



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

DEC 29 2014

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

Section 10012 of the Agricultural Act of 2014 (Pub. L. 113-79), or the 2014 Farm Bill, charged the Secretary of Agriculture with developing a report for the Commissioner of the U.S. Food and Drug Administration, describing how a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture.

The statutory language further required that, in preparing the report, the U.S. Department of Agriculture (USDA) take into account the March 2006 Standard of Identity citizens' petition filed with the Food and Drug Administration, including any current industry amendments or clarifications necessary to update the petition.

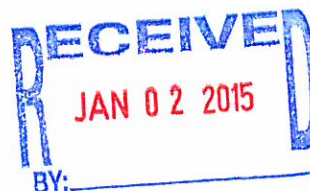
The enclosed report highlights USDA's findings on the need for a Federal standard of identity for honey based on comments received via a notice to the public, which included updated input from the March 2006 petitioners.

Sincerely,

A handwritten signature in blue ink, reading "Tom J. Vilsack", is positioned above the printed name and title of the Secretary.

Thomas J. Vilsack
Secretary

Enclosure



Report to the Commissioner of the Food and Drug
Administration
as Required by the 2014 Farm Bill

“How an Appropriate Federal Standard of Identity for Honey
Would be in the Interest of Consumers,
the Honey Industry, and U.S. Agriculture”

December 2014

EXECUTIVE SUMMARY

Section 10012 of the Agricultural Act of 2014 (Pub. L. 113-79), or the 2014 Farm Bill, charged the Secretary of Agriculture with developing a report describing how a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture. By definition, ([FFDCA Ch. 4. Sec. 401. Sec. 341](#)), a Federal standard of identity, promotes honesty and fair dealing in the interest of consumers.

The Secretary delegated responsibility for completing the report to the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS), Specialty Crops Inspection (SCI) Division. Among its other roles, SCI develops and maintains U.S. standards for many commodities, including honey.

Pursuant to the Farm Bill mandate, AMS gathered input from stakeholders on their interest in a Federal standard of identity for honey. In February 2014, AMS contacted the signatories of the March 2006 standard of identity citizens' petition to the Food and Drug Administration (FDA) to request any current industry amendments or clarifications to the original petition. On April 8, 2014, the petitioners supplied AMS with revised draft language for a standard of identity for honey. On August 20, 2014, AMS published "United States Standard of Identity for Honey" in the Federal Register ([79 FR 49279](#)), with a 30-day comment period. The notice included the most recent information from the petitioners and solicited comments on how a Federal standard of identity would be in the interest of stakeholders. On September 22, 2014, AMS published a notice of extension to the comment period for an additional 30 days until October 19, 2014.

During the 60-day comment period, AMS received 85 comments. This report summarizes those comments. It does not offer a comprehensive representation of the opinions of all consumers, members of the honey industry, or representatives of American agriculture.

Seventy-six, or 89 percent, of the 85 respondents favored establishment of a Federal standard of identity for honey, in some form. The rationale and suggestions for its contents varied among respondents, indicating that while a standard is desired, there is not a clear consensus on its specific content.

BACKGROUND

Farm Bill Mandate

Section 10012 of the Agricultural Act of 2014 (Pub. L. 113-79), the 2014 Farm Bill, charged the Secretary of Agriculture with developing a report describing how a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture. Specifically, the Act called for:

(a) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Agriculture, in consultation with persons affected by the potential establishment of a Federal standard for the identity of honey, shall submit to the Commissioner of Food and Drugs a report describing how an appropriate Federal standard for the identity of honey would be in the interest of consumers, the honey industry, and United States agriculture.

(b) CONSIDERATIONS.—In preparing the report required under subsection (a), the Secretary shall take into consideration the March 2006, Standard of Identity citizens petition filed with the Food and Drug Administration, including any current industry amendments or clarifications necessary to update such petition.

AMS Data Collection

In February 2014, AMS contacted signatories to the original March 2006 standard of identity citizens' petition by email and telephone to request any current industry amendments or clarifications to the original petition that would help its work in implementing the Farm Bill. On April 8, 2014, the petitioners supplied AMS with [revised language for the proposed standard of identity for honey](#). AMS continued correspondence with the petitioners on the content of the proposed revised standard through June 2014.

