

AMS. FGIS grading and inspection services are provided through a network of federal, state, and private laboratories that conduct tests to determine the quality and condition of corn. These tests are conducted in accordance with applicable standards using approved methodologies and can be applied at any point in the marketing chain. Furthermore the tests yield rapid, reliable, and consistent results. In addition, FGIS-issued certificates describing the quality and condition of graded corn are accepted as *prima facie* evidence in all Federal courts. U.S. Standards for Corn and the affiliated grading and testing services offered by FGIS verify that a seller's corn meet specified requirements, and ensure that customers receive the quality of corn they purchased.

In order for U.S. standards and grading procedures for corn to remain relevant, AMS is issuing this request for information to invite interested parties to submit comments, ideas, and suggestions on all aspects of the U.S. Standards for Corn and official procedures.

**Authority:** 7 U.S.C. 71–87k.

Dated: June 26, 2018.

**Greg Ibach,**

*Under Secretary, Marketing and Regulatory Programs.*

[FR Doc. 2018–14017 Filed 6–28–18; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 810

[Doc. No. AMS–FGIS–18–0054]

#### United States Standards for Soybeans

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Request for information.

**SUMMARY:** The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is seeking comments from the public regarding the United States (U.S.) Standards for Soybeans under the United States Grain Standards Act (USGSA). To ensure that standards and official grading practices remain relevant, AMS invites interested parties to comment on whether the current soybean standards and grading practices need to be changed.

**DATES:** We will consider comments we receive by August 28, 2018.

**ADDRESSES:** Submit comments or notice of intent to submit comments by any of the following methods:

- **Postal Mail:** Please send your comment addressed to Kendra Kline, AMS, USDA, 1400 Independence Avenue SW, Room 2043–S, Washington, DC 20250–3614.

- **Hand Delivery or Courier:** Kendra Kline, AMS, USDA, 1400 Independence Avenue SW, Room 2043–S, Washington, DC 20250–3614.

- **Internet:** Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

**FOR FURTHER INFORMATION CONTACT:**

Patrick McCluskey, USDA AMS;

Telephone: (816) 659–8403; Email:

[Patrick.J.McCluskey@ams.usda.gov](mailto:Patrick.J.McCluskey@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** Section 4 of the USGSA (7 U.S.C. 76(a)) grants the Secretary of Agriculture the authority to establish standards for soybeans and other grains regarding kind, class, quality, and condition. The soybean standards, established by USDA on November 20, 1940, were last revised in 2006 (71 FR 52403) and appear in the USGSA regulations at 7 CFR 810.1601–810.1605. The standards facilitate soybean marketing and define U.S. soybean quality in the domestic and global marketplace. The standards define commonly used industry terms; contain basic principles governing the application of standards, such as the type of sample used for a particular quality analysis; the basis of determination; and specify grades and grade requirements. Official procedures for determining grading factors are provided in Grain Inspection Handbook, Book II, Chapter 10, “Soybeans”. The Handbook also includes standardized procedures for additional quality attributes not used to determine grade, such as oil and protein content. Together, the grading standards and official procedures allow buyers and sellers to communicate quality requirements, compare soybean quality using equivalent forms of measurement, and assist in price discovery.

The realignment of offices within the U.S. Department of Agriculture authorized by the Secretary's Memorandum dated November 14, 2017, “Improving Customer Service and Efficiency”, eliminates the Grain Inspection, Packers and Stockyards Administration (GIPSA) as a standalone agency. Federal Grain Inspection Service (FGIS) activities, formerly part of GIPSA, are now organized under AMS. FGIS grading and inspection services are provided through a network of federal, state, and private laboratories that conduct tests to determine the quality and condition of soybeans. These tests are conducted in accordance with applicable standards using

approved methodologies and can be applied at any point in the marketing chain. Furthermore the tests yield rapid, reliable, and consistent results. In addition, FGIS-issued certificates describing the quality and condition of graded soybeans are accepted as *prima facie* evidence in all Federal courts. U.S. Standards for Soybeans and the affiliated grading and testing services offered by FGIS verify that a seller's soybeans meet specified requirements, and ensure that customers receive the quality of soybeans they purchased.

In order for U.S. standards and grading procedures for soybeans to remain relevant, AMS is issuing this request for information to invite interested parties to submit comments, ideas, and suggestions on all aspects of the U.S. Standards for Soybeans and official procedures.

**Authority:** 7 U.S.C. 71–87k.

Dated: June 26, 2018.

