

**Subject to Legal Review for Accuracy, Clarity and Consistency**

[Date]

Dear Ambassador Froman,

The Government of Japan and the Government of the United States of America decided on April 12, 2013 to address in parallel to the Trans-Pacific Partnership (TPP) negotiations a number of key non-tariff measures (NTMs) in the areas of insurance, transparency/trade facilitation, investment, IPR, standards, government procurement, competition policy, express delivery and SPS, when both Governments confirmed the successful conclusion of our bilateral consultations prior to Japan's joining the TPP negotiations.

The two Governments have conducted parallel negotiations on these NTMs since August 2013. I am pleased to hereby confirm that the two Governments have addressed the issues related to the abovementioned NTMs and successfully concluded the parallel negotiations. I also have the honor to confirm, on behalf of the Government of Japan, the outcomes achieved on these NTMs, as reflected in the attachment to this letter. The two Governments expect that these outcomes will be implemented no later than the date of entry into force of the TPP Agreement for the two countries, unless otherwise stated. I am confident that these outcomes will serve as a basis for further enhancing economic growth and expanding bilateral trade and investment.

The Government of Japan stands ready to engage in a dialogue with the Government of the United States, by continuing to work through existing frameworks for bilateral dialogue or other appropriate means, in the interest of further enhancing economic growth and expanding bilateral trade and investment.

I look forward to your letter in response confirming these outcomes on behalf of the Government of the United States.

Yours sincerely,

[ ]

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[Date]

Dear [ ],

On April 12, 2013, the Government of Japan and the Government of the United States of America confirmed the successful conclusion of our bilateral consultations on Japan's joining the Trans-Pacific Partnership (TPP) negotiations. As reflected in my predecessor's letter exchange with Ambassador Kenichiro Sasae, the Government of Japan and the Government of the United States decided to address in parallel to the TPP negotiations a number of key non-tariff measures (NTMs) in the areas of insurance, transparency/trade facilitation, investment, IPR, standards, government procurement, competition policy, express delivery and SPS.

The two Governments have conducted parallel negotiations on these NTMs since August 2013. I am pleased to hereby confirm that the two Governments have addressed the issues related to the abovementioned NTMs and successfully concluded the parallel negotiations. I also have the honor to confirm, on behalf of the Government of the United States, the outcomes achieved on these NTMs, as reflected in the attachment to this letter. The two Governments expect that these outcomes will be implemented no later than the date of entry into force of the TPP Agreement for the two countries, unless otherwise stated. I am confident that these outcomes will serve as a basis for further enhancing economic growth and expanding bilateral trade and investment.

I welcome the prospect of a further dialogue with the Government of Japan, by continuing to work through existing frameworks for bilateral dialogue or other appropriate means, in the interest of further enhancing economic growth and expanding bilateral trade and investment regarding specific issues related to NTMs which may arise in the future.

Sincerely,

Ambassador Michael B. G. Froman

## INSURANCE

The Government of Japan and the Government of the United States have confirmed the following commitments and practices regarding the sale of insurance in Japan by Japan Post Insurance (JPI).

### 1. Definition

For purpose of this section,

**Japan Post** means Japan Post Holdings (JPH), Japan Post Company (JPC), and any successor entities.

### 2. Access to the Japan Post network

- (a) The Government of Japan confirms the importance of affording private suppliers of insurance access to the Japan Post network in a manner that is transparent and competitive by affirming that:
  - (i) no provisions in the Postal Service Privatization Act (Act No.97 of 2005, as amended) require JPC to maintain a contract with JPI to distribute JPI's life insurance products or, in a way that would negatively affect conditions of competition, restrict Japan Post's ability to distribute other suppliers' insurance products; and
  - (ii) Japan Post's universal service obligation with regard to insurance products under the Postal Service Privatization Act, the Japan Post Holdings Act (Act No.98 of 2005, as amended), and the Japan Post Company Act (Act No.100 of 2005, as amended) does not prevent Japan Post from distributing the insurance products of suppliers other than JPI, even where such products are in competition with JPI's products.
- (b) The Government of Japan recognizes the benefits of Japan Post improving its services, including distribution of private sector suppliers' products, including those that compete with JPI products, throughout its network. The Government of Japan will ensure that Japan Post is not discouraged from distributing private insurance suppliers' products, including those that compete with JPI products, throughout its network. The Government of Japan will not prevent JPC from making its network available for distribution of products of private insurance suppliers, with the actual number and location of distribution outlets determined through discussions between JPC and private insurance suppliers. The Government of Japan will ensure that distribution of insurance products by Japan Post is conditioned on Japan Post and private insurance suppliers maintaining appropriate management systems for the solicitation and supply of insurance from the

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viewpoint of customer protection.

