INDIA – MEASURES CONCERNING THE IMPORTATION OF CERTAIN AGRICULTURAL PRODUCTS FROM THE UNITED STATES

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US – Poultry	Panel Report, United States – Certain Measures Affecting Imports of Poultry from China, WT/DS392/R, adopted 25 October 2010

TABLE OF ABBREVIATIONS

ABBREVIATION	FULL FORM
AI	Avian Influenza
DAHD	Department of Animal Husbandry, Dairying & Fisheries, Ministry of Agriculture, Government of India
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
GATT 1994	General Agreement on Tariffs and Trade 1994
НРАІ	Highly Pathogenic Avian Influenza
HPNAI	Highly Pathogenic Notifiable Avian Influenza
LPAI	Low Pathogenicity Avian Influenza
LPNAI	Low Pathogenicity Notifiable Avian Influenza
NAI	Notifiable Avian Influenza
OIE	World Organization for Animal Health
OIE Code	The Terrestrial Animal Health Code of the OIE
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SPS Committee	The Committee on Sanitary and Phytosanitary Measures established under the SPS Agreement
Terrestrial Manual	OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
USDA	United States Department of Agriculture

WTO	World Trade Organization		
WTO Agreement	Marrakesh Agreement Establishing the World Trade Organization		

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US-106	Statement of Rebecca D. Jones	Jones Statement
US-107	Dennis J. Alexander, A Review of Avian Influenza in Different Bird Species, 3-13 VETERINARY MICROBIOLOGY 74 (2000).	
US-108	Dr. Stuart C. MacDiarmid, Critical review of the document "India's Risk Assessment on Avian Influenza for imposing ban on import of poultry and poultry products from Avian Influenza positive countries," 30 Sept. 2011.	Critical Review of India's Risk Assessment
US-109	New Zealand Ministry of Agriculture And Forestry, Import Risk Analysis: Chicken Meat and Chicken Meat Products; Bernard Matthews Foods Ltd Turkey Meat Preparations from the United Kingdom, March 1999.	New Zealand Risk Assessment
US-110	India's Risk Assessment on Avian Influenza for imposing ban on import of poultry and poultry products from Avian Influenza positive countries	Summary Document
US-111	DAHD D.O. 53-53/2006-LDT, September 5, 2012	
US-112	OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2011), Chapter 2.3.4	OIE Terrestrial Manual, Chapter 2.3.4
US-113	India, Department of Animal Husbandry, Dairying, and Fisheries,	S.O. 1859(E)

	Notification, S.O. 1859(E), Nov. 1, 2007	
US-114	The Live-Stock Importation Act, 1898	
US-115	The Live-Stock Importation (Amendment) Act, 2001	

I. INTRODUCTION

1. A fundamental requirement of the Agreement on the Application of Sanitary and *Phytosanitary Measures* ("SPS Agreement") is that a Member's SPS measures be based on scientific principles and scientific evidence.¹ A Member generally complies with these obligations by either basing its measures either on relevant international standards, guidelines, or recommendations or on a risk assessment.² With respect to the measures at issue here – measures that have been in place for over six years – India has done neither.

2. India's measures prohibit the importation of various agricultural products from countries that report outbreaks in poultry and wild birds of what is known as Notifiable Avian Influenza ("NAI"), including a subset known as Low Pathogenic Notifiable Avian Influenza ("LPNAI").³ The World Animal Health Organization ("OIE"),⁴ the organization whose standards, guidelines and recommendations are designated in the SPS Agreement as international standards, guidelines and recommendations for purposes of that agreement for animal health and zoonoses, has issued recommendations for reporting NAI and for the safe trade of poultry and poultry products with respect to NAI.⁵

3. Those scientifically based recommendations explicitly disclaim the types of import prohibitions India maintains. For example, while the OIE recommends precautionary control measures for NAI that still permit trade, including less burdensome measures for LPNAI when detected in poultry, India maintains outright import prohibitions.⁶ Having imposed measures that contradict rather than conform to international standards, India is obligated to ensure, among other things, that its measures are based on a risk assessment. And for a time, India claimed it had one – until its trading partners demanded to see it. Shortly thereafter, India finally acknowledged that it had failed to carry out a risk assessment before putting in place its measures, and still lacks one.

4. The aforementioned failures are particularly troubling because India treats its *own products* entirely differently from imported products. India does not engage in surveillance activities that are likely to detect LPNAI, a disease, which if found in other countries, triggers

³ United States, Panel Request.

⁴ The World Organization for Animal Health is referred to as OIE because it chose to keep its historical acronym from when the organization was titled the Office International des Epizootics.

⁵ SPS Agreement, Annex A, para. 3(b).

⁶ OIE, Terrestrial Animal Health Code (2012) [hereinafter "OIE Code"], Article 10.4.1.9 (Exhibit US-1).

¹ SPS Agreement, Article 2.2.

² See e.g., SPS Agreement, Articles 3.2, 5.1. 5.2; see also Australia – Salmon (AB), para. 137 ("in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence.").

application of its import prohibitions. Moreover, India does not impose any comparable restrictions on the internal movement of the products that it prohibits for import. For example, when it comes to imports, India's measures treat an outbreak of LPNAI in the U.S. state of Hawaii as meaning imports from the state of Delaware, half an ocean and continent away, must also be prohibited. In contrast, India finds that an outbreak in its territory of the more dangerous Highly Pathogenic Notifiable Avian Influenza ("HPNAI") should only affect the movement of products if they are within a few kilometers' radius of the outbreak. Moreover, India has gone so far as to apply the OIE principle of "zones" in its territory.⁷ India asserts that any avian influenza outbreaks in its territory in these zones would not affect the health status of areas outside these zones – and thus allow them to continue exports unimpeded. And finally, India, which has suffered over 90 recorded outbreaks of HPNAI, cites the very OIE standards it rejects for imports as justification that restrictions by other countries on its own exports are unreasonable.

