In addition, soy is a field crop; therefore, no impacts on species survival are expected to result from approval of the petitioned action

The proposed action applies only to specific soy lecithin products produced by Solae when used as a release agent applied to food-contact surfaces. The sticking of foods to food-contact surfaces causes manufacturers to experience product loss, increased re-working of products and increased downtime for cleaning. Lecithin's dual molecular structure, which gives it an affinity both for fat and water, enables it to prevent food items from sticking. Soy lecithins provide multi-functional benefits in release applications.

Solae's soy lecithin products are manufactured from crude soybean oil. USDA statistics as of August 2012 show an increase in soybean oil supply and use between the 2000/2001 and 2010/2011 marketing years, with biodiesel representing an increasing share of use. In 2009, soybean oil comprised 28% of worldwide edible oil production. In 2010, it represented 65% of U.S. vegetable oil consumption. Domestic soybean oil production increased in 2011/12 over 2009 and 2010 levels, and is projected to continue to rise.

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<sup>1</sup> See also 21 CFR 184.1(b)(1)

Lecithin production is but one aspect of a larger soy-based product market. Furthermore, soy lecithin used as a release agent applied to food-contact surfaces represents a smaller subset of lecithin applications. A 2005 report by the Food Extract Manufacturer's Association (FEMA) lists a lecithin market disappearance (= use) rate of 120,500 lbs/yr for all uses of lecithin, regardless of source. According to USDA Economic Research Service (ERS), domestic soybean oil production reached 17,300 million pounds in 2005.<sup>2</sup> Thus, lecithin use in 2005 represented  $7 \times 10^{-6}$  % of soybean oil production.

A number of factors technically limit the amount of lecithin that is applied to food products as processing aids during food production. These factors include food processing equipment design, finished product quality (color and flavor), cost, and ease of clean-up. Consequently, inclusion levels, for processing aid purposes, are constrained by a variety of factors and depend on the application, customer, etc. Although individual use levels are confidential, the highest use level listed, by weight of the finished product, is ■■■.

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<sup>2</sup> <http://www.ers.usda.gov/data-products/agricultural-baseline-database/custom-queries.aspx> accessed on 9/26/12

These data and statistics serve to illustrate the robust and expanding nature of the U.S. soybean oil market and the Agency's position that FDA approval of this food allergen labeling petition submitted under section 403(w)(6) of the FD&C Act for Solae soy lecithin used as a release agent applied food-contact surfaces is expected to lead to an incremental increase in soybean demand above current trends, and, thus, will not result in significant environmental impacts. Furthermore, approval of this petition is not expected to result in significant changes to agricultural growing practices or land use patterns.

Prepared by \_\_\_\_\_ Date: December 12, 2012

Leah D. Proffitt  
Biologist  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Approved by \_\_\_\_\_ Date: December 17, 2012

Annette M. McCarthy, Ph.D.  
Senior Science and Policy Staff  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

## **Environmental Assessment for FALCPA Petition 003 for Solae Soy Lecithin**

**1. Date:** December 11, 2012

**2. Name of Petitioner:** Solae, LLC.

**3. Address:** 4300 Duncan Avenue, St. Louis, MO 63110

**4. Description of the Proposed Action:**

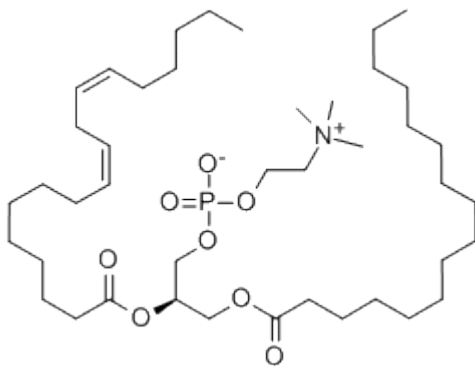
Request for an exemption from the Section 403(w)(1) labeling requirements as described in Section 403(w)(6) for soy lecithin products described in Item 5 of this EA when used as release agents applied to food-contact surfaces.<sup>1</sup> The products in question are already being used as release agents in the production of foods currently on the market. The proposed action requests that these food products henceforth be exempted from allergen labeling requirements.

