Japan – Measures Affecting the Importation of Apples (WT/DS245) Recourse by the United States to Article 21.5 of the DSU

Answers of the United States of America to Questions from Japan

November 11, 2004

Q1. The United States states, in the oral statement at the substantive meeting of the Panel, that U.S. quality controls for apple fruit includes highly accurate electronic scanning, and U.S. apple growers and packers apply "required qualities/parameters" and "test methods" which are set forth in the OECD guidelines. Do these specifics (electronic scanning and OECD guidelines) form part of the United States' alternative measures within the meaning of Article 5.6 of the SPS Agreement? In other words, is the United States planning to impose on U.S. apple growers and packers to abide by these requirements?

1. The measures at issue for purposes of an Article 5.6 analysis are those to be implemented and maintained by Japan, not, as Japan's question suggests, U.S. measures or practices. A more-detailed discussion of the U.S. Article 5.6 argument may be found in the U.S. answers to Panel Questions 24 and 25.

Q2. According to the oral statement of the United States, no apple shipment from the United States has ever been rejected for phytosanitary reasons. Can Japan have access to the database.

2. Japan misquotes the U.S. oral statement. The United States did not state that apple shipments have never been rejected for "phytosanitary reasons," which would seem to include other pests and diseases that could possibly be found in apple shipments. The United States stated that no U.S. apple exports "have been rejected by foreign importers due to either *immaturity* or *symptoms of fire blight*."¹ U.S. efforts to obtain information regarding apple fruit shipments were limited to these two criteria, as they are the only criteria relevant to this dispute.

3. Further, the United States does not understand what Japan means by requesting "access" to the database. The United States has performed the relevant search of the database and provided the results of that search to the Panel. The United States describes in detail how its research was conducted in its answer to Panel Question 30. Again, the United States reiterates that at issue in this proceeding are the measures maintained by Japan, not U.S. practices.

Q3. Azegami et al. (2005) found that apple fruit inoculated with fire blight bacteria on cut surface of pedicels on August were latently infected with fire blight bacteria. Namely, the Azegami study assumes that infection from pedicel would occur

¹U.S. Opening Statement, para. 39. (Emphasis added).

before formation of the abscission layer. However, their conclusion is that even after the abscission layer is formed, fire blight bacteria can infect fruit through abscission layer from spur. Does the United States have direct evidence which demonstrates that abscission layer can trap fire blight bacteria.

4. As noted by the United States in its second submission and opening statement, while the Azegami study does in fact conclude this, it does so in the absence of results that support the conclusion. Azegami's results indicate that when shoots bearing fruiting spurs with mature apples attached were wound-inoculated with *E. amylovora*, the bacteria did not move into mature apple fruit, but were stopped at the spur side of the abscission layer. In fact, the results of Azegami support the opposite conclusion, noting that in the instance of mature fruit still attached to the fruiting spur, "a luminous area was observed *on the abscission layer* of one fruit 8 days after inoculation, *but not on fruit.*"²

5. Further, previous scientific studies support the conclusion that bacteria do not enter mature apple fruit through the pedicel or stem. Roberts (1989, 2000) and Dueck (1974) did not isolate fire blight bacteria from the internal tissues of mature apple fruit harvested directly from heavily blighted trees. Upon further review of notes from the 2000 joint study in Washington State, the United States recalls that although subject trees were jointly designated at 0, 10, 25, 50, 100, and 300 meters from a source of fire blight inoculum as per Japan's experiment requirements, Japan refused to sample and evaluate any of the fruit from the 0-meter trees (trees infected with fire blight) for the presence of internal populations of *E. amylovora*. Because it was these very fruit that were and are at the center of the technical divide between the United States and Japan, the U.S. decided to analyze the 0-meter fruit, and did so in the laboratory shared with Japanese scientists. Japan was provided with the results of the 0-meter analyses. All other fruit were analyzed jointly by the United States and Japan (using slightly different methods). The results of all of the analyses were unanimous - no internal populations of E. amylovora were found, and no fruit developed fire blight symptoms during storage (Roberts (2002)).

