



November 12, 2024

Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
1400 Independence Ave, SW  
Mailstop 3758  
Washington, DC 20250-3700

Re: FSIS-2024-0010 Availability of FSIS Guideline on Substantiating Animal-Raising or Environment-Related Labeling Claims

Thank you for the opportunity to comment on the *FSIS Guideline on Substantiating Animal-Raising or Environment-Related Labeling Claims* released in August 2024.

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. [www.FMI.org](http://www.FMI.org)

### **Consistency is needed between FSIS and FDA for Labeling Claims**

The criteria set forth in FSIS Guideline on Substantiating Animal-Raising or Environment-Related Labeling Claims, FSIS-GD-2024-0006 (August 2024) (the “Guidance”), for substantiating animal-raising claims is not consistent between FDA and USDA.

Producers of both USDA and FDA regulated products make animal-raising claims on their labels, yet USDA has not aligned with FDA prior to issuance of this guidance, thereby creating confusion for industry and tension between sister agencies. Simply stating that the USDA guidance does not apply to FDA related product labeling is not sufficient to allay the important business concerns that retailers have about regulatory compliance, consumer understanding, and a fair playing field for all products, particularly with respect to products derived from foods over which FDA and USDA share jurisdiction. In order for the industry to comply with all labeling regulations, consistency is needed between agencies.

### **Guidance requires significant administration efforts and requires information not readily available**

This guidance appears to impose requirements on producers to substantiate the raising conditions of every individual animal, rather than seeking substantiation of the producer's animal-raising system as a whole. See Guidance page 17 (requiring producers to substantiate that "the majority of each animal's life was spent on pasture"). It is not practical for producers to provide substantiation documentation on a per-bird basis, nor could FSIS reasonably enforce labeling claims with respect to every individual animal.

### **Scientific Consensus and Scope of Animal Raising Claims Needs to be Considered**

While we understand that Agency Guidance reflects the Agency's current thinking as it relates to special claims, FSIS should rely on the scientific consensus around the appropriate definitions of terms as agreed upon by experts such as veterinarians, animal behaviorists and food safety professionals, and ensure that any such definitions account for the animals' natural instincts. As currently drafted, the Guidance fails to consider the variety of animal-raising options available to producers that take animal welfare and pasture-rotation into account. FSIS should revise its approach in the Guidance to focus on the animal raising system as a whole, rather than any individual animal, which would bring FSIS in alignment with USDA's systems-based approaches in other contexts, i.e., organic certification.

### **Reliance on Third Party Certification**

We are concerned about the potential unintended consequences that may result from the Agency's strong recommendation for the use of third-party certification for substantiation of claims. These concerns include the additional cost resulting from third-party certifications to substantiate claims, lack of oversight over the third-party certification programs and the resources for FSIS to evaluate each third-party certification program (see Guidance page 27).

In the guidance, "FSIS strongly encourages the use of third-party certification to substantiate animal-raising or environment-related claims due to limits of FSIS jurisdiction." We are concerned with FSIS's "strong" recommendation is misleading and suggests to establishments the need for third party certification programs in order to substantiate claims. In many cases, the additional costs of third-party certification may not be feasible and ultimately could limit the variety of products offered for sale, but most importantly, could result in a cost to consumers.

While FSIS indicates in the guidance that they will evaluate certification programs to assess its suitability for substantiating the specific claim, it is not clear how and when the Agency will make this determination. Moreover, how will the "limits of FSIS jurisdiction" impact this evaluation and will the Agency have the appropriate resources available? While third-party certification can be a helpful tool to ensure claims are truthful and not misleading, the third-party programs for animal raising or environment-related claims are not designed to assess regulatory compliance. Without oversight and standardization for the third-party certification programs there will be variability among the different third-party certifications for substantiating a claim. As a result, animal-raising or environment-related claims may have different meanings, depending on the third party.

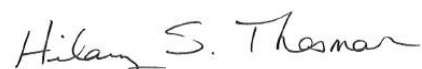
### **Impact of Guidance Needs to be Evaluated**

Changes to labeling policy, including the way in which FSIS evaluates special claims, should be predicated on existing and emerging production practices; economics of production, products and labels; and most importantly evaluation and impact of any changes to consumers. It does not appear that the Agency has conducted such analysis based on information available and we encourage the Agency to do so.

Consumers are increasingly demanding more information about the way their food is manufactured and are willing to pay a premium for products that are manufactured in a way that aligns with their values. While some research exists on consumer perceptions of labeling terms for meat, poultry and egg products, we know that different interpretations exist and can change over time. It is not clear to us whether the Agency has evaluated consumer perceptions of the terms included in the Guidance and, if it has done so, whether it has relied on balanced and fair-minded resources in connection with any such evaluation. Consumer perceptions of the label claims should be evaluated.

We appreciate your consideration of these comments and welcome additional conversations or questions about these comments.

Sincerely,



Hilary Thesmar, PhD, RD, CFS  
Chief Science Officer and SVP Food & Product Safety