- (c) The Government of Japan confirms that when Japan Post selects insurance products to sell through its network, Japan Post makes its selection on a commercial basis and independent of Japan Post's relationship with any prospective supplier.
- (d) The Government of Japan recognizes that the application of principles of non-discrimination and openness to any insurance suppliers in the process for providing access to Japan Post network is an important part of providing equivalent conditions of competition between JPI and other insurance suppliers. The Government of Japan will make available to the Government of the United States a point of contact upon its request to provide information regarding the processes and principles by which Japan Post provides access to its network.

### **3. Regulatory oversight and treatment**

- (a) In accordance with paragraph 2 of Section C of Annex 11-B to Chapter 11 of the Trans-Pacific Partnership Agreement, the Government of Japan will not adopt or maintain any measure that creates conditions of competition that are more favorable with respect to the supply of insurance services by JPI as compared to any private suppliers of like insurance services, including with regard to enforcement of the Insurance Business Act (Act No.105 of 1995, as amended).
- (b) The Financial Services Agency of Japan (FSA) will undertake a review of JPI's business operations upon the filing of an application for new insurance products, based on the Insurance Business Act, to evaluate whether JPI has the capacity to administer new products soundly and has established other internal controls and systems called for under the Act and related regulations, including those pertaining to claims payments and customer protection. In reviewing JPI's business operations, FSA will apply the same standards as applied to other suppliers of insurance, in order to provide equivalent conditions of competition between JPI and other insurance suppliers.
- (c) The Government of Japan confirms, considering JPI is in the course of privatization, that the Office for Postal Savings and Insurance Supervision of FSA has responsibilities to ensure proper and consistent supervision of JPI under both the Insurance Business Act and the Postal Service Privatization Act, that both the Office for Postal Savings and Insurance Supervision and the Insurance Business Division are subject to supervision by the Director General of the Supervisory Bureau of FSA, and that the existence of the Office and the Division will never harm fairness of supervision on JPI.

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- (d) The Government of Japan will ensure that the supervisory responsibilities of the Ministry of Internal Affairs and Communications (MIC) do not impede FSA's ability to independently regulate JPI. The Government of Japan will also confirm that any FSA official transferred or detailed from MIC, with oversight responsibilities over JPI, reports exclusively to the director of the relevant FSA office.
- (e) If fifty percent or more of shares of JPI have been sold and a notification system for JPI's new products commences under the Postal Service Privatization Act, FSA and MIC will evaluate, upon JPI's submission of a notification of its new product, whether equivalent conditions of competition with other suppliers of insurance are hampered and, where necessary, take appropriate action based on the results of that evaluation.

### **4. Licensing procedures**

- (a) The Government of Japan confirms that:
  - (i) the business plan submitted by JPH on April 27, 2007, included all of the documentation that FSA would require a private supplier of like insurance products to submit in order to obtain a license to supply insurance;
  - (ii) the procedure for review of such documents was not more favorable to JPI than the procedures for review of comparable documents submitted by private suppliers of like insurance products; and
  - (iii) FSA has the authority to revoke JPI's license to supply insurance if JPI commits offenses that would justify the revocation of a private company's business license.
- (b) The Government of Japan certifies that JPI has satisfied all requirements under the Insurance Business Act for receipt of a license to supply insurance.

### **5. Transparency**

- (a) Recognizing the importance of providing interested persons, including foreign suppliers of insurance, with a full opportunity to understand legal, regulatory, policy, or other matters related to the Japan Post Group, the Government of Japan:
  - (i) on October 22, 2013, provided the Government of the United States with the copy of the contractual agreement on reinsurance between JPI and the Management Organization for Postal Savings and Postal Life Insurance, which the Government of

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Japan received from that Organization;

- (ii) will ensure that JPH publishes consolidated earnings statements once a year, and recognizes that such a statement is currently published on a quarterly basis; and
  - (iii) will ensure that JPI publishes its balance sheet, profit and loss statement, and other financial statements once a year, with a level of transparency equivalent to comparable documents issued by other private suppliers of like insurance products, and recognizes that such documents are currently published on a quarterly basis.
- (b) The Government of Japan reaffirms its commitment to the transparency principles related to JPI outlined in the 2009 Regulatory Reform and Competition Policy Initiative Report to Leaders.