On August 20, 2014, to garner input from all interested parties, AMS published a notice in the Federal Register ([79 FR 49279](#)), requesting comments on if a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture. The notice included the petitioners' updated language. Originally, the notice included a 30-day comment period. In response to a request from stakeholders to provide additional time for meaningful public participation, on September 22, 2014, AMS published a notice in the Federal Register ([79 FR 56555](#)), extending the comment period by an additional 30 days. The 60-day comment period closed on October 19, 2014.

March 2006 Petition for Federal Standard of Identity for Honey

On March 8, 2006, the American Beekeeping Federation and several other honey producer related associations submitted a [citizens' petition asking the Food and Drug Administration \(FDA\) to adopt a U.S. standard of identity for honey under the Federal Food, Drug, and Cosmetic Act](#). While they sought to base the standard on the Codex Standard for Honey

(CODEX STAN 12-1981, Rev.2 (2001)), the petitioners specified some deviations from the Codex standard. The petitioners asserted that a U.S. standard of identity for honey would do the following: (1) clarify what the term “honey” means with respect to the food’s composition and therefore promote honesty and fair dealing in the interest of consumers; (2) combat economic adulteration of honey by aiding enforcement and industry compliance; and (3) promote honesty and fair dealing within the food trade in general, where pure honey is used as an ingredient in other foods.

On August 7, 2006, the Commissioner of the National Association of State Departments of Agriculture (NASDA) submitted a [letter to the FDA supporting the petition](#). NASDA urged the “FDA to adopt certain provisions of the Codex Standard for Honey [CODEX STAN 12-1981, Rev. 2 (2001)], pursuant to 401 of the Federal Food Drug and Cosmetic Act.” Further, NASDA asked the FDA to ensure that “foods which do not conform to the Honey Codex Standard (by virtue of added ingredients or modifications) be required to be distinguished from ‘Honey’ through non-misleading common or usual name labeling, as would be the case for a food with a standard of identity.”

On October 5, 2011, the [FDA denied the petition](#), noting that the petition did not provide reasonable grounds for the FDA to adopt the Codex standard for honey. The FDA also concluded that the petitioners’ goals could be achieved by existing authorities, and that a standard of identity for honey would not promote honesty and fair dealing in the interest of consumers. To address the labeling issues relevant to the petition and reinforce existing laws and regulations to the industry, in April 2014, the FDA issued a guidance document, which included a summary of the current legal authorities that are most relevant to the labeling of honey, and questions and answers on the labeling of honey.

In April 2014, the FDA published [Draft Guidance for Industry, Proper Labeling of Honey and Honey products](#), which describes the FDA’s current position on the topic and are only recommendations, unless specific regulatory or statutory requirements are cited.

On June 9, 2014, the March 2006 petitioners (i.e., the American Beekeeping Federation, American Honey Producers Association, National Honey Packers and Dealers Association, and Western States Honey Packers and Dealers Association) [submitted comments responding to the FDA draft guidance](#). “[A]s organizations directly affected by language accepted into the Federal Register with any reference to honey, [the petitioners] do not believe a guidance document addressing the proper labeling of honey and honey products will adequately clarify the term “honey” with respect to the food’s composition or promote honesty and fair dealing in the interest of producers, manufacturers, importers, exporters or consumers. We assert that these goals can only be achieved through a federally adopted Standard of Identity for Honey.”

RESPONSES TO AMS FEDERAL REGISTER NOTICE

AMS published a Federal Register notice on August 20, 2014, seeking public comment on how a Federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture. During the 60-day comment period, we received 85 non-duplicative comments.

Summary of Comments

Overall, 76, or 89 percent, of the 85 comments supported establishing a Federal standard of identity for honey in some form. Only 1 commenter clearly stated that a standard of identity is not needed.

Comment	Total Like Responses
1. Standard of identity not needed	1
2. Support a standard of identity	76
3. Request to extend comment period	1
4. Unrelated comments	7
<i>Total Number of Comments</i>	85

Some commenters who favored a standard of identity for honey averred that a standard would bring consistency to marketing, and facilitate transactions in domestic commerce where states currently have varied requirements for, and definitions of, honey.

Some commenters expressed concern that current marketing practices, which allow unrestricted import of substandard product because there is no defined standard for honey, are incrementally putting small honey producers out of business. By defining honey, and establishing separate requirements for major and minor production by volume, small domestic producers could thrive and continue to expand.