6. By asking the United States to prove a negative, Japan is attempting to improperly reverse the burden of proof, asserting that the United States must prove that something that does not occur in nature does not, in fact, occur. The simple fact is that Japan's conclusion that fire blight bacteria move through the abscission layer is not supported by the results in Azegami. In fact, Azegami proves the exact opposite. Further, the United States has described other studies which examined the internal tissues as well as stem and calyx portions of apple fruit harvested from severely blighted trees, and which did not isolate fire blight bacteria in the fruit. Japan must provide evidence that the conclusion/phenomenon on which it rests a significant portion of its argument could actually occur. Insofar as Japan relies on Azegami to accomplish this, Japan fails.

²Azegami *et al.*, "Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes" (2005). (Exhibit JPN-6).

7. The United States notes that Japan's question indicates that the Azegami study was concluded in August of this year. As a result, significant portions of the Kimura study and Japan's revised PRA, both of which rely heavily on the conclusions of Azegami, could not have been completed until after August. Yet, Japan's measures taken to comply, purportedly based on these studies and Pest Risk Analysis, were implemented in June.

8. Further, the United States notes that Japan's question demonstrates that Japan's argument that fire blight bacteria enter apple fruit through intact pedicels prior to physiological maturity is nothing more than speculation. Japan states that "the Azegami study *assumes* that infection from pedicel would occur before formation of the abscission layer." Unproven assumptions or hypotheses cannot be employed as scientific evidence in support of Japan's revised measures.³

Q4. The United States argues that the Azegami study is nothing but a rehash of McLarty (1922-27). McLarty (1922-27), however, reported that fire blight bacteria were detected from inside of harvested mature apple fruit after storage, which had been inoculated by needle inoculation method at immature stage. The McLarty study was not conducted for the purpose of determination of pathway of fruit infection or demonstration of multiplication of fire blight bacteria in fruit. On the other hand, the Azegami study demonstrated infection of apple fruit with fire blight bacteria through pedicel from spur, which is described in handbooks by van der Zwet and Beer (1999) and others. Does the Untied States have any direct evidence which contradicts Azegami study?

9. Again, as noted in the U.S. second submission, opening statement, and answer immediately above, the Azegami simply does not demonstrate that fire blight bacteria invade apple fruit from the fruiting spur through the pedicel. The study's own results demonstrate that bacteria failed to enter the fruit through an intact pedicel attached to a fruiting spur.

10. In addition, Japan misinterprets the relevant scientific literature. H.R. McLarty (1923) published in his Annual Report for 1922 the results of a study entitled, "To determine the longevity of *Bacillus amylovorus* in the <u>mature</u> fruit." (Emphasis added). In this study, he wound-inoculated mature fruit of three varieties and documented the recovery of *E. amylovora* (as *B. amylovorus*) from these fruit after refrigerated storage.

11. The United States discusses Japan's attempt to inappropriately reverse the burden of proof in its response to Question 3 above.

Q5. The United States argues that infection of apple fruit with fire blight bacteria

³See Panel Report, paras. 8.92-93, 8.101-103 (defining "scientific evidence" as "evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method", and concluding that "[b]y using the term 'scientific evidence', Article 2.2 excludes in essence not only insufficiently substantiated information, but also such things as a non-demonstrated hypothesis.")

through the pedicel can not occur in natural conditions. What is the scientific basis of the United States' argument?

