

BODYBIO

SOP# 02-014.2	Standard Operating Procedure	Written/Revised by: <i>[Signature]</i> 08/19/22
Effective Date AUG 22 2022	BodyBio's Allergen Control Program	Approved By: <i>[Signature]</i> 8/22/22
Supersedes 03-06-19		Page 1 of 5

1.0 Purpose

- 1.1 To control the use, storage and labeling of allergens in the plant, in our products and on labels.

2.0 Scope

- 2.1 This procedure applies to all personnel involved in the manufacturing, processing, packaging, or holding of product at Bodybio.

3.0 Responsibility and Frequency

- 3.1 Manufacturing Manager, Demand and Logistics Manager, Quality Control and Warehouse personnel will be responsible for Allergen management.

4.0 References

- 4.1 Food Allergen Labeling And Consumer Protection Act of 2004 (FALCPA)
- 4.2 Components of an Effective Allergen Control Plan
- 4.3 Writing and Implementing an Allergen Control Plan

5.0 Allergens

- 5.1 Approved for use in plant
 - 5.1.1 Lecithin (Soy)
 - 5.1.1.1 Solec F
 - 5.1.1.2 Solec FP-40
 - 5.1.1.3 Bulk Phosphatidylcholine Liquid
 - 5.1.1.3.1 Bulk Capsules
 - 5.1.2 Fish Oil (Fish)
 - 5.1.2.1 Bulk Capsules
 - 5.1.3 CoQ10 (Soy)

BODYBIO

SOP# 02-014.2	Standard Operating Procedure	Written/Revised by: <i>[Signature]</i> 08/19/22
Effective Date AUG 22 2022	BodyBio's Allergen Control Program	Approved By: <i>[Signature]</i> 8/22/22
Supersedes 03-06-19		Page 2 of 5

5.1.3.1 Bulk Capsules

5.2 Location in plant

5.2.1 All approved allergen components will be kept together and not stored above a non-allergen product.

5.2.1.1 Area will be marked to designate area, a bright yellow sign that says "Allergen Area".

5.2.1.2 Non-allergen products may be stored above allergen products if necessary

5.2.1.3 Each pallet/box will also be labeled as an allergen

5.2.1.3.1 Each type of Allergen will have a designated color

5.2.1.3.1.1 Soy-yellow

5.2.1.3.1.2 Fish-grey

5.2.2 When Allergen is in process the line will be labeled with an allergen sign in its designated allergen color.

5.2.3 When the Allergen is being sampled, the sampling area will be well ventilated, away from non allergen products and designated with an Allergen sign.

5.3 Equipment for Allergen Products

5.3.1 Scoops, Utensils and Bins

5.3.1.2 Use disposable whenever possible or a cleaned and sanitized item.

5.3.2 Liquid Filler Machine

5.3.2.1 Dedicated to Allergen product

5.3.3 Capsule Counter

5.3.3.1 Must be washed and sanitized between products or prior to running a non allergen product

BODYBIO

SOP# 02-014.2	Standard Operating Procedure	Written/Revised by: <i>Janet</i> 08/19/22
Effective Date AUG 22 2022	BodyBio's Allergen Control Program	Approved By: <i>Elly</i> 8/22/22
Supersedes 03-06-19		Page 3 of 5

6.0 Suppliers

6.1 Verify that your suppliers have an Allergen Control Plan (ACP)

6.1.1 Initial Qualification and Requalification of Vendor (SOP 04-036)

6.1.1.1 Ensure that all suppliers have a completed Vendor Audit Form (SOP 04-002).

7.0 Label Requirements of Products containing an Allergen

7.1 FALCPA is an amendment to FDA and requires that the label of a food/dietary supplement that contains a protein from a "major food allergen" must declare the presence in the manner described by the law.

7.1.1 "Major Food Allergens"

7.1.1.1 Milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans

7.2 Declaration of Allergen

7.2.1 In the list of ingredients, highlight the allergen in parenthesis after the food source.

7.2.1.1 Lecithin (**soy**)

7.2.2 Place the word "Contains" followed by the name of the food source immediately after or adjacent to the list of ingredients.

7.2.2.1 Contains Soy

7.2.3 The type of tree nut, fish, and crustacean shellfish must be declared

7.3 Labels must be reviewed and monitored during, but not limited to, the following processes:

BODYBIO

SOP# 02-014.2	Standard Operating Procedure	Written/Revised by: <i>Janet</i> 08/19/22
Effective Date AUG 22 2022	BodyBio's Allergen Control Program	Approved By: <i>Elia Rom</i> 8/22/22
Supersedes 03-06-19		Page 4 of 5

7.3.1 Label approval, review of incoming labels, inventory and staging control.

7.3.2 All formulation changes are immediately reflected on labels and all out of date labels are discarded in a timely manner.

8.0 Training

8.1 All employees at all levels will have general allergen control and awareness training.

8.2 Documentation of specific training to those employees dictated by their job responsibilities will be filed in the employees training file.

8.3 All training will include information on the reasons and the consequences should the plan not be followed.

9.0 Documentation

9.1 Production batch folders, processing signs and paperwork must have "Allergen" declaration.

9.2 Documented cleaning records of equipment used with allergen material

9.3 Documented training records

9.4 Documenting any problems or non conformances with the Allergen Control Plan

9.4.1 Define the extent of the problem and the corrective action needed (SOP 04-009)

BODYBIO

SOP# 02-014.2	Standard Operating Procedure	Written/Revised by: <i>Jawad</i> 08/19/22
Effective Date AUG 22 2022	BodyBio's Allergen Control Program	Approved By: <i>Elly Romy</i> 8/22/22
Supersedes 03-06-19		Page 5 of 5

Revision History

Date	Revision	Comments
08/31/16	0	New
03-06-19	1	Removed Attachment 1. Updated format. Corrected numbering of sections.
AUG 22 2022	2	Fixed Format. Added Demand and Logistics Manager to responsibility. Changed Kirunal to Fish Oil.