**5. Identification of substances that are the subject of the proposed action**

The proposed action applies only to specific soy lecithin products produced by Solae when used as a release agent applied to food-contact surfaces. These products, trade names SOLECT™ E, SOLECT™ F, SOLECT™ NVS, SOLECT™ 152, SOLECT™ K-EML, SOLECT™ HR, and SOLECT™ M, are modified versions of lecithin (C<sub>42</sub>H<sub>80</sub>NO<sub>8</sub>P) sourced from soy.

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<sup>1</sup> Original petition received June 12, 2007. Addenda Nos. 1 & 2 received April 14, 2008, and February 17, 2011, respectively



Molecular structure of lecithin

Product Standard sheets are provided with the petition and are attached to this EA as attachments 1 - 7. Furthermore, Addendum #2 describes each of the above-listed products as follows:

- SOLEC™ E is the most water dispersible lecithin product offered. It is commonly used on oven belts and griddles where a lecithin-in-water dispersion (typically 5-15% lecithin in water) is preferred.
- SOLEC™ F is included in the list because it is a powder while all others are liquids. A powdered lecithin is required by customers who cannot weigh, transfer or blend fluids in their production process.
- SOLEC™ NVS is used where a very low viscosity lecithin product (max. 300 cP at 25°C) is necessary in order for it to be finely atomized through an air assisted spraying system without heating or further diluting to reduce the viscosity of the lecithin.
- SOLEC™ 152 is a viscosity controlled lecithin that is required by some customers who have systems designed to handle liquids with a maximum viscosity of 1,500 cP at 25°C.
- SOLEC™ K-EML and SOLEC™ HR are modified lecithin products designed to meet the in-process requirement unique to certain food processors.
  - o The modification of SOLEC™ K-EML allows it to associate with starch to a much greater degree than other lecithin products.
  - o The modification of SOLEC™ HR makes it resistant to darkening when exposed to heat thereby enabling normal processing conditions for foods where other lecithin products would impart an undesirable dark color to the food surface.
- SOLEC™ M is a fluid lecithin product that is produced by combining powdered lecithin (SOLEC™ F) with special vegetable oils to obtain a fluid having unique

properties. It is unique in that it is a bland flavored lecithin product that also has high stability against the development of off flavors from lipid oxidation. This product is used as a release agent on cooled contact surfaces for processed cheese where preventing a flavor impact from the lecithin is essential.

#### ***6. Lecithin Use from All Sources***

Lecithin is authorized for use in food with no limitation other than current good manufacturing practice under 21 CFR 184.1400(a)<sup>2</sup> which states that “Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils.” Furthermore, the regulations state in 21 CFR 184.1400(b) that food grade soy lecithin must meet the specifications of the Food Chemicals Codex, 8th Edition (2012), pages 634-634.

No new uses of lecithin from all sources (e.g., soy, corn, etc.) will be authorized as a result of the requested labeling exemption. Furthermore, although the requested action may result in increased production of lecithin sourced from soy, we do not anticipate an increase in overall lecithin production, as soy, safflower, and corn are considered interchangeable sources, and an increase in demand and production from one source is expected to result in a decrease in one or both of the other sources, depending on market conditions and availability of finite land area. This expectation is supported by a 2007 report from the North Dakota field office of USDA National Agriculture Statistics Service (NASS) which explains that “the extent of future [soybean] acreage and production increases could be limited by several factors, particularly competition for area from other crops (primarily corn)...” (North Dakota Farm Reporter, May 4, 2007, Ref # 1).

A market research report completed in 2005 by the Food Extract Manufacturers Association (FEMA) lists a lecithin market disappearance (= use) rate of 120,500 lbs/yr

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<sup>2</sup> See also 21 CFR 184.1(b)(1)

for *all uses* of generic lecithin (i.e. direct or indirect additive as anticaking agent, antioxidant, drying agent, emulsifier, etc.). (2005 Market Disappearance Report for Lecithin, Food Extract Manufacturer's Association, Ref # 2). This use rate captures lecithin produced from all sources, including soy.

