

AMENDMENT TO CCC 000039 TO BELIEVER MEATS CULTIVATED CHICKEN SUBMISSION

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Substances used During Cell Culture

Removal of Soy-Derived Enzyme from Production Phase Media

Believer Meats has successfully tested growing chicken fibroblast cells from the commercially approved avian cell line in production phase media containing no soy-derived enzyme. The soy-derived enzyme is the only media input used in the production phase for CCC 000039 containing a food allergen covered by the FASTER Act (U.S. Food and Drug Administration, 2024). While there is no detectable soy-protein present in washed biomass at limit of detection 2.5 ppm, we have conservatively listed "Contains: Soy" as an allergen declaration for the washed cell cultivated chicken because the enzyme manufacturer declares "soy" as an allergen for the enzyme." Removing the soy-derived enzyme from production phase media means there is no allergenicity risk from soy. Additional details were shared as a supplement confidential portion of consultation CCC 000039.

Changes to Allergen Control Plan

For completeness of the administrative record, we would like to confirm and amend previously shared aspects of the allergen control plan based on the removal of the soy-derived enzyme from the media recipe.

Confirmation of Allergen Considerations from Section 7.2.2 of the May 21, 2024, DSN:

In Section 7.2.2 the May 21, 2024 DSN, we discussed allergy considerations for cell cultured chicken related to egg and soy allergens. The removal of the soy-derived enzyme does not affect the safety conclusion that egg allergens are not present in cell cultured chicken. The removal of the soy-derived enzymes eliminates the allergenicity risk for soy and the allergen declaration "Contains: Soy" is not necessary for cell cultured chicken.

Amended Response to Question 8 on the October 4, 2024, DSN:

Believer Meats has an allergen control program to address cross-contamination for milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame as identified by the FALCPA and FASTER Acts. Allergen containing ingredients used in the downstream USDA regulated production process are segregated from media components and materials used in the cell culturing process steps to prevent cross-contamination during storage.

All raw material allergen declarations are reviewed as part of our supplier qualification process. We only source from approved suppliers and verify supplier and material accuracy upon receipt. For any new ingredients or ingredient suppliers, allergen declarations are reviewed and evaluated for new allergen risks as part of our Supplier and Ingredient Qualification Program. If a new allergen is introduced to the facility; the allergen control program is reviewed and updated with appropriate segregation and changeover procedures to prevent cross-contamination.

For cross-contamination within the facility, no food or drink is permitted outside of break areas. Personal hygiene protocols including use of smocks and hand washing prevent undeclared allergens from being introduced to the production area.

Finished product labeling is a control point in our downstream HACCP plan to ensure the appropriate label is present and accurate for the finished product.

References

U.S. Food and Drug Administration. (2024, April 12). *The FASTER act: Sesame is the ninth major food allergen*. . <https://www.fda.gov/food/food-allergies/faster-act-sesame-ninth-major-food-allergen>

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Conclusion for Removal of Soy-Derived Enzyme from Production Phase Media

Based on cell growth data and review of our allergen control plan, removing the soy-derived enzyme from the production phase media has no impact on the safety, composition or regulatory status of cultured cell material, except for removal of soy allergen from cultured cell material.

References

U.S. Food and Drug Administration. (2024, April 12). *The FASTER act: Sesame is the ninth major food allergen*. . <https://www.fda.gov/food/food-allergies/faster-act-sesame-ninth-major-food-allergen>