5. The United States would also note that the present matter is different from a number of prior disputes under the SPS Agreement. This dispute does not involve a review of whether a Member's assessment of scientific evidence is adequate. To the contrary, the record shows that India has not conducted such an assessment. Accordingly, as the United States will show in this submission, India has failed to comply with the most basic procedural obligations in the SPS Agreement, and thus no detailed scientific analysis is required to reach this conclusion.

6. As far as India's Request for a Preliminary Ruling ("PRR") is concerned, the United States will show that India's request has no merit. The U.S. panel request is one of the most detailed panel requests ever put forward in an SPS dispute. It identifies both the measures and the claim well beyond the level of precision required by Article 6.2 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"). India asserts that textual explanations provided in the panel request, including examples of specific breaches by India somehow impair its defense. Not surprisingly, neither the Appellate Body nor any panel has found that such could be the case. The United States respectfully submits, as this submission will demonstrate, that India's problem is not that the U.S. panel request precludes India from preparing a defense, but that India's measures are, in fact, simply indefensible.

II. SUMMARY OF ARGUMENTS

7. India asserts that the present dispute is likely to be "particular complex."⁸ The United States disagrees. This dispute can be distilled to a few central facts that clearly establish India's breaches of its WTO obligations. Specifically, there are facts that establish that India needed to

⁷ OIE Code, Glossary (A compartment under the OIE Code "means an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.") (Exhibit US-2)

⁸ India, Preliminary Ruling Request ("PRR"), para. 60.

undertake a risk assessment – and that India failed to do so; that India's measures hold the exports of other Members to severe requirements – that India's own products can safely ignore; and that India was obligated to notify its measures and allow a reasonable interval before putting them in force – but clearly did not. The United States will address in this submission these facts and the breaches that arise as a result as follows.

Factual Background

Different Diseases

8. The United States will begin its presentation by providing background on the assortment of diseases that are termed avian influenza in order to provide subsequent context on the international standards that govern its control. Avian influenza is first and foremost a concern with respect to its impact on poultry stocks. Some variants of avian influenza viruses, Highly Pathogenic Avian Influenza ("HPAI"), are highly contagious and can decimate poultry flocks.

9. There are also avian influenza virus strains, termed Low Pathogenicity Avian Influenza ("LPAI"), that cause a much milder, often asymptomatic disease. The natural reservoir for these viruses is wild birds that are found on all continents. Essentially, all countries, including India, have LPAI viruses and their complete eradication is not possible. In poultry, the nature of LPAI viruses is such that when they affect poultry, the infection is primarily limited to the respiratory tract. Such infections are not systemic and therefore, do not spread to internal organ systems including the musculoskeletal (meat) and the reproductive (eggs) systems. Certain subtypes of LPAI, specifically H5 and H7 subtypes, however, are of concern because , they have the potential to mutate into the more virulent highly pathogenic strains

10. Most avian influenza strains do not affect humans because they do not readily transmit to humans. Where human infection has occurred, close handling and contact with birds is typically required. With LPAI viruses, when human infection occurs, it is generally mild and results in symptoms that include conjunctivitis and mild fever.⁹ One HPAI strain, the H5N1 Eurasian strain, presents particular concerns because although transmission remains difficult, when people are infected, the mortality rate is high. Even with this strain, however, human infections are typically associated with those who have been closely handling poultry. More pertinently, the United States has not had any outbreaks of HPAI H5N1. In contrast, India has had over ninety HPAI H5N1 outbreaks in the last ten years, and still asserts its products are safe for export.

⁹ Conjunctivitis (commonly referred to as "pink eye") is an inflammation or infection of the transparent membrane (conjunctiva) that lines the eyelid and covers the white part of the eyeball. Mayo Clinic, Definition of Pink eye (conjunctivitis), available at <u>http://www.mayoclinic.com/health/pink-eye/DS00258</u> (last accessed March 29, 2013) (Exhibit US-3).

Different Control Measures

11. The SPS Agreement designates the OIE as the relevant organization for setting standards and recommendations for the safe trade in animals and animal products with respect to animal diseases such as avian influenza. The OIE's recommendations are risk based to assure the safe trade of animal commodities.¹⁰ For avian influenza, these recommendations recognize that the virus is not always the same and should be treated accordingly. Whereas India imposes blanket import prohibitions, the OIE standards recognize the differences between the low and high pathogenicity strains and recommends different measures to ensure that trade safely continues. For example, the OIE recognizes that LPAI is not found in the insides of eggs and recommends trade be allowed with surface sanitation.

India's Measures are Inconsistent with International Standards

12. Whereas the OIE's recommendations provide that various products can be in fact imported with the proper control measures, India has chosen to ban those products outright. Moreover, the trigger and scope of India's measures are inconsistent with the OIE recommendations. For example, the OIE recommendations provide that notifications of highly pathogenic avian influenza in wild birds made to the OIE are not a basis to impose import prohibitions.¹¹ India conversely uses such notifications as a basis to apply its prohibitions. Moreover, while the OIE encourages countries to consider principles such as regionalization – i.e. limiting the territory to which a measure need be applied – India categorically rejects their consideration. The United States additionally notes that when it comes to its measures, India notifies them to the WTO after they have already gone into force with no opportunity for Members to provide comments.

13. In the SPS Committee, India initially asserted its measures were consistent with OIE recommendations until multiple Members highlighted the obvious inconsistencies. India then asserted it had conducted a detailed risk assessment that justified its measures. Various Member's representatives in the SPS Committee asked to review it. After a lengthy delay, India provided a document that it described at the time as, and was titled as, a risk assessment. The United States requested the OIE to provide its insights on the document. At a subsequent meeting of the SPS Committee, an official with the OIE reviewed the document and noted numerous deficiencies with the document if it were held out to be a risk assessment, including the fact that it failed to identify what, if anything, it was addressing, that its authorities were outdated, and that it was difficult to see how the document supported India's measures since it copied part of another Member's risk assessment and that Member's risk assessment concluded that the products India prohibits could be safely imported. Since then, India has disclaimed that document as a risk assessment and acknowledged it presently lacks one. To ensure clarity

¹⁰ OIE Code, Chapter 10.4 (Exhibit US-1).