The proposed action applies only to specific soy lecithin products produced by Solae when used as a release agent applied to food-contact surfaces. The sticking of foods to food-contact surfaces causes manufacturers to experience product loss, increased re-working of products and increased downtime for cleaning. Lecithin's dual molecular structure, which gives it an affinity both for fat and water, enables it to prevent food items from sticking. Soy lecithin products provide multi-functional benefits in release applications.<sup>3</sup>

## **7. Environmental consequences of proposed action**

Since Solae's products are derived from a natural source, this environmental assessment must examine the possibility of significant impacts to the natural environment. Approval of this food allergen labeling petition can be reasonably expected to lead to an increase in consumer demand for foods produced with Solae products used as release agents applied to food contact surfaces. However, soy is a field crop with many uses. Therefore, no impacts on species survival are expected to result from approval of the petitioned action. However, an increase in the demand for soybeans does have the potential to cause considerable changes in existing growing practices and land use patterns. An analysis of whether potential significant impacts could occur as a result of changes to existing growing practices or land use patterns resulting from the action is explored in detail below.

### *a. Soybean Production*

Soybean production has exhibited an upward trend over the past 2 decades with the exception of 2007 which represents an abnormal decrease in overall production. (Table

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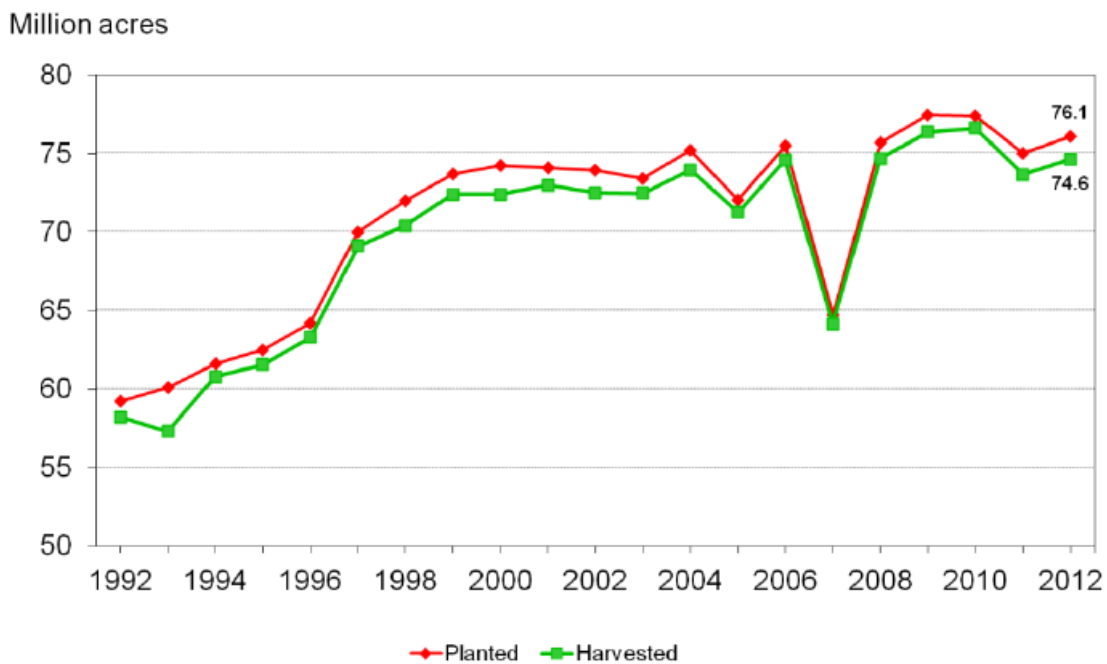
<sup>3</sup> <http://www.solae.com/Soy-Ingredients/Lecithin/Lecithin-Applications.aspx#spray>



1, 2007 Census of Agriculture, USDA NASS, Ref # 3). In 2011, total land in farms for all crops was approximately 917 million acres (Page 8, Farms, Land in Farms, and Livestock Operations 2011 Summary, February 2012, USDA NASS, Ref # 4), with soybeans comprising roughly 75 million acres for 8.17% of all land in farms. This is in comparison to the roughly 59 million acres of soybeans planted in 1992.