**Greg Ibach,**

*Under Secretary, Marketing and Regulatory Programs.*

[FR Doc. 2018–14015 Filed 6–28–18; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 15 CFR Part 960

[Docket No. 100903432–8557–01]

**RIN 0648–BA15**

#### Licensing Private Remote Sensing Space Systems

**AGENCY:** National Environmental Satellite, Data, and Information Service (NESDIS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (Department, or Commerce).

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** Commerce is considering revisions to its regulations for the licensing of private remote sensing space systems, currently administered by NOAA. These revisions would facilitate the continued growth of this critical industry and update the regulatory regime to address significant technological developments, new business models, and increased foreign competition since their last update in 2006. In support of this effort, the Department through NOAA seeks public comment on substantive and procedural matters involved in commercial remote

sensing licensing. Based in part on this public input, and based on a potential public meeting, the Department may draft proposed regulations and issue a Notice of Proposed Rulemaking.

**DATES:** Comments must be received by August 28, 2018.

**ADDRESSES:** You may send comments by the following method:

*Federal eRulemaking Portal:* Go to: [www.regulations.gov](http://www.regulations.gov) and search for the docket number NOAA–NESDIS–2018–0058. Click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

*Mail:* NOAA Commercial Remote Sensing Regulatory Affairs, 1335 East-West Highway, G101, Silver Spring, Maryland 20910.

*Instructions:* The Department of Commerce and NOAA are not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will be posted without change to [www.regulations.gov](http://www.regulations.gov), including any personal or commercially proprietary information provided.

**FOR FURTHER INFORMATION CONTACT:**

Tahara Dawkins, Commercial Remote Sensing Regulatory Affairs, at 301–713–3385, or Glenn Tallia, NOAA Office of General Counsel, at 301–628–1622.

**SUPPLEMENTARY INFORMATION:**

**Background**

Per Article VI of the Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and Other Celestial Bodies (“Outer Space Treaty”), activities of private U.S. entities in outer space require the “authorization and continuing supervision” of the United States Government. Subchapter VI of Title 51, National and Commercial Space Programs (51 U.S.C. 60121 *et seq.*, hereinafter “Statute”), authorizes the Secretary of Commerce (“Secretary”) to fulfill this responsibility for operators of private remote sensing space systems, by authorizing the Secretary to issue and enforce licenses for the operation of such systems. The Secretary’s authority under the Statute is currently delegated to the Assistant Administrator for Satellite and Information Services and implemented through NOAA’s existing regulations, 15 CFR part 960, last updated in 2006. Under the Statute, NOAA has issued 119 licenses to U.S. corporations, universities, and people to operate over 1,000 imaging satellites,

helping to ensure that the United States remains the clear world leader in this industry.

Through the National Space Council, the Administration has made clear that long-term U.S. national security and foreign policy interests are best served by ensuring that U.S. industry continues to lead this rapidly maturing and highly competitive market. The priorities for the National Space Council and the Department are to: Encourage companies to do business in the United States; help businesses maintain a competitive advantage here; facilitate the growth of this important industry; and support innovation within it. To that end, the Department and NOAA wish to relieve any unnecessary regulatory burdens in the remote sensing area.

Additionally, technological and other developments have highlighted ambiguities in the current regulatory regime, many of which were unforeseeable even just a few years ago. Specific examples include:

- Dramatic increase in the number of license applications
- Increasing remote sensing capabilities in other countries
- Cubesat constellations
- Non-Earth imaging
- Satellite servicing
- Innovative systems capable of imaging in different spectral bands
- Live video broadcasting from space
- Venture capital investment, including significant amounts from foreign nationals and corporations
- New entrants to space markets
- Hosted payloads
- Increasing use of public-private partnerships
- Complex contractual relationships
- Satellite servicing missions, including proximity operations
- Ground station networks located in multiple countries with different regulatory regimes
- Launch vehicles imaging on orbit

The Department recognizes that there have been many proposals to improve the commercial remote sensing regulatory regime, some of which may require new or revised statutory authority to implement. However, the Department may be able to make significant improvements to the licensing of remote sensing even under the existing statute, simply by revising its regulations. Therefore, to support the Administration’s above-mentioned priorities and to reflect the dramatic changes in the remote sensing industry since the last update of remote sensing regulations, the Department plans to revise its regulations. Before drafting

specific provisions, the Department is seeking input from stakeholders regarding how it should best address a variety of important issues.

**Request for Public Comments**

The Department welcomes input on any matters related to commercial remote sensing regulation, including specific examples of industry standards, alternative regulatory approaches, and legal definitions that work well in other areas. The Department also invites comment on the overall cost of complying with NOAA’s existing regulations and any specific regulatory requirements that are particularly burdensome.