¹¹ OIE Code, Article 10.4.1.9 (Exhibit US-1).

regarding India's position, the United States sent a request to India under Article 5.8 of the SPS Agreement over one year ago.¹² The request asked, *inter alia*, for India to provide any risk assessments that support its measures. India responded by asserting it would need more time to respond to the U.S. request, and has never provided any other response.

India's Different Standards for its Own Products

14. India's publicly stated concerns about the risk that imports present in respect to avian influenza stand in stark contrast to its internal practices for its own industry. India is inconsistent with respect to both surveillance of NAI and movement of affected products. With respect to surveillance, India prohibits imports from any country that reports an outbreak of LPNAI to the OIE. India's own surveillance regime, however, makes no mention of LPNAI and is unlikely to be able to detect it. When an outbreak of NAI or rather HPNAI (India has never found LPNAI) occurs in India, India only limits the movement of products that are within a few kilometers of the outbreak.

15. Additionally with respect to regionalization, India certifies zones in its own territory as meeting OIE standards. The logic behind establishing zones is that other countries should recognize that areas outside these zones should be allowed to continue exports. Thus, while India demands that imports be permitted only from countries that are completely free of avian influenza, it sees no irony is asserting that other countries should accepts its exports from areas outside these zones

<u>Claims</u>

16. As explained in detail below, the foregoing facts establish that India has sanitary measures in place that are not based on international standards or a risk assessment, that result in unfair treatment of imports, and that were never properly notified to the WTO. As detailed below, they result in the following breaches of the WTO Agreement.

Risk Assessment Claims

17. The relevant international standards, those of the OIE, contain specific science-based recommendations for addressing the risks posed by avian influenza. Since India's measures do not conform to international standards, India was obligated to undertake a risk assessment and base its measures on such, which it has not done. Accordingly, India has breached the following WTO obligations as a result.

 Article 5.1 of the SPS Agreement: India breached this provision by failing to undertake a risk assessment;

¹² United States, Letter from Ambassador Michael Punke to H.E. Mr. Jayant Dasgupta (Jan. 17, 2012) [hereinafter "5.8 Request"] (Exhibit US-4).

- Article 5.2 of the SPS Agreement: Since India failed to undertake a risk assessment, it necessarily breached Article 5.2 since it did not take into account the considerations mandated by that provision in conducting a risk assessment, including, *inter alia*, the available scientific evidence;
- Article 2.2 of the SPS Agreement: As India lacks a risk assessment, its measures are not based on scientific evidence and principles – and the available science would not support such measures in any event – India breached Article 2.2.
- Article 3.1 of the SPS Agreement: As India lacks a risk assessment, and in any event its appropriate level of protection is satisfied by the OIE's standards, it may not introduce or maintain sanitary measures that are not based on the OIE's standards;
- Article 5.6 and 2.2 of the SPS Agreement: India has an obligation to ensure that its measures are not more trade restrictive than required to achieve its appropriate level of protection. Because the OIE Code is a reasonably available alternative that exceeds India's level of protection and is less trade restrictive, India breached Article 5.6. Because these facts also establish that India's measure is not applied to the extent necessary, India has breached Article 2.2 as well.

Regionalization Claims

18. India is fully cognizant of the principle of regionalization: when assessing the eligibility of a country to export products, account may be taken of the sanitary status of regions within the country. In other words, not all territory in a country requires uniform treatment. Indeed, India asserts such a right for itself by maintaining compartments with respect to avian influenza. However, India refuses to take in account this principle when it comes to its trading partners. India's refusal to do so results in the following breaches of the SPS Agreement.

- Article 6.1 of the SPS Agreement: India's measures do not take into account disease-free areas or areas of low disease prevalence, or the existence of eradication or control programs. Moreover, India has not taken into account the relevant guidelines of the OIE in assessing the sanitary characteristics of a region. Accordingly, India has breached Article 6.1 of the SPS Agreement.
- Article 6.2 of the SPS Agreement: As India's avian influenza measures do not recognize disease-free areas or areas of low disease prevalence, India has breached Article 6.2 of the SPS Agreement.

National Treatment Claims

19. With regard to its own products, India essentially asserts it is free of LPAI simply because India does not bother to take the steps that would actually result in its discovery. Moreover, India places very limited restrictions on the movement of commodities internally in response to detections of the more dangerous HPAI. But for imported products, India bans all imports upon an LPAI notification, regardless of whether the measure can be regionalized, and without any finding of risk with respect to such products. These doubles standards result in the following breaches of the SPS Agreement.

- Article 2.3 of the SPS Agreement: As India does not apply similar avian influenza related controls with respect to like domestic products and their internal movement within India, India has breached both the first and second sentences of Article 2.3 of the SPS Agreement.
- Article 5.5 of the SPS Agreement: To the extent that India's treatment of avian influenza by way of U.S. agricultural products is viewed as a "different situation" than the transmission of avian influenza by way of India's domestic agricultural products, India is maintaining arbitrary or unjustifiable distinctions in its appropriate levels of sanitary protection in different situations, and these distinctions result in discrimination or a disguised restriction on international trade. India has thereby breached Article 5.5.

Notification Claims

20. India's failure to notify properly its measures result in the following breaches of the SPS Agreement.

 Article 7, and Annex B, paragraphs 2 and 5(a)-(d) of the SPS Agreement: India is not in compliance with its obligations under Article 7 and Annex B because it did not notify S.O. 1663(E) to the WTO or before it took effect, thereby preventing other Members, like the United States, from having a meaningful opportunity to comment on it.

Consequential Breach of GATT Article XI 1994

21. India has breached Article XI of GATT 1994 because its measures that are inconsistent with the SPS Agreement constitute import prohibitions or restrictions other than duties, taxes, or other changes.