Further, some expressed concern if small domestic honey producers continue to be hindered in the market, they may cease operations, including the pollination services they provide. This, in turn, could decrease the overall domestic honeybee population, and negatively impact other small and large honey producers, and U.S. agriculture at large.

Overall, the majority of commenters shared a common concern that the lack of an adequate definition for honey is inconsistent with the interest of the general public, honey producers, and U.S. agriculture. Many commenters provided suggestions for the content and language to be used in a standard of identity for honey. While there was a consensus about the need for a clear

definition for honey, there were disparate opinions about how to frame it. For example, some recommended the inclusion of detailed analytical data, such as:

- Defined filtration levels; commenters voiced on both sides of this subject from no filtration of any kind, to a breakdown by microns with specific allowances for defined styles;
- Raw honey should have a maximum hydroxymethylfurfural (HMF) content of less than 25 mg/kg;
- And requiring a measurable pollen count to identify floral sources, growing region, and excessive filtration.

Others contended that a less detailed standard would be better.

All of the comments received, in their entirety, appear on Regulations.gov at <http://www.regulations.gov/#!docketDetail;D=AMS-FV-14-0025>.

Respondents

Of the 85 comments received, 66 were from individuals. The remaining comments supporting a standard of identity were from organizations with various affiliations with the honey industry.

Respondent Organization	Location
1. Alamo Area Beekeepers Association	Texas
2. American Beekeeping Federation	Georgia
3. American Honey Producers Association	Utah
4. Center for Food Safety	Washington, D.C.
5. Central Maryland Beekeepers Association	Maryland
6. Florida Department of Agriculture and Consumer Services	Florida
7. Food and Water Watch	Washington, D.C.
8. Impex Group	California
9. Monsanto Corporation	Missouri
10. Montgomery County Beekeepers Association	Maryland
11. National Honey Packers and Dealers Association	New Jersey
12. Natural American Foods	Michigan
13. Northeast Texas Beekeepers Association	Texas
14. Robert Mondavi Institute for Wine and Food Science, UC Davis	California
15. Sioux Honey Association	Iowa
16. Specialty Food Association	New York
17. Texas Beekeepers Association	Texas
18. U.S. Pharmacopeial Convention	Maryland
19. Western States Honey Packers and Dealers Association	California

Locations of Commenters

Location	Number of Comments
United States	
- California	9
- Washington, D.C.	3
- Florida	4
- Georgia	2
- Hawaii	1
- Iowa	1
- Illinois	2
- Kansas	1
- Maryland	5
- Michigan	1
- Missouri	1
- North Carolina	1
- New Jersey	3
- New York	2
- Ohio	1
- Tennessee	3
- Texas	29
- Virginia	1
- Wisconsin	1
Mexico	1
Northern Mariana Islands	1
Location unspecified	12
Total Number of Comments	85

In Summary

AMS finds that: 1) the preponderance of comments across multiple regions and organizations support the establishment of a standard of identity for honey; and 2) there are divergent opinions on the content and wording of such a standard, and its relationship to existing international standards. The comments received indicate that while a standard is desired, there is not a clear consensus on its specific content.

REFERENCES

- Comments received, in their entirety, in response to an August 20, 2014, Federal Register notice seeking comment on a Federal standard of identity for honey.
<http://www.regulations.gov/#!docketDetail;D=AMS-FV-14-0025>.
- August 20, 2014, USDA Federal Register Notice Seeking Comment on a Federal Standard of Identity for Honey ([79 FR 49279](#))
 - September 22, 2014, USDA Federal Register Notice Extending Comment Period [79 FR 56555](#)
- [June 9, 2014, Petitioners Response to Draft Guidance](#)
- April 29, 2014, Federal Register Notice Announcing the Availability of Draft Guidance for Industry on the Proper Labeling of Honey ([79 FR 19620](#))
 - April 2014, [FDA Draft Guidance](#), “Proper Labeling of Honey and Honey Products”
- [April 8, 2014, Petitioners’ Draft Proposed Standard of Identity for Honey](#)
- [March 2006, Standard of Identity Citizens’ Petition](#)
- [August 7, 2006, Letter From NASDA to FDA](#)
- [October 2011, Letter of Denial From the FDA](#)