## U.S. Soybean Acres



USDA-NASS  
08-10-12

### *b. Production of Lecithin from Soybeans*

According to the information provided in the petition, Solae’s soy lecithin products that are the subject of this action belong to one of three classes, defined by their respective manufacturing processes: refined lecithin, reacted lecithin, and de-oiled lecithin. The individual processes are designated “company confidential;” however, crude soybean oil is the feedstock for all three processes. According to a petition submitted by Clarkson Soy Products, LLC., to the USDA Agricultural Marketing Service on June 26, 2008, refined, reacted and de-oiled lecithin made up approximately 58% of the world market

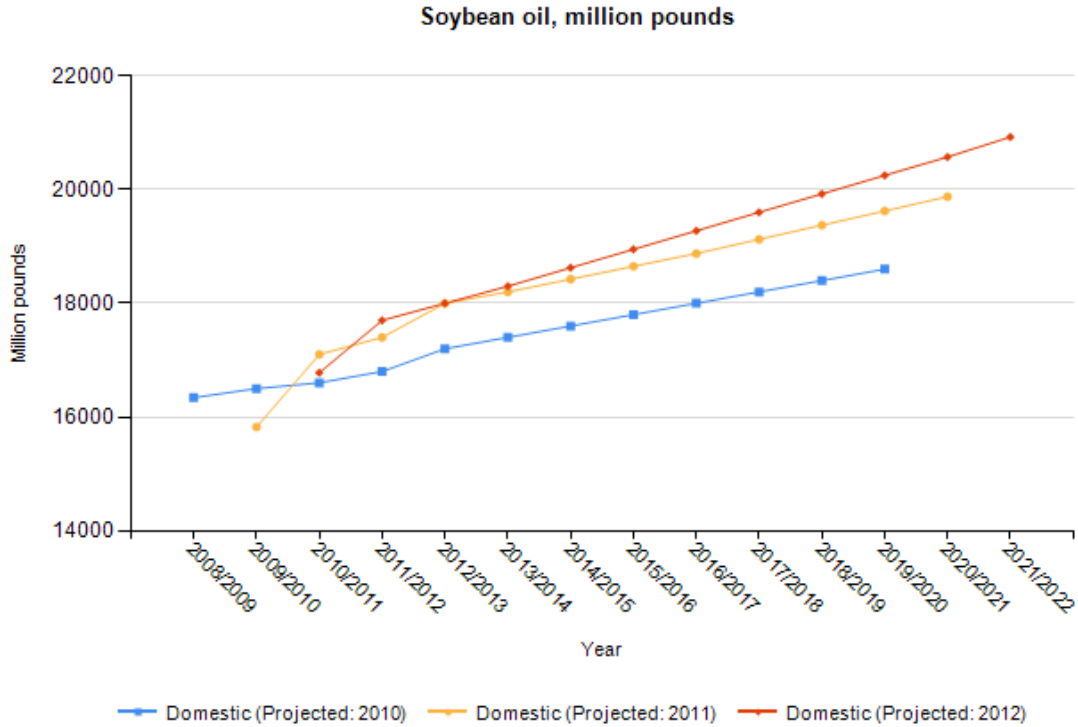
share of lecithin products (Ref # 5). Furthermore, USDA statistics as of August 2012 show an increase in soybean oil supply and use between the 2000/2001 and 2010/2011 marketing years, with biodiesel representing an increasing share of use.<sup>4</sup>

In 2009, soybean oil comprised 28% of worldwide edible oil production (An Overview of the Edible Oil Markets: Crude palm Oil vs. Soybean Oil, July 2010 CME Group, Ref # 6). In 2010, it represented 65% of U.S. vegetable oil consumption (Soybean Oil Innovations, United Soybean Board, Ref # 7). Domestic soybean oil production increased in 2011/12 over 2009 and 2010 levels, and is projected to continue to rise, as illustrated below:

**Soybean oil, million pounds**

	2008/20 09	2009/20 10	2010/20 11	2011/20 12	2012/20 13	2013/20 14	2014/20 15	2015/20 16	2016/20 17	2017/20 18	2018/20 19	2019/20 20	2020/20 21	2021/20 22
Domestic (Projected: 2010)	16339	16500	16600	16800	17200	17400	17600	17800	18000	18200	18400	18600		
Domestic (Projected: 2011)		15822	17100	17400	18000	18200	18425	18650	18875	19125	19375	19625	19875	
Domestic (Projected: 2012)			16779	17700	18000	18300	18625	18950	19275	19600	19925	20250	20575	20925

<sup>4</sup> Table 6 at <http://www.ers.usda.gov/data-products/us-bioenergy-statistics.aspx#30037> accessed on 9/19/12)