### **6. Review Process**

Both Governments will meet, upon request by either side, to review implementation of the actions described in the above commitments and practices.

## TRANSPARENCY

### 1. Advisory Councils / Committees

The Government of Japan affirms the importance of transparency with respect to the formation and operation of advisory councils and similar groups (“advisory councils”) that are established by the Government of Japan to advise or provide recommendations to the Government on the development of regulations and other measures which have an impact on trade and investment between Japan and the United States.

Accordingly, the Government of Japan will ensure that the relevant authorities:

- (a) permit interested persons to attend, appear before, or file statements with advisory councils, subject to reasonable rules or regulations, including by providing meaningful opportunities for all interested parties, including foreign parties, to file statements on terms no less favorable than those accorded to its own parties in like circumstances;
- (b) provide timely public notice of the formation of advisory councils;
- (c) open meetings of advisory councils to the public;
- (d) provide timely public notice of each advisory council meeting, such as by posting notifications of meetings on the website of the responsible ministry or agency, so as to ensure that interested persons are notified prior to the meeting date;
- (e) make available for public inspection and copying, such as by posting on the website of the responsible ministry or agency, the minutes and other documents made available to the advisory councils;
- (f) require detailed minutes of each meeting of the advisory councils to be kept, including a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory councils; and
- (g) provide interested persons with the opportunity to seek redress in the event of a failure of any of the above mentioned requirements through complaints filed with the secretariats of the advisory councils, which will report to the advisory councils a summary of any comments or complaints received;

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with exceptions to these requirements only in the event the relevant authorities determine that a meeting or portion of a meeting needs to be closed to the public for national security or other reasonable grounds (such as protection of information that would otherwise be exempted from disclosure under relevant laws and regulations). In that event, the relevant authorities will be required to make public the reasons for this determination.

Further, the Government of Japan will ensure that any rules enacted for the formation and operation of the advisory councils are made publicly available and are consistent with all general transparency requirements for advisory councils.

The Government of the United States ensures the transparency of Federal advisory committees that provide advice to the executive branch of government, through the Federal Advisory Committee Act (FACA)<sup>1</sup>, as amended, and implementing regulations.

The FACA and its regulations impose robust requirements for transparency in the establishment, operation, and termination of Federal advisory committees by requiring departments and agencies to provide to the public:

- advance notice of committee formation<sup>2</sup>;
- advance notice of scheduled meetings<sup>3</sup>;
- contemporaneous access to advisory committee records<sup>4</sup>;
- opportunities to provide information to committees<sup>5</sup>; and
- access to information on Federal advisory committees and their activities on the Internet at <http://www.facadatabase.gov>.

Committee meetings are also required to be open to the public except under specific circumstances when meetings can be legally closed, such as when the committee's work involves classified material, proprietary business information, or personal information.

Details of the transparency requirements under U.S. law and regulations may be found at <http://www.gsa.gov/portal/category/21244>.

## **2. Public Comment Procedure**

Both Governments will take necessary measures for the smooth and effective implementation of the relevant provisions in Article 26.2.4 of the TPP Agreement.

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<sup>1</sup> P.L. 92-463, codified at 5 U.S.C. App.

<sup>2</sup> 5 U.S.C. App., §9(a)(2).

<sup>3</sup> 5 U.S.C. App., §10(a)(2).

<sup>4</sup> 5 U.S.C. App., §10(b).

<sup>5</sup> 5 U.S.C. App., §10(a)(3).

## **INVESTMENT/M&A**

### **1. Corporate Governance – Independent Directors**

The Companies Act (Act No. 86 of 2005), as amended in June 2014, and its relevant ordinances:

- (a) strengthen qualification requirements for outside directors, by excluding individuals such as parent company directors and employees;
- (b) require any listed company not having at least one outside director to disclose in its business report and explain at its annual meeting of shareholders “reasons why appointing an outside director would be inappropriate”; and
- (c) introduce the audit and supervisory committee form of corporate governance as a means of facilitating the use of outside directors.