12. The Azegami study itself, for one, provides evidence that mature apple fruit, when attached to the fruiting spur, will not be infected with fire blight bacteria through the apple fruit's pedicel. When Azegami attempted to introduce fire blight bacteria into apple fruit with intact pedicels (*i.e.*, fruit still attached to the fruiting spur), the bacteria failed to enter the fruit, stopping at the intact abscission layer. The Azegami study documents the following result for apple fruit attached to the fruiting spur: "As for 60 apples with fruit bearing twigs cut-inoculated 1-2 cm distant from the abscission layer, a luminous area was observed *on the abscission layer* [*i.e.*, stopped at the abscission layer/not entering the apple fruit] of one fruit 8 days after inoculation, *but not on fruit*."⁴

13. Further, multiple studies, cited previously, investigated the incidence of internal populations of *E. amylovora* in mature symptomless apple fruit from trees with severe blight. This is an important fact because Japan, in several places, has asserted that previous studies did not examine the necessary tissues of apple fruit for the presence of fire blight bacteria. In fact, it is through this mischaracterization of earlier studies that Japan attempted to "reconcile" the Azegami results with the wealth of earlier studies and results in its first submission. There is no reconciliation because earlier studies did in fact examine these tissues.⁵ In particular, Japan notes that the Roberts (2002) study "did not investigate the stem of apples, the likely part of infection when bacteria enter through the pedicels."⁶ Roberts did not, as Japan appears to suggest, overlook this potential (and simply hypothetical) avenue for fruit infection. Also, Kimura notes that "Dueck (1974), Roberts et al. (1989), and Roberts et al. (2002) tried to detect E. amylovora only from the cores of fruit. This fact is likely to be the reason why E. amylovora was not detected."⁷ Further, Japan's PRA repeats this miscasting of previous studies' methodology, opining that "[i]t is also noteworthy the Dueck (1974), Roberts et al. (1989) and Roberts (2002a) tried to detect *E. amvlovora* only from the cores of fruit."⁸ As noted by the United States in its opening statement, earlier studies, including Roberts (1989), examined the "core and cortex [*i.e.*, flesh] tissues, including the stem, if present, and the entire calyx" of apple fruit harvested from and near severely blighted trees, and failed to recover any Erwinia amylovora. Similarly, the 1974 Dueck study, which found that Erwinia amylovora is not

⁴Azegami *et al.*, p. 9, first full paragraph. (Parenthetical inserted).

⁵See, e.g., Section C(b)(v) of Japan's First Submission, entitled "Reconciliation of Previous Evidence with New Evidence." In this section Japan alleges that is new studies (including Azegami) can "be well reconciled with the previously established facts and conclusions of the original Panel." First Submission, para. 45.

⁶Japan First Submission, para. 48.

⁷Kimura *et al.*, "The probability of long-distance dissemination of bacterial diseases via fruit" (2005), p. 12, lines 6-8. (Exhibit JPN-10). (Emphasis added).

⁸Japan Pest Risk Analysis, September 2004, p. 17. (Exhibit JPN-3). (Emphasis added).

⁹Roberts *et al.*, "Evaluation of Mature Apple Fruit from Washington State for the Presence of *Erwinia amylovora*", Plant Disease 73: 917-921, p. 918. (Parenthetical inserted).

internally-isolated in mature apple fruit, even when harvested from severely infected trees, sampled the internal and external parts of 60 mature apples from three severely blighted trees. This included three cylinders "from the cortex [*i.e.*, flesh] of each apple", the stem, the calyx and the core.¹⁰

14. Despite Japan's contention that bacteria is entering apple fruit through the pedicel, Roberts and Dueck, which analyzed the internal tissues and stems of apple fruit, simply did not find any fire blight bacteria in the fruit.

Q6. The United States denies the existence of a vector, namely common flies, demonstrated by Tsukamoto et al. (2005b), arguing that fire blight bacteria "cannot be transmitted" by flies under natural conditions. Many scientists such as Miller & Schroth (1972), however, suspect that flies are able to transmit fire blight bacteria to host plants. What is the scientific basis on which the United States argues that common flies cannot be a vector under natural conditions?