In addition, the Department seeks input on the following specific topics:

**Topic 1: Requirement To Obtain a License**

The Statute authorizes the Secretary of Commerce to license “private sector parties to operate private remote sensing space systems” and prohibits a “person that is subject to the jurisdiction or control of the United States” from “operat[ing] any private remote sensing space system” without a license (51 U.S.C. 60121(a), 60122(a)).

In pursuit of the Department’s goal to facilitate innovation, the Department seeks input on how to define these and other statutory terms in its regulations, and at what level of specificity. Definitions that are more specific would provide greater certainty to industry in determining whether a license is required, but specific definitions could quickly be outpaced by technological change, becoming obsolete or burdensome. Alternatively, less specific definitions could adapt as technology and business models develop, but might provide insufficient certainty to industry. The Department may be able to augment less specific definitions in its regulations with interpretive guidance, which could be updated more regularly to reflect industry developments.

With this background in mind, the Department seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. How should Commerce define the statutory terms “private sector party” and “person subject to the jurisdiction or control of the United States?”

b. How should Commerce define the statutory term “private remote sensing space system?”

c. How should Commerce determine which entity is the operator of a private remote sensing system (the operator is required to obtain a license under the

statute) in complex cases, such as when there are multiple entities involved in the operation of the system?

## Topic 2: License Application and Review Processes

Before a license can be granted, the Statute requires the Secretary to determine that the applicant will comply with the Statute, the regulations, and any international obligations and national security concerns (51 U.S.C. 60121(b)(1)). The Statute also requires the Secretary to consult with the Secretaries of Defense and State (51 U.S.C. 60147(a), (b)).

The Department seeks to expedite review of applications as much as possible within statutory constraints. Commerce recognizes that modern remote sensing space systems present a broad range of technical capabilities and possible risks to national security, foreign policy, and international obligations of the United States. Commerce would prefer that the majority of applicants, whose systems present few, if any, such risks, could be reviewed more quickly and be subject to a lighter regulatory approach overall. In addition to providing certainty and quicker review for most applicants, this approach would allow Commerce and its interagency partners to work with industry to focus resources on mitigating only the most critical risks posed by the most capable proposed systems.

With this background in mind, the Department seeks general comments on this topic. In addition, Commerce seeks input in response to the following specific questions:

a. Commerce is considering grouping proposed systems into two or more categories based on the potential risk presented by their capabilities. Those systems categorized as posing only a de minimis risk would be subject to an expedited review process, less restrictive license conditions, and less burdensome compliance requirements (note: Comments are sought on factors potentially relevant for defining review categories and review processes for different categories (Topic 2, below), on license conditions (Topic 3), and on compliance requirements (Topic 4)). The Department seeks input on whether such a strategy is advisable, and if so, how to implement it.

1. Would the proposed category system be advisable?

2. How should Commerce define categories in such a system? Consider the following factors, for example:

A. Earth-surface imaging capabilities, including temporal and spatial resolution

B. Non-Earth imaging capabilities, including temporal and spatial resolution

C. Other technical factors, including spectral range, data management cycle, and duration of the on-orbit capabilities

D. Non-technical matters, including business structure, foreign investment, and the degree of third-party investment in the system

3. What application information should Commerce collect from applicants in different categories (*e.g.*, applications in a de minimis sensing capability category versus moderate or precise sensing capability categories)?

4. How should the review process for the different categories differ, including interagency consultation? Should Commerce issue a license based solely on notification by the applicant and confirmation by Commerce that the proposed system satisfies the criteria for the de minimis category?

5. How and how often should Commerce reevaluate its definition of these categories over time?

b. Should all applications or only applications for some categories of commercial remote sensing licenses enjoy a “presumption of approval?” If so, how should Commerce implement this presumption?

c. Would it be helpful to require a pre-application consultation? If so, under which circumstances?

d. How can the Department improve transparency during the application review process?

e. Noting that new technologies can require extensive study, how can Commerce work proactively with the other reviewing agencies and potential future licensees to ensure that the Department is prepared to swiftly review any submitted applications?

## Topic 3: License Conditions

While some license conditions are required by statute or regulation, the Secretaries of Defense and State also determine additional individual conditions addressing national security, foreign policy, and international obligations (51 U.S.C. 60122, 60147; 15 CFR 960.11). The Secretary of Commerce, through NOAA, ultimately implements and enforces all license conditions.

Listing standard license conditions in Commerce’s regulations would provide applicants with certainty. However, some flexibility may be necessary to allow the Department to tailor conditions to specific systems, as appropriate. Additionally, the Department recognizes that some license conditions can impose a heavy

cost burden, which harms industry and frustrates U.S. policy. Commerce seeks to impose those conditions only when legally required or when critical risks to national security, foreign policy, and international obligations are identified. Finally, Commerce recognizes that once a license is issued, permanent retroactive changes to license conditions can be disruptive to a licensee’s operations and business.