The amended Act took effect on May 1, 2015. Two years after the amendment took effect, the Government of Japan will reconsider its rules on corporate governance in order to determine whether additional steps, including a mandatory requirement for listed companies to include at least one outside director, are necessary. Further, in line with the amended Companies Act, the amendment to the Tokyo Stock Exchange (TSE) listing requirements, which requires TSE-listed companies to aim to ensure the presence of at least one independent director who is an outside director, was implemented in February 2014. In addition, on June 1, 2015, the TSE established Japan’s Corporate Governance Code. The Code adopts a “comply or explain” approach for implementation, and indicates that listed companies should appoint at least two independent directors.

### **2. Anti-takeover Defenses**

The Government of Japan recognizes that it is improper for directors to use takeover defense measures to prevent an acquisition that would enhance corporate value and shareholders’ common interests. In this connection, the measures described in the section above concerning independent directors could help to prevent such outcomes. The Government of Japan will receive comments and recommendations on takeover defense measures for consideration and possible action.

### **3. Regulatory Reform**

In keeping with the Growth Strategy of the Government of Japan aiming for at least the doubling of inward foreign direct investment stocks by 2020, the Government of Japan will seek comments and recommendations from foreign investors and other stakeholders for the purpose

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of promoting foreign direct investment and enhancing the effectiveness and transparency of Japan's regulatory framework. Comments and recommendations will be referred to the Council on Regulatory Reform on a regular basis, along with responses from relevant ministries and agencies with respect to the feasibility of such comments and recommendations, for consideration and possible action. The Government of Japan will take necessary measures in compliance with the Council's recommendations.

## **INTELLECTUAL PROPERTY RIGHTS**

Both Governments will take necessary measures for the smooth and effective implementation of the relevant provisions in Chapter 18 (Intellectual Property) of the TPP Agreement.

### **Private Copying Exception**

On the scope of copyright protection, the Copyright Working Group under the Council for Cultural Affairs of Japan studied the scope of the private use exception and concluded in 2009 that it is appropriate that the private use exception should not be applied for downloading of sound recordings and motion pictures from illegal sources.

The Government of Japan will resume its consultation with the Copyright Working Group with respect to whether the private use exception should not be applied for downloading of other works from any illegal sources as soon as possible and no later than the time when the TPP Agreement takes effect with respect to both countries. In order to facilitate this process, the Government of the United States and the Government of Japan will exchange relevant information in this respect.

Both Governments also recognize that it is important for both countries to continue to work toward enhancing the protection of intellectual property rights in the Asia-Pacific region, including with respect to copyrighted works such as manga, animation, software and books.

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### STANDARDS

1. With a view to facilitating trade in goods between the United States and Japan, including by eliminating unnecessary technical barriers to trade, enhancing transparency, and promoting greater regulatory cooperation and good regulatory practice, the Governments of the United States and Japan establish a working group on technical regulations, standards and conformity assessment procedures (“the Working Group”).
2. The mandate of the Working Group is to:
  - (a) address specific trade concerns raised by either Government related to technical regulations, standards and conformity assessment procedures prepared, adopted or applied by either Government;
  - (b) enhance joint cooperation with respect to technical regulations, standards and conformity assessment procedures;
  - (c) promote greater use of relevant international standards, guides and recommendations as the basis for technical regulations and conformity assessment procedures, consistent with obligations under the WTO Agreement on Technical Barriers to Trade;
  - (d) exchange timely information on technical regulations, standards and conformity assessment procedures prepared, adopted or applied by either Government; and
  - (e) identify, as appropriate, ways to improve processes or procedures used by each Government to prepare, adopt or apply technical regulations, standards and conformity assessment procedures including ways to provide interested persons a reasonable opportunity to provide input, and to take such input into account in the development of the measure.
3. The Working Group, comprised of officials of each Government, will hold meetings at such times and venues and through such means as may be decided by both Governments.

## GOVERNMENT PROCUREMENT

### 1. Bid-Rigging

In addition to imposing strict sanctions and penalties to combat bid-rigging and related anti-competitive practices, the Government of Japan will implement preventive measures, including by:

- (a) conducting on a regular basis anti-cartel, bid-rigging, and collusion training programs by central government procuring entities and supporting implementation of such programs by local government entities and special corporations and incorporated administrative agencies<sup>1</sup>;
- (b) enforcing the National Public Service Act which requires the elimination of conflicts of interest by prohibiting officials from seeking employment at companies which they oversee or regulate,<sup>2</sup> outplacement of officials and retired officials by the government, and requests of favors by retired officials to their previous government workplaces; and
- (c) providing guidelines for and promoting the establishment in central government entities, local government entities, and special corporations and incorporated administrative agencies<sup>3</sup> of third-party auditing organizations, which conduct thorough inspections of procurement processes to enhance transparent and competitive opportunities for procurements.

The Government of Japan affirms its commitment to take all possible measures, including through stringent enforcement of domestic laws, to eradicate bid-rigging and related anti-competitive practices.

### 2. Improving the Bidding Process

The Government of Japan will increase transparency in tendering decisions and allow for greater participation by qualified bidders through implementing the following measures:

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<sup>1</sup> Includes entities detailed in Article 2 (2) of the Kansei Dango Prevention Act, and listed at [http://www.jftc.go.jp/en/legislation\\_gls/List\\_of\\_entities.files/List\\_of\\_entities.pdf](http://www.jftc.go.jp/en/legislation_gls/List_of_entities.files/List_of_entities.pdf).

<sup>2</sup> Categories of those companies are specified by Cabinet Order No. 389 of December 25, 2008 regarding the retirement management of officials.

<sup>3</sup> Includes entities detailed in Article 1 of the Order for Enforcement of the Act for Promoting Proper Tendering and Contracting for Public Works and the Cabinet Decision concerning Check and Review of Procurement Contracts by Incorporated Administrative Agencies, and listed at [http://www.mlit.go.jp/totikensangyo/const/totikensangyo\\_const\\_fr1\\_000038.html](http://www.mlit.go.jp/totikensangyo/const/totikensangyo_const_fr1_000038.html) and [http://www.cas.go.jp/jp/gaiyou/jimu/jinjikyoku/files/18\\_iaa.pdf](http://www.cas.go.jp/jp/gaiyou/jimu/jinjikyoku/files/18_iaa.pdf).

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- (a) increase the use of electronic bidding systems by central government entities and local government entities, thereby expanding opportunities for participation and ensuring greater transparency for all parties;
- (b) increase the utility of the online location<sup>4</sup> containing, in a searchable format, direct access in both Japanese and English to procurement notices and invitations covering central government entities, special corporations and incorporated administrative agencies<sup>5</sup>, as well as prefectural and major municipal governments;
- (c) maintain the national open data portal website,<sup>6</sup> which the Government of Japan established in 2014, in order to make information and data on prior government procurements (e.g. estimated and final bid prices, bid winners, dates of bids, and procuring entities) publicly available and searchable by the public;
- (d) ensure the effective and non-discriminatory operation of the Government Procurement Review Board, which receives and reviews complaints concerning government procurement of goods and services, in order to secure enforcement of open and transparent bidding processes;
- (e) ensure that participation of foreign suppliers is not precluded, by prohibiting practices that would unduly limit competition, including consolidation of procurements of goods and/or services into a single procurement, where such consolidation would unduly limit competition;
- (f) enforce the prohibition on procuring entities from conducting any acts that favor one supplier over another and harm the fairness of bidding, including acts such as informing a particular supplier prior to the publication of a notice of intended procurement of the target price or any other information not available to other suppliers concerning the procurement; and
- (g) fulfill the obligations arising under the WTO Agreement on Government Procurement (GPA) and further take voluntary measures at the GPA-plus level in accordance with the Operational Guideline on Procedures for Government Procurement etc.

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<sup>4</sup> The Government of Japan recognizes that the following online database of Japanese government procurement is available as of [date]: <https://www.jetro.go.jp/en/database/procurement/>.

<sup>5</sup> Includes entities detailed in Japan's Annex 3 of the WTO Agreement on Government Procurement and Japan's Voluntary Measures on Government Procurement, and listed at <http://japan.kantei.go.jp/procurement/2014/ch/1-5FY2013ch1-5.pdf>.

<sup>6</sup> Open data catalogue information portal site, <http://www.data.go.jp/?lang=english>.