15. Japan, in its failure to prove the positive, i.e., that a vector actually exists to transmit fire blight from infected apple fruit to host materials, has instead opted to improperly reverse the burden of proof to have the United States prove the negative – that no such risk exists. As noted above in the discussion of the Azegami study's results, Japan must present evidence in support of this fundamental portion of its argument. As is the case with conclusions drawn from Azegami, however, Japan similarly fails to find support for its conclusions regarding the vectoring of fire blight via flies from the results of the Tsukamoto study.

16. First, Japan's Tsukamoto study, much like Azegami, makes a simple definitive conclusion that is entirely unsupported by the study's own results. In fact, the study's title, "Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies" is unsupported by those very findings. The study clearly <u>does not demonstrate</u> that flies obtained *E. amylovora* bacteria from infected fruit and then transmitted the bacteria to susceptible host materials. In short, Japan fails to present any scientific studies that demonstrate transmission of *E. amylovora* from infected fruit to susceptible host tissues by *any insect*, which disproves the basic conclusion in Tsukamoto, even with its contrived and biologically irrelevant conditions.

17. To date, there is simply no scientific evidence that demonstrates the existence of a vector that has transmitted fire blight bacteria from apple fruit to host materials under orchard conditions.

Q7. Tsukamoto et al. (2005a) is not intended to demonstrate that fire blight bacteria can be recovered from artificially inoculated fruit. This study suggests that fire blight bacteria in latently infected apple fruit can survive for 6 months and will be

¹⁰Dueck, J., "Survival of *Erwinia Amylovora* in association with mature apple fruit", Can. J. Plant Sci. 54: 349-350 (1974). (Parenthetical inserted).

able to act as an inoculum source for next spring. Does the United States have any scientific evidence that would contradict Tsukamoto et al. (2005a)?

18. Tsukamoto (I) relies on the Azegami findings that such a thing as an internally infected/infested mature, apparently healthy fruit exists or could exist in nature. Therefore, before discussing the Tsukamoto (I) study for what its results may offer, it must be emphasized that the study is premised on a commodity that simply does not exist (except by artificial inoculation under laboratory conditions).

19. As noted by the United States, artificially inoculating apple fruit and later recovering bacteria from the fruit is eighty-year-old science. McLarty reported the very same feat in 1923. The relevant question is, do these mature, symptomless yet latently infected fruits occur in nature? Japan's studies fail to demonstrate that they do, and there is a significant body of scientific evidence that demonstrates that they do not.

Q8. Fire blight, which does not occur in Japan, is one of the most threatening foreign plant diseases for Japan. Consequently, studies of fire blight bacteria in Japan must be conducted under strictly closed conditions to prevent the spread of bacteria. Particularly, a study which uses a vector (i.e., fly) must be conducted under completely closed conditions. Therefore, Tsukamoto et al. (2005b) had to be conducted in a box in a containment room of P3 level (highest level of security in MAFF standard to assure that bacteria would not leave the room). How could the United States conduct epidemiological study of the most significant disease for the United States (e.g., citrus canker) in the field?

20. While the United States understands the constraints on Japanese scientists studying fire blight transmission in Japan, it must make two critical points on this issue. First, these constraints do not justify Japan's extrapolation that the highly artificial laboratory results are reflective of the real-world biology of *E. amylovora* and pathology of the fire blight disease. Second, even given the constraints of having to imprison flies with artificially infected fruit, or putting artificially contaminated flies into a small container with wounded host tissues, the fundamental truth of the Tsukamoto study is that <u>it did not demonstrate transmission of *E. amylovora* from infected fruit to a susceptible host, and therefore the results contradict the very title of the report and the conclusions drawn from the report by Japan. Third, Japan's question ignores the fact that there is another option to conducting phytosanitary research in-country, and that is to research vectors and fire blight disease in a country where the disease is already present. The joint U.S.-Japan fire blight experiments conducted in 2000 are an example of this potential avenue of research.</u>