With this background in mind, the Department seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. Considering the default conditions in 15 CFR 960.11, are there any conditions that should be added, removed, or modified in light of technological changes or impacts to the industry?

b. Should there be different default conditions for the different “categories” of systems as described in Topic 2?

c. When considering license conditions, how should NOAA think about the cost and benefit of conditions? What information could licensees provide to NOAA to inform that analysis?

d. How should Commerce respond to emerging and unforeseeable national security, foreign policy, and international obligation issues for existing licensed systems (*e.g.*, retroactive conditions, temporary restrictions)?

e. Should the U.S. Government be required to attempt to mitigate any national security or other risks before imposing conditions? If such mitigation would be costly, how should Commerce balance the taxpayer cost with any avoided cost to licensees?

f. Under the Convention on International Liability for Damage Caused by Space Objects, the U.S. Government and taxpayers may be liable for damage caused by a licensee to a space object, person, or property of another nation. The U.S. Government would not be liable if a licensee damages a space object, person, or property of another U.S. entity, but the licensee may lack the financial means to pay damages to an aggrieved entity. NOAA currently requires licensees to submit an orbital debris assessment report and spacecraft disposal plan, but should Commerce also consider a license condition requiring licensees to obtain some level of insurance to cover these potential liabilities? If such insurance is prohibitively expensive, should Commerce consider other, less burdensome means to protect U.S. taxpayers and other U.S. satellite owners?

g. How should Commerce adjust conditions in response to the increasing capabilities of non-U.S. entities? How frequently should NOAA evaluate those increasing capabilities?

h. How can Commerce best provide transparency to licensees regarding classified national security risks?

#### Topic 4: Compliance and Enforcement

The Secretary is required to ensure compliance with the regulations and with licenses (51 U.S.C. 60123, 15 CFR 960.13–960.15). To meet this obligation, NOAA must collect information, but it seeks to minimize the burden on licensees.

With this background in mind, the Department seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. What are appropriate mechanisms for ensuring compliance? Currently, Commerce uses site visits, virtual inspections, quarterly and annual audits, and no-notice inspections as needed.

b. How should Commerce ensure compliance when multiple parties (including investors) play a role in a single licensed system? Options could include licensing all involved parties, or holding a single licensee responsible for the entire system.

c. Are there any improvements the Department could make to its formal adjudication procedures in the regulations?

d. Should Commerce mandate licensees to use certain technical standards, or particular software, for compliance purposes? If so, what standards or software should Commerce require?

e. Should Commerce adopt different compliance policies and procedures for the different categories described in Topic 2? If so, what policies and procedures would be appropriate for the different categories?

#### Topic 5: Integration With Other Licensing and Regulatory Regimes

The Department recognizes that many NOAA-licensed systems also require licenses from other U.S. Government agencies, and occasionally from agencies in other countries. The Department seeks to reduce the overall regulatory burden to licensees, when possible.

With this background in mind, Commerce seeks general comments on this topic. In addition, the Department seeks input in response to the following specific questions:

a. Within statutory constraints, how can Commerce avoid redundancies and

inconsistencies between domestic regulatory regimes?

b. Within statutory constraints, how can Commerce minimize burdens to licensees who operate in multiple countries and are subject to multiple countries' regulatory regimes?

#### Classification

This advance notice of proposed rulemaking was determined to be significant for purposes of E.O. 12866.

Dated: June 25, 2018.

**Stephen Volz,**

*Assistant Administrator for Satellite and Information Services, National Oceanic and Atmospheric Administration, Department of Commerce.*

[FR Doc. 2018–14038 Filed 6–28–18; 8:45 am]

**BILLING CODE 3510–HR–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 15

[Docket No. FDA–2018–N–2309]

#### The Food and Drug Administration Predictive Toxicology Roadmap and Its Implementation; Public Hearing; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing a public hearing to solicit comments on FDA's Predictive Toxicology Roadmap, which was issued by FDA on December 6, 2017. FDA is seeking comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate these methods and technologies into regulatory review, as applicable.

**DATES:** The public hearing will be held on Wednesday, September 12, 2018, from 9 a.m. to 4 p.m. Persons seeking to attend or to present at the public hearing must register by Wednesday, August 29, 2018. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Friday, October 12, 2018.

**ADDRESSES:** The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for public hearing participants

(non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to: <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

#### Electronic Submissions

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted via the <https://www.regulations.gov> electronic filing system by midnight Eastern Time on October 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

• **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

• **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA–