

	<b>Standard Operating Procedure</b> <b>Declaration Claims and Allergen</b> <b>Requirements for Raw Materials and</b> <b>Finished Products</b>	<b>SOP Number</b> <b>D-307</b>	<b>Revision</b> <b>2</b>
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## 1.0 Purpose

The purpose of this procedure is to provide details regarding any declaration claims and allergen requirements necessary for raw materials and finished products to support any label claims. Example declaration would be organic, kosher, Halal, not Bioengineered, etc. Example allergen requirement would be, gluten free, soy free, dairy free, etc.

## 2.0 Scope

This procedure is applicable in establishing the definition and internal coding for any declaration claims for raw materials. This procedure will also be the reference point for any raw material that is required to be evaluated for a declaration claims, meaning if the release of any raw material requires the material to be classified with any declaration then this procedure will be used as a trigger mechanism on the specification for this evaluation. Management of allergen requirements on finished products is also included in the scope of this procedure.

## 3.0 Responsibility

3.1 It is the responsibility of the Account Managers, QC Laboratory, R&D, QA, and Purchasing to establish any appropriate raw material declaration and/ or Finished product allergen requirements.

3.1.1 The account managers must request any declaration claims or allergen requirements from the client at the beginning stages of establishing any new finished product.

3.1.2 R&D will formulate to and apply these declarations and/or allergen requirements to any raw materials associated with them.

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## 4.0 Definitions

- 4.1 **Organic** – Ingredients grown without the use of pesticides, synthetic fertilizers, sewage sludge, genetically modified organisms, or ionizing radiation
- 4.2 **Kosher** – Ingredients that fulfill the requirements of Jewish dietary law
- 4.3 **Halal** – Ingredients that fulfill the requirements of Islamic dietary law
- 4.4 **Allergen Free** – Ingredients declared to not contain any of the specific allergens, i.e. gluten, nut, dairy, shellfish, soy
- 4.5 **GMO (Bioengineered)** – Genetically modified organism; any organism whose genetic material has been altered using genetic engineering techniques. The special declaration in this case is typically “Non-GMO” or “Non-Bioengineered”.
- 4.6 **Vegan** – Ingredients not of animal origin, including milk, eggs, honey, and gelatin
- 4.7 **Vegetarian** – Ingredients not of animal origin, with the exception of milk, eggs, beeswax, honey and propolis, their constituents and products derived from them
- 4.8 **NSF** - National Sanitation Foundation
- 4.9 **QA** – Quality Assurance
- 4.10 **QC** – Quality Control
- 4.11 **R&D** – Research and Development
- 4.12 **PPM** – Parts per Million

## 5.0 References

- 5.1 D-105, SOP, Out of Specification / Out of Trend Investigation

**6.0 Procedure**

6.1 Establishment of Declarations

6.1.1 At the time of project initiation, the responsible account manager will determine if any declaration claims are necessary for the finished product. R&D will transfer these declaration claims to raw materials associated with the formulation of the product. This information will be communicated with purchasing to facilitate obtaining the appropriate documents from the raw material suppliers to support needed declarations.

6.2 Storage of Declarations

6.2.1 Once the needed declarations are obtained, purchasing will forward all documents to Document Control and/or QA. Document Control and/or QA will store documents in an electronic controlled central location.

6.3 Declaration Codes

6.3.1 When a raw material is required to be of a declaration claim, the raw material should be identified with the necessary declaration. When a new raw material is created in Batchmaster, the corresponding declaration box will be checked as part of its Item master details page set-up. Allergens will also be identified as of part of the raw material’s item master details page set up. The declarations are coded as defined below:

Declaration	Abbreviation
Vegan	VGN
Vegetarian	VGT
Organic	ORG
Not Bioengineered	nBE
Kosher	KOSH
Halal	HAL
Gluten-Free	GF
Soy-Free	SF
Allergen-Free	AF

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#### 6.4 Testing – Raw Materials

6.4.1 If a specific declaration is needed for any raw material, the raw material specification will be set-up to indicate this as a necessary test to complete for raw material release. This SOP number will be referenced on the specification along with the specific declaration. This “test” will then be completed by the QC Lab by locating the document(s) in the electronic location, confirming the necessary documents are present, and indicating this on the raw material test ticket. If the required documentation is not available then that test for the RM is not complete until the documentation is collected, or it is confirmed that the material does not support the declaration claim. If the declaration is not supported, then the test will fail and the material will be dispositioned as applicable.

#### 6.5 Testing – Finished Products

6.5.1 For allergen-free finished product certifications, testing procedures will be executed using the following guidelines:

6.5.1.1 The name of the testing kit or outside lab used will be identified on testing documentation.

6.5.1.2 Allergens will be evaluated individually on, at minimum, beginning, middle, and end of the final packaged product. Final Packaged product is defined as the final process step completed internally before batch can be released.

6.5.1.3 For NSF Certified Gluten-Free products, the product lot is considered compliant if gluten is observed at <15 ppm.

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6.5.1.4 If the results of the allergen testing do not meet acceptance criteria, proceed with an Out of Specification investigation per SOP D-105 Out of Specification / Out of Trend Investigation.

6.5.1.5 If a product is found to be out of compliance, the quality unit will notify NSF of the failure.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/27/19	New procedure.	N/A	J. Sassman
1	06/09/22	Scheduled review: Updated logo and format.	CC-22-0269	K. Burris
2	10/19/23	Added Finished Products into scope. Added allergen requirements.	CC-23-0521	J. Sassman