India's Preliminary Ruling Request

22. The final issue the United States will address in its submission is India's Preliminary Ruling Request. The United States' Panel Request is required to identify the measures and

claims in accordance with Article 6.2 of the DSU. This the Panel Request more than amply does.

23. With respect to measures, the Panel Request clearly identifies the measures at issue: India's import restrictions imposed on countries because of NAI. The United States' Panel Request additionally cited specific legal instruments that reflect these measures, thus providing additional clarification to India. The United States has done so notwithstanding India's failure to respond to a request made by the United States under Article 5.8 of the SPS Agreement asking India to identify its measures.¹³

24. With respect to the claims, the Panel Request identifies the precise treaty provisions at issue, not simply the parent articles. The Appellate Body has noted that such level of detail might be necessary in *some* circumstances. The United States, however, provided more detail than what might be required in *some* circumstances. The Panel Request also provides a textual explanation after each cited provision as to the nature of the breach. As confirmed by a review of this submission, there is nothing presented here that the Panel Request did not provide fair notice of to India.

III. BIOLOGY OF AVIAN INFLUENZA

25. In the late 19th century, a highly contagious disease decimated poultry stocks in Europe. This disease was commonly known as "foul plague."¹⁴ Today, that disease is called Highly Pathogenic Avian Influenza ("HPAI") and it has continued to appear in various countries around the world causing death primarily to poultry such as chickens and turkeys.¹⁵ The United States fully recognizes that WTO Members have a legitimate interest in seeking to protect their poultry stocks from HPAI exposure – and as discussed below the milder disease known as LPAI as well.¹⁶ The United States is not requesting that the Panel decide otherwise. What the United

¹³ United States, Article 5.8 Request (Exhibit US-4).

¹⁴ Hans-Dieter Klenk, Mikhail Matrosovich and Jűrgen Stech, "Avian Influenza: Molecular Mechanisms of Pathogenesis and Host Range," ANIMAL VIRUSES: MOLECULAR BIOLOGY (Eds. Thomas C. Mettenleiter and Francisco Sobrino) (2008), p. 256. [hereinafter "Klenk & Matrosovich"] (Exhibit US-5).

¹⁵ *Id.*; *see also* D.E. Swayne and D.A. Halvorson, "Influenza," DISEASES OF POULTRY, Eds. Y.M. Saif et. al. (12th Ed. 2008) p. 153. [hereinafter "Swayne & Halvorson"] (Exhibit US-6).

¹⁶ C.W. Beard, "Minimizing the vulnerability of poultry production chains for avian influenza," AVIAN INFLUENZA: PREVENTION AND CONTROL, Eds. Remco S. Schrijver & G. Koch (2005) p. 134 ("It is usually when the AI viruses apparently 'spill over' from their natural hosts and become adapted to domestic poultry species that they become the cause for concern. The highly pathogenic members of the AI viruses can result in very serious economic losses to commercial poultry.") [hereinafter "Beard"] (Exhibit US-7).

States does take issue with are measures such as India's that broadly block trade without any consideration of the relevant scientific evidence. As explained below, the science behind avian influenza reflects different diseases that present distinct risks. Yet, as demonstrated *infra* in this submission, nowhere has India bothered to consider this evidence and whether its measures – that treat these different diseases uniformly – are appropriate as a result.

A. Overview And Classification

26. At the outset, it is important to clarify that the term "avian influenza" does not refer to a single or homogenous disease, but rather different diseases caused by an assortment of different viruses. The common denominator to the viruses is that they are all Type A influenza viruses that have been isolated from and adapted to avian hosts.¹⁷ Some avian influenza viruses are endemic to certain avian species and cause mild symptoms, if any, while others result in a severe disease that can often be highly contagious among avian species and fatal to infected animals.¹⁸ Accordingly, the term "avian influenza," without any further indicia as to the specific variant of virus, provides little information as to the risk presented and the methods by which to address it.¹⁹

¹⁸ David L. Suarez, "Influenza A Virus," AVIAN INFLUENZA, Ed. David Swayne (2008), p. 3 ("Avian influenza (AI) virus in poultry is unusual in that it can cause a range of disease symptoms from a subclinical infection to being highly virulent with 100% mortality. The difference between low pathoegenicity (LP) and high pathogenicity (HP) viruses can be as small as a single amino acid change in the hemagglutinin (HA) fusion cleavage site. Therefore, it is important not only to assess an AI virus's ability to cause disease in poultry but also to assess the potential for AV viruses to cause disease in poultry.") [hereinafter "Suarez"] (Exhibit US-10).

¹⁷ Avian influenza viruses, like other influenza viruses, belong to the family orthomyxoviridae. There are three types of influenza viruses: A, B, and C. Erica Spackman, "A Brief Introduction to the Avian Influenza Virus," AVIAN INFLUENZA VIRUS, Ed. Erica Spackman, Humana Press (2008), p. 1 [hereinafter "Spackman"] (Exhibit US-8); Abert D.M.E. Osterhau, Vincent J. Munster, & Ron A.M. Fouchier, "Epidemiology of Avian Influenza," AVIAN INFLUENZA, Eds. H.-D. Klenk et al., (2008) [hereinafter "Osterhau"] (Exhibit US-9).

¹⁹ See Dennis J. Alexander, "Orthomyxoviridae – Avian Influenza," POULTRY DISEASES (6th Ed.), Ed. Dennis J. Alexander (2008), p. 318 ("Because of the marked difference of the disease in susceptible poultry caused by avian influenza AI) viruses depending on the virulence of the virus strain ... it is necessary to make clear definitions of the different viruses for trade and control purposes.") [hereinafter "Alexander"] (Exhibit US-11); Food and Agriculture Organization of the United Nations, Epidemiology of Avian Influenza, available at http://www.fao.org/avianflu/en/clinical.html (last accessed March 30, 2013) [hereinafter "FAO, Epidemiology"] ("A particular isolate may produce severe disease in turkeys but not in chickens or any other avian species. Therefore, it would be impossible to generalize on the host range for avian influenza, for it will likely vary with the isolate.") (Exhibit US-12).