## COMPETITION POLICY/PROCEDURAL FAIRNESS

1. The Antimonopoly Act of Japan (AMA, Act No.54 of 1947), which was amended in December 2013 and took effect on April 2015, contributes to further enhancing procedural fairness and transparency in the enforcement of the AMA by Japan Fair Trade Commission (JFTC) in the following ways.
  - (a) **Independent review of violation orders:** Under the amended AMA, the JFTC's administrative review of its orders has been abolished and jurisdiction for appeals in the first instance of JFTC orders, including cease and desist and surcharge payment orders, has been transferred to the Tokyo District Court.
  - (b) **Access to evidence:** Under the amended AMA, access by defendants to evidence used by the JFTC for fact-finding has been enhanced, including by allowing each company concerned to photocopy records of statements by its employees, from the time the company received the notice of the hearing until the end of the hearing.
  - (c) **Pre-order procedures:** With respect to pre-order procedures, the amended AMA provides that JFTC officers who have not been involved in the investigation of the case be designated to preside over a procedure for hearing opinions from to-be recipients, and that they may ask questions to investigators during the pre-order procedures.
2. In recognition of other issues not addressed by the amendment regarding JFTC investigation procedures, the Government of Japan formed the Advisory Panel on Administrative Investigation Procedures under the AMA to consider JFTC investigation procedures consistent with Article 16 of the supplementary provisions of the amended AMA. As a result of discussion, the Advisory Panel issued a report in December 2014. The report examined JFTC investigation procedures regarding on-the-spot inspections, attorney-client privilege and depositions<sup>1</sup>, and it proposed in certain instances that the JFTC clarify its procedures on issues related to on-the-spot inspections and depositions in manuals or guidelines. Taking into account the Advisory Panel's report, the JFTC is in the final stage of drawing up guidelines.

The Government of Japan will exert its utmost effort for the enforcement of the AMA.

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<sup>1</sup> See Report Issued by the Advisory Panel on Administrative Investigation Procedures under the Anti-Monopoly Act (December 24, 2014) from the website of the Cabinet Office, Government of Japan: <http://www8.cao.go.jp/chosei/dokkin/finalreport/body-english.pdf>.

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With respect to confidentiality, pursuant to Article 39 of the AMA and under Article 100 of the National Public Service Act (Act No.120 of 1947), the JFTC will ensure its employees will continue to comply with confidentiality obligations.

## **EXPRESS DELIVERY**

### **1. Cross-Subsidization**

To provide for greater transparency, the Government of Japan will ensure that Japan Post Company (JPC) will annually disclose the revenue and expense statement of its Express Mail Service (EMS) consistent with standard accounting principles in accordance with the laws and regulations of Japan. The Ministry of Internal Affairs and Communications has started considering necessary measures and intends to complete taking the necessary measures at the earliest possible timing.

### **2. Customs Treatment**

Both Governments will proactively contribute to operational developments in support of providing electronic advance data on international postal items to enhance the security of international postal supply chain, meet electronic submission requirements to be adopted by the governments of the member countries of the Universal Postal Union, and to be implemented by their postal operators, and contribute to the efficiency of customs procedures applied to postal items, based on Article 9 of the Universal Postal Convention. In parallel with these efforts, both Governments strongly expect that JPC and United States Postal Service will intensify participation in pilot programs in multilateral fora for providing such electronic advance data on international postal items, including EMS items for outbound shipments. This will be accomplished, for example, through the advance electronic data efforts being undertaken at the Universal Postal Union or at the Kahala Posts Group.

## SPS

### 1. Post-Harvest Fungicide

The Ministry of Health, Labour and Welfare (MHLW) will implement a streamlined approval process for fungicides that may be applied both pre-harvest and post-harvest by utilizing a unified application and deliberation process for approval of pesticides and food additives.

In the application process, one set of documents will be required in order to obtain approval for pre-harvest and post-harvest use of a fungicide.

In the deliberation process of the Pharmaceutical Affairs and Food Sanitation Council, the Committee on Pesticides and Veterinary Drugs and the Committee on Food Additives will jointly deliberate.

### 2. Food Additives

The Government of Japan confirms that it will faithfully implement the Cabinet Decision dated July 10, 2012, which determined that the Government of Japan would, within approximately one year, in principle, excluding the period of time necessary for gathering additional documents, complete approval of all four not-yet-designated food additives from the 2002 list of 46 internationally commonly-used food additives.

### 3. Gelatin / Collagen

The MHLW requested the Food Safety Commission of Japan (FSC) to conduct a risk assessment on the use for human consumption of gelatin and collagen derived from cattle, including U.S. cattle, and received a risk assessment report from the FSC in October 2014. The report concluded that, on condition that the control measures suggested by the MHLW are taken, the risk to human health by the revision of restrictions on imports of gelatin and collagen is negligible. The MHLW has eased restrictions on imports of gelatin and collagen based on the report.