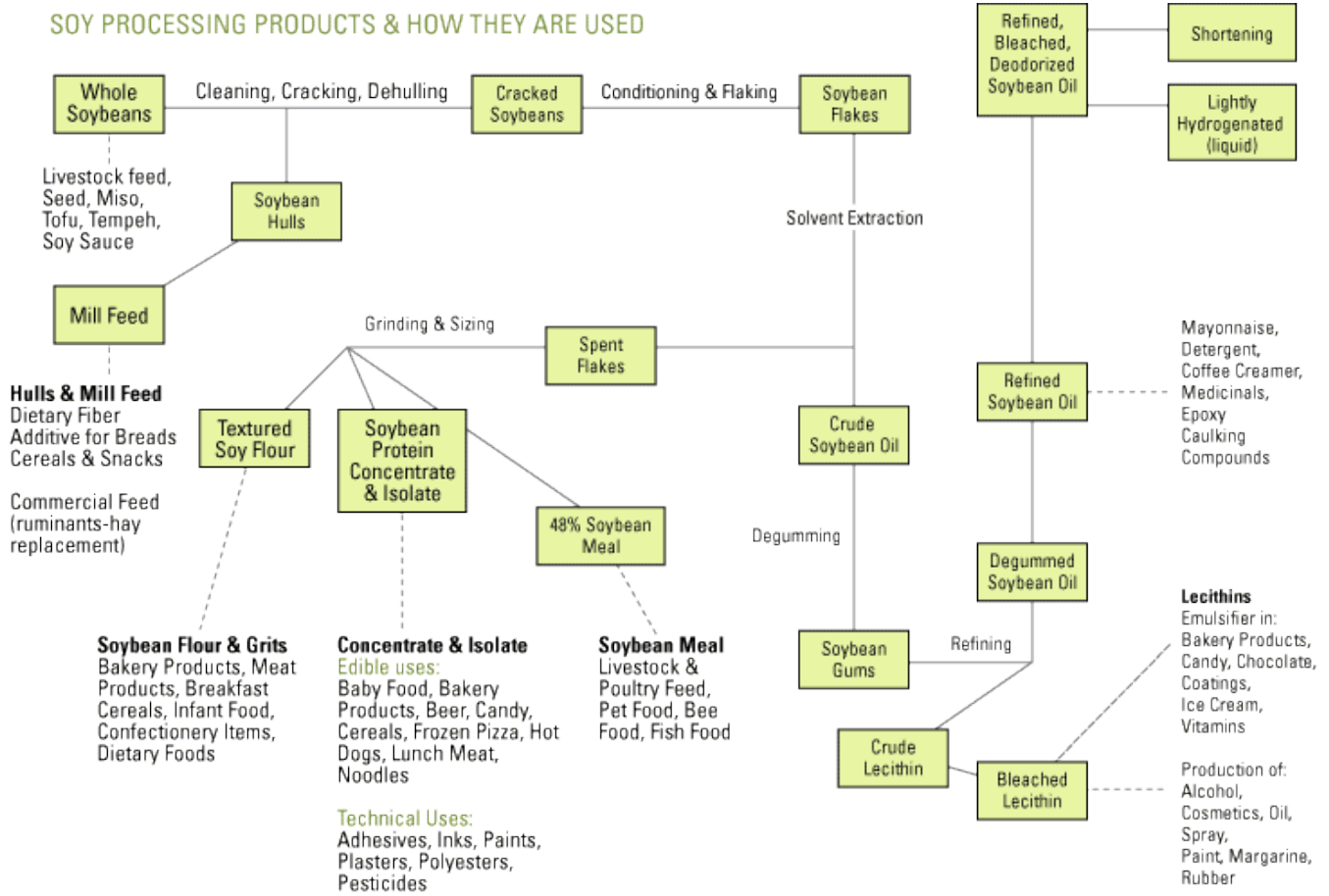


Source: USDA ERS <http://www.ers.usda.gov/data-products/agricultural-baseline-database/custom-queries.aspx>

As shown in the graphic below, lecithin production is but one aspect of a larger soy-based product market. Furthermore, soy lecithin used as a release agent applied to food-contact surfaces represents a smaller subset of lecithin applications. As stated earlier, the 2005 FEMA report lists a lecithin market disappearance (= use) rate of 120,500 lbs/yr for all uses of lecithin, regardless of source. According to USDA Economic Research Service (ERS), domestic soybean oil production reached 17,300 million pounds in 2005.<sup>5</sup> Thus, total lecithin use in 2005 represented  $7 \times 10^{-6}$  % of soybean oil production. Based on market trend data 82 to 93% of lecithin on the market is derived from soybeans. Therefore, even if it is assumed that, as a result of this action, the use of soy lecithin increases such that it accounts for 100% of the total lecithin market, the production

<sup>5</sup> <http://www.ers.usda.gov/data-products/agricultural-baseline-database/custom-queries.aspx> accessed on 9/26/12

volume is insignificant relative to other soybean oil uses and even smaller relative to the overall soybean market.<sup>6</sup>



Source: National Soybean Research Laboratory  
[http://www.nsrll.illinois.edu/aboutsoy/images/processing\\_diagram.gif](http://www.nsrll.illinois.edu/aboutsoy/images/processing_diagram.gif)

A number of factors technically limit the amount of lecithin that is applied to food contact surfaces as release agents during food production. These factors include food processing equipment design, finished product quality (color and flavor), cost, and ease of clean-up. Consequently, inclusion levels, for use as release agents applied to food contact surfaces, are constrained by a variety of factors and depend on the application, customer, etc. Although individual use levels are confidential, the highest use level

<sup>6</sup> Information & findings published above was sourced from LabelBase by FoodEssentials with product label data provided by Gladson Interactive and Mintel International Group, accessed on 12/5/12

listed, by weight of the finished product, is ■ (Table 1 in Attachment 8, Confidential Information).

These data and statistics provided in this EA serve to illustrate the robust and expanding nature of the U.S. soybean oil market, and support the Agency's position that FDA approval of this food allergen labeling petition submitted under section 403(w)(6) of the FD&C Act for Solae soy lecithin used as a release agent applied food-contact surfaces is expected to lead to an incremental increase in soybean demand above current trends, and, thus, will not result in significant environmental impacts. Furthermore, approval of this petition is not expected to result in significant changes to agricultural growing practices or land use patterns.

#### ***8. Use of Resources and Energy***

No increase in energy or resource use is expected, since no new uses will result from this action.

#### ***9. Mitigation measures***

No mitigation is needed because no significant environmental impact is expected.

#### ***10. Alternatives to the Proposed Action***

Alternatives to the proposed action need not be considered, because no potential adverse environmental effects have been identified.

#### ***11. Certification***

The undersigned officials certify that the information presented is true, accurate, and complete to the best of the knowledge of the Agency.

**12. Preparer(s)**

\_\_\_\_\_  
Date: December 12, 2012

Leah D. Proffitt  
Biologist  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

\_\_\_\_\_  
Date: December 17, 2012

Annette M. McCarthy, Ph.D.  
Lead Environmental Review Scientist  
Senior Science and Policy Staff  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

## **12. References**

- 1 North Dakota Farm Reporter, May 4, 2007,  
[http://www.nass.usda.gov/Statistics\\_by\\_State/North\\_Dakota/Publications/Farm\\_Reporter/2007/fr0907.pdf](http://www.nass.usda.gov/Statistics_by_State/North_Dakota/Publications/Farm_Reporter/2007/fr0907.pdf), accessed on 9/26/12
- 2 2005 Market Disappearance Report for Lecithin, Food Extract Manufacturer's Association (FEMA)
- 3 2007 Census of Agriculture, USDA NASS
- 4 Farms, Land in Farms, and Livestock Operations 2011 Summary, February 2012, USDA NASS
- 5 Clarkson Soy Products, LLC petition to remove "Lecithin – Bleached" from National List, June 26, 2008, Figure 3;  
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5073281>;  
accessed on 9/26/12
- 6 An Overview of the Edible Oil Markets: Crude palm Oil vs. Soybean Oil, July 2010 CME Group
- 7 Soybean Oil Innovations, 2<sup>nd</sup> Ed., United Soybean Board

## **Attachments**

- 1: Solae SOLEC<sup>TM</sup> E Product Standard sheet
- 2: Solae SOLEC<sup>TM</sup> F Product Standard sheet
- 3: Solae SOLEC<sup>TM</sup> NVS Product Standard sheet
- 4: Solae SOLEC<sup>TM</sup> 152 Product Standard sheet
- 5: Solae SOLEC<sup>TM</sup> K-EML Product Standard sheet
- 6: Solae SOLEC<sup>TM</sup> HR Product Standard sheet
- 7: Solae SOLEC<sup>TM</sup> M Product Standard sheet
- 8: Confidential information

Attachments redacted, pages 16-23, (b)(4)