27. The variants (subtype) of avian influenza viruses are classified according to two surface antigens on the particular virus: the hemagglutinin (H) and neuraminidase (N) antigens.²⁰ There are 16 H types (H1 to H16) and nine N types (N1 to N9).²¹ Accordingly, an avian influenza virus referred to as H5N7 has hemmagglutinin antigen type 5 and neuraminidase antigen type 7. The HN subtypes are generally classified as belonging to one of two groups, according to their ability to cause disease, *i.e.*, pathogenicity, *in chickens*: (i) Highly Pathogenic Avian Influenza (HPAI) and (ii) Low Pathogenic Avian Influenza.²² HPAI viruses have either H protein 5 or 7 *and are highly virulent for chickens* (75 percent of higher mortality).²³ LPAI viruses encompass all other types of avian influenza, including those that have H protein 5 or 7 and are not highly virulent.²⁴ In other words, having an H5 or H7 protein is a prerequisite for HPAI, but not sufficient in itself.²⁵

²¹ Spackman, p. 1; CDC, Avian Influenza (Bird Flu): Influenza Viruses (Nov. 18, 2005), p. 2-3 (Exhibit US-16).

²² See, e.g., David E. Swayne and Mary Pantin-Jackwood, "Pathobiology of Avian Influenza Virus Infections in Bids and Mammals,", p. 87 [hereinafter "Swayne and Pantin-Jackwood"] (Exhibit US-18).

²³ *See, e.g.*, D.E. Swayne & D.L. Suarez, "Highly Pathogenic Avian Influenza," Rev. Sci. tech. Off. Int. Epiz, 2000, p. 464 [hereinafter "Swayne & Suarez"] (Exhibit US-19).

²⁰ The full nomenclature for influenza virus requires the listing of the (1) influenza virus type,(2) the host origin (omitted in the case of human origin), (3) the geographical site, (4) the strain reference number, (5) year of isolation, and (6) for Type A viruses, the H and N subtypes. For example, A/turkey/England/1999/79 (H7N7). *Id.*, p. 318; David Swayne, "Epidemiology of Avian Influenza in Agricultural and Other Man-Made Systems," AVIAN INFLUENZA, Ed. David Swayne (2008), p. 62[hereinafter "Swayne, Epidemiology"] (Exhibit US-13); Douglas Causey and Scott V. Edwards, "Ecology of Avian Influenza Virus in Birds," JOURNAL OF INFECTIOUS DISEASES 2008; 197:S29–33, p. S30 [hereinafter "Causey & Edwards"] (Exhibit US-14); Hiroshi Ushirogawa and Masanobu Ohuchi, "Novel Antiviral Activity of Neuraminidase Inhibitors Against an Avian Influenza A Virus," Virology Journal 2011 8:411, p.1 ("HA helps the virus enter target cells. The function of NA is to destroy viral receptors by removing sialic acid residues from sialoglycans, thereby contributing to the release of progeny viruses from infected cells.") (Exhibit US-15).

²⁴ Klenk & Matrosovich, p. 258 (HPAI viruses are defined as H5 and H7 viruses that cause 75% or higher mortality after experimental infection of chickens and that have a polybasic hemagglutinin cleave site. ... All viruses that do not meet these criteria are classified as LPAI viruses.") (Exhibit US-5)

²⁵ FAO, Epidemiology; Canada Food Inspection Agency, Fact Sheet – Avian Influenza (last modified Dec. 22, 2012), p.1 ("For example, the H5N1 strain that has been reported in various parts of Europe is low pathogenic and is distinctly different from the Asian strain, which is highly pathogenic.") (Exhibit US-20).

1. LPAI

28. With respect to LPAI viruses in avian species, there are four salient features to note for the purposes of this dispute: (1) endemicity, (2) disease severity, (3) viral replication, and (4) mutation.

29. First, LPAI viruses are endemic (natural) to certain species of birds, particularly aquatic birds, and found on all seven continents.²⁶ LPAI viruses have been found in more than 100 different wild bird species of more than 25 different families.²⁷ Wild birds are thus a natural reservoir for LPAI viruses.²⁸ If a country has wild birds, which almost every country must (including India), that country also has LPAI.²⁹ Therefore, the reality is that no country can realistically declare that it is free of LPAI or that it has eradicated it.³⁰

²⁸ OIE, Avian Influenza Disease Card ("In wild birds, it is common during routine testing to find some influenza viruses. The vast majority of these viruses do not cause disease.") (Exhibit US-23).

²⁶ David E. Swayne, "The Global Nature of Avian Influenza," AVIAN INFLUENZA, Ed. David Swayne (2008), p. 123 [hereinafter "Swayne, Global Nature"] (Exhibit US-21); FAO, Epidemiology ("AI viruses are probably ubiquitous in wild water birds. Pathogenic strains could emerge and cause disease in domestic poultry in any country at any time without warning. In fact, outbreaks have occurred at irregular intervals on all continents.") (Exhibit US-12).

²⁷ Osterhau, p. 2 (Exhibit US-9); R.A.M. Fouchier & V.J. Munster, Epidemiology of Low Pathogenic Avian Influenza Viruses in Wild Birds, Rev. sci. Off. Int. Epiz. 2009, p. 49 (Exhibit US-22); *see also* Swayne, Epidemiology, p. 63 ("However, the number of naturally infected bird species in most likely greater than the 105 reported species.") (Exhibit US-13).

²⁹ David Swayne, "Avian Influenza Control Strategies" AVIAN INFLUENZA, Ed. David E. Swayne (2008) p. 287 ("The existence of LPAI viruses in a variety of wild acquatic birds, causing mostly asymptomatic infections and as part of ecosystems on all seven continents suggests the presence of LPAI viruses is natural, has existed for eons, and is of minimal consequence in its natural setting. Therefore, humans have had and will continue to have minimal impact on control of LPAI viruses in wild bird populations.") [hereinafter "Swayne, Control Strategies"] (Exhibit US-24); Antonio Petrini and Bernard Vallat, "Notification of Avian Influenza and Newcastle Disease to the World Organisation for Animal Health (OIE),"AVIAN INFLUENZA AND NEWCASTLE DISEASE: A FIELD AND LABORATORY GUIDE, Eds. Illaria Capua & Dennis J. Alexander (2009), p. 29 ("The presence of AI viruses in wild birds creates a particular problem. In essence, no country can declare itself free from AI carried in wild birds.") [hereinafter "Petrini & Vallat"] (Exhibit US-25).

³⁰ *Id.*; Petrini & Vallat, p. 29 ("The presence of AI viruses in wild birds creates a particular problem. In essence, no country can declare itself free from AI carried in wild birds.") (Exhibit US-25); David E. Stallknecht and Justin D. Brown, "Ecology of Avian Influenza in Wild Birds," AVIAN INFLUENZA, Ed. David E. Swayne (2008), p. 51 ("Because there are no realistic options for reducing AI virus prevalence in wild bird populations, prevention through decreased direct or environmental contact is the primary defense and such prevention should be centered on wild bird-domestic animal interface."). [hereinafter "Stallknecht & Brown"] (Exhibit US-26).

30. Second, LPAI strains cause mild disease, often with few, if any, clinical symptoms.³¹ Some birds, such as domestic and wild waterfowl, may have the virus and yet show no clinical signs of the disease.³² In broiler chickens, "LPAI infections are often inapparent and, when present, can be confused with other conditions."³³ To the extent there are symptoms, they include reduced egg production and respiratory difficulties.³⁴ Mortality, in the absence of secondary infections, is generally below five percent.³⁵ This lack of apparent clinical signs impairs detection and control of LPAI in birds, including poultry:

The early detection of LPAI is the key to controlling its spread. Often the first flocks to be infected go through a silent infection or become ill from second disease agent so that the diagnosis of AI is missed. Clinical signs and lesions may lead to an incomplete diagnosis of pasteurellosis or colibacillosis. These flocks,

³¹ Illaria Capua and Calogero Terregino, "Clinical Traits and Pathology of Avian Influenza Infections, Guidelines for Farm Visit and Differential Diagnosis," AVIAN INFLUENZA AND NEWCASTLE DISEASE: A FIELD AND LABORATORY GUIDE, Eds. Illaria Capua & Dennis J. Alexander (2009), p. 45 [hereinafter "Capua & Terregino"] (Exhibit US-27); *see also* Food and Agriculture Organization of the United Nations, Questions & Answers: The Facts of Bird Flu, Response to Q. 1, available at <u>http://www.fao.org/avianflu/en/qanda.html</u>. (last accessed March 29, 2013) ("Low pathogenic avian influenza is a natural infection of waterfowl that may cause minimal to no signs of disease in domestic poultry and wild birds and is not a serious threat.") (Exhibit US-28).

³² Capua and Terregino, p. 45 (Exhibit US-27).

³³ *Id.* at 49 (Exhibit US-27). In contrast to broiler chickens, turkeys are more susceptible to infection and mortality, although the extent of clinical symptoms is contingent on the age of the bird. Clinical symptoms vary and may include depression, ruffled feathers, drop in feed consumption, reluctance to move, respiratory distress, decrease in egg production, conjunctivitis, and mortality. *Id.* at 45-46 (Exhibit US-27). In India, the turkey industry is in its infancy. Government of India, Department of Animal Husbandry & Dairying (Central Poultry Development Organization, Southern Region), Turkey – Management Guide, available at <u>http://www.cpdosrbng.kar.nic.in/</u> (last accessed March 29, 2013) (Exhibit US-29).

³⁴ Spackman, p.3 ("In chickens and turkeys, LPAI virus infection may be subclinical; however, in the field, mild to moderate respiratory disease is the primary presentation. Lethargy and a drop in egg production are also frequently observed. Although the LPAI virus may cause mortality in the field, mortality is generally low and may be due to, or exacerbated by, secondary causes.") (Exhibit US-8); Swayne, Global Nature, p. 128 ("Infections in the field with LPAI virus infection typically procures respiratory disease or drops in egg production, but mortality is usually low unless accompanied by secondary agents such as bacteria, which can result in mortality as high as 80% in turkeys and 75% in quail.") (Exhibit US-21).

³⁵ Swayne & Pantin-Jackwood, p. 91-92 (Exhibit US-18).

as well as incubating and convalescent flocks, may be excreting virus while they appear healthy; thus, there is no such thing as 'known noninfected' flock."³⁶

In short, without testing, LPAI infections go easily undetected.

31. Third, LPAI virus replication is generally not systemic, which has important implications for the safe trade in poultry products.³⁷ LPAI virus replication is usually limited to the respiratory and intestinal tracts.³⁸ In particular, scientific studies have found that LPAI viruses do not spread to muscle, i.e., poultry meat, or to the insides of eggs.³⁹ As there is no virus in these vectors, there is also nothing that could transmit an infection provided precautions are taken to avoid contamination from other sources.

32. The final and critical feature to note is that certain subtypes of LPAI can mutate to HPAI if introduced in poultry. Specifically, H5 and H7 subtypes if introduced in poultry can mutate into forms that cause HPAI.⁴⁰ As described by a scientist who has studied the issue:

The HPAI viruses, for unknown reasons, have been restricted to the H5 and H7 subtypes, but most H5 and H7 influenza viruses are of low pathogenicity. It is a rare occurrence that these LPAI viruses mutate into the HPAI viruses. It is

³⁸ Swayne & Halvorson, p. 169 (Exhibit US-30).

³⁹ David E. Swayne and Collen Thomas, "Trade and Food Safety Aspects for Avian Influenza Viruses," AVIAN INFLUENZA, Ed. David E. Swayne (2008), p. 505 ("HPNAI virus has been isolated from the internal contents laid by infected hens, while LPNAI of LPAI virues have not been demonstrated in the internal contents of eggs laid by acutely infected hens.") [hereinafter "Swayne & Thomas"] (Exhibit US-31); Statement of Dr. David Swayne, p. 1 (Exhibit US-97).

⁴⁰ Swayne, Epidemiology, p. 64 ("Historically, HPAI viruses have arisen from LPAI viruses after circulation in gallinaceous poultry and are the result of mutations at the poreolytic cleavage site of the hemagglutinin protein.") (Exhibit US-13); Klenk & Matrosovich, p. 259 ("HPAI viruses arise by introduction and circulation of H5 and H7 LPAI viruses in domestic poultry with subsequent mutations in HA. In general, aquatic birds are not the natural host of HPAI viruses. However, there is evidence that the H5N1 HPAI viruses circulating in Asia have recently been re-introduced from poultry into wild aquatic birds.") (Exhibit US-5).

³⁶ David A. Halvorson, "Control of Low Pathogenicity Avian," AVIAN INFLUENZA, Ed. David E. Swayne (2008).

³⁷ Swayne & -Pantin-Jackwood, p. 88 (On rare occasions, LPAI viruses have spread systemically to organs that contain epithelial cells with typsin-like enzymes such as kidney tubules and the pancreatic acinar epithelium.) (Exhibit US-18).

generally believed that HPAI viruses arise from H5 and H7 LPAI viruses that have been allowed to circulate in poultry for extended periods of time.⁴¹

The precise triggers for the mutation process are not well understood. For example, a 2004 outbreak of a low pathogenicity H7 subtype in Canada quickly mutated into an HPAI form within a matter of days. Conversely, LPNAI strains have circulated in poultry flocks in some Central American countries for a number of years without becoming highly pathogenic.⁴² Thus, it is presently impossible to predict if and when an LPAI virus in poultry will mutate into a HPAI form.

2. HPAI

33. With respect to the four features noted above for LPAI, the first three (the fourth being inapplicable) stand in stark contrast with respect to HPAI.

34. First, whereas LPAI is endemic to wild bird species, HPAI viruses "are not believed to be normally present in the wild bird reservoir."⁴³ The significance of this is two-fold. One, it is in fact possible for countries to eradicate HPAI.⁴⁴ Two, it supports the need to engage in surveillance of H5 and H7 LPAI subtypes in poultry. Accordingly, the United States emphasizes that it is not arguing in this dispute that LPAI, particularly H5 and H7 subtypes, are irrelevant, but rather different. The United States, and other countries, recognize that monitoring is appropriate and in fact engages in such surveillance:

In the United States, Canada, European Union (EU), Australia, and other developed countries, serological and virologic active and passive surveillance programs in commercial poultry farms are free of AI infections. In these

⁴² Swayne & Halvorson, p. 169 (Exhibit US-6).

⁴³ Suarez, p. 11 (The recent outbreaks with mortality in wild birds with Asian H5N1 HPAI viruses are believed to be related to spillover of HPAI virus from domestic birds to wild birds, and it is currently unclear if this lineage of HPAI has become endemic in some wild bird species.") (Exhibit US-10); Swayne, Control Strategies, p. 288 ("The HPAI viruses have not arisen nor are they maintained in a wild bird reservoir. Instead, H5 and H7 LPAI viruses are introduced from wild aquatic birds into village or commercial poultry and HPAI virus strains arise through specific mutations in the HA gene following circulation to years. ... There are two exceptions to this rule: (1) an H5N3 HPAI virus infected common terns in South Africa during 1961 and (2) the Asian lineage of H5N1 HPAI virus that initially did not involve wild birds, but in 2002, strains emerged with the capacity to infect a variety of wild and captive birds") (Exhibit US-24).

⁴⁴ Swayne, Control Strategies, p. 289 ("From 1959 to 1992 most developed countries eradicated HPAI epizootics or outbreaks within a few weeks to a year by traditional stamping out programs.") (Exhibit US-24).

⁴¹ Suarez, p. 11 (Exhibit US-10).

countries, the primary control strategy has been preventing the introduction of LPAI virus into agricultural systems.⁴⁵

As will be discussed *infra*, the more pertinent question here is whether Members that engage in such surveillance, and inevitably finding LPAI, should be punished for doing so by a Member that fails to even engage in such surveillance.

35. Second, HPAI infections are severe and typically lethal for chickens and other gallinaceous poultry.⁴⁶ Mortality rates for poultry flocks infected with HPAI often approach 100%, sometimes within 72 hours of infection. Poultry infected with HPAI also show obvious clinical signs. Afflicted poultry, assuming they are not dead, may suffer from facial edema (swelling), hemorrhaging (bleeding), and necrosis (death of body tissue). Thus in contrast to LPAI, a farmer whose flocks are afflicted with HPAI should be able to readily discern that his flocks have a problem.

36. Third, HPAI viruses replicate systemically. Therefore, the virus can be found in most organ systems.⁴⁷ The nature of HPAI viruses allow them to replicate in various cell types including "brain, heart, skeletal muscle, and pancreas."⁴⁸ The damage to the organs as well as the cells lining blood vessels result in the various symptoms and death of the bird.⁴⁹ Accordingly, while LPAI replication is typically limited and thus means certain commodities such as meat and eggs do not contain virus, the same cannot be said for HPAI.

B. Transmission

1. Among Avian Species

37. Birds excrete avian influenza virus through their nostrils (nares), mouth, conjunctiva, and cloaca.⁵⁰ In other words, bird respiratory secretions, saliva, and feces contain virus, with feces in

⁴⁵ Swayne, Control Strategies, p. 287 (Exhibit US-24).

⁴⁶ Swayne & Pantin-Jackwood, p. 87. 92 ("but such viruses typically do not cause illness in ducks and geese.") (Exhibit US-18) The Center for Food Security & Public Health, Iowa State University, High Pathogenicity Avian Influenza, (Jan. 2010), p. 1 [hereinafter "CFSPH"] (Exhibit US-32).

⁴⁷ Mary Lea Killian, "Avian Influenza Virus Sample Types, Collection, and Handling," AVIAN INFLUENZA VIRUS, Ed. Erica Spackman, Humana Press (2008), p. 7 (Exhibit US-33); Klenk & Matrosovich, p. 258 (Exhibit US-5).

⁴⁸ Suarez, p. 11 (Exhibit US-10).

⁴⁹ *Id*. (Exhibit US-10).

⁵⁰ Swayne & Halvorson, p. 165 (Exhibit US-6).
particular containing large amounts of virus.⁵¹ Fecal-oral transmission appears to be the main route for transmission in wild bird populations.⁵² The fecal droppings of wild birds, particularly ducks, are also often how LPAI is introduced to poultry that are raised in ranges or open flight pens.⁵³ With respect to HPAI viruses, the high virus levels in tissues means that consumption of carcasses by birds can also be a route for transmission.⁵⁴

38. There are other routes by which influenza virus can infect poultry as well. Humans can help transmit the virus through contaminated clothing and equipment and particularly by moving dead infected birds.⁵⁵ It should be noted that pigs can be a concern with respect to influenza viruses as turkeys are susceptible to *swine viruses* including H1N1, H2N2 or H3N2.⁵⁶

39. With respect to vertical transmission (chicken to egg), as noted previously, LPAI does not replicate to inside eggs. HPAI viruses have been found inside eggs, but they are embryo lethal. Hatching of eggs infected with HPAI has never been demonstrated.⁵⁷

40. Critically, in considering the issue of transmission, it is essential to consider that avian influenza viruses can be inactivated or destroyed. Avian influenza viruses are not typically stable in the environment. While avian influenza viruses may be able to sustain themselves for an extended time in water, feces, or low temperatures,⁵⁸ a "hot, dry sunny day will cause rapid natural inactivation of the virus."⁵⁹ Heat, extremes of pH, and dryness can all inactivate the virus. Because the virus has a lipid envelope, organic solvents and detergents as well as

⁵¹ CFSPH, p. 3 (Exhibit US-32); FAO, Q&A, Response to q. 7 (Exhibit US-28).

⁵² Stallknecht & Brown, p. 47 (Exhibit US-26).

⁵³ FAO, Q&A, Response to Q. 10 (Exhibit US-28); Swayne & Halvorson, p. 165-166; U.S. Food & Drug Administration, What Consumers Need to Know About Avian Influenza, available at <u>http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm085550.htm</u> (last updated October 19, 2006) (Exhibit US-34).

⁵⁴ Swayne & Halvorson, p. 165 (Exhibit US-6).

⁵⁵ Swayne & Halvorson, p. 165-166 (Exhibit US-6).

⁵⁶ Swayne & Halvorson, p. 166 (Exhibit US-6).

⁵⁷ *Id.* (Exhibit US-6).

⁵⁸ CFSPH, p. 3 (Exhibit US-32); *see* Halvorson, p. 513 ("it is generally inactivated within 1 week at 21°C but may survive for 5 weeks at 4 C°.") (Exhibit US-30).

⁵⁹ Nathan G. Birnbaum and Bethany O'Brien, "Methods for Inactivation of Avian Influenza Virus in the Environment," AVIAN INFLUENZA, Ed. David E. Swayne (2008), p. 391 [hereinafter "Birnbaum & O'Brien"] (Exhibit US-35).

chemical disinfectants can also all inactivate or destroy the virus.⁶⁰ In fact, "[s]oapy water and detergents may be the first choice for AI virus decontamination of many items."⁶¹

2. From Avian to Human

41. As noted by the World Health Organization, "[m]ost avian influenza viruses do not cause disease in humans."⁶² Thus, as an initial matter, it is important to recognize that avian influenza is distinct from human influenza. The United States is not suggesting that the possibility of human infection by avian influenza should be discounted. It is, however, critical to appreciate the relevant science in order to devise measures that actually address rather genuine risks. That is what the OIE has done in developing its standards.⁶³ India, however, apparently has ignored the science and instead imposed measures that only serve to obstruct trade while providing no additional protection.

42. With respect to transmission of avian influenza to humans, the United States notes two points in particular.

43. First, avian influenza transmission to humans is rare and difficult. Avian influenza viruses "express host adaptation with transmission and infection occurring most frequently and with ease between individuals of the same or closely related species...."⁶⁴ As a result, infection of humans are very rare, especially in light of the amount of exposure humans have likely had to infected birds.⁶⁵ The circumstances of avian influenza transmission to humans typically entail

⁶³ C. Bruschke & B. Vallat, "OIE Standards and Guidelines Related to Trade and Poultry Disease," *Rev. sci. tech. Off. int. Epiz.*, 2008 [hereinafter "Bruschke & Vallat"] ("The OIE strategy … focuses on eradication at the animal source … thereby decreasing the risk of human infections and the development of a human pandemic virus.") (Exhibit US-47).

⁶⁴ Swayne, Control Strategies, p. 293 (Exhibit US-24).

⁶⁵ Nancy J. Cox & Timothy M. Uyeki, "Public Health Implications of Avian Influenza Viruses," AVIAN INFLUENZA, Ed. David E. Swayne (2008), p. 454-455 (table of all reported human illness from avian influenza viruses from 1996 to July 16, 2007) [hereinafter "Cox & Uyeki"] (Exhibit US-37); Swayne, Control Strategies, p. 294 (Exhibit US-24); Swayne and Thomas, p. 501 ("Although some AI strains are more likely than others to infect humans, the risk of human infection from any AI strain is low.") (Exhibit US-31); Gabrielle Neumann, Taisuke Horimoto, Yoshihiro Kawaoka, "Reverse Genetics of Viruses – Applications in research and Vaccine Design, "Reverse Genetics of Influenza Viruses –

⁶⁰ Swayne & Halvorson, p.159 (Exhibit US-6).

⁶¹ Birnbaum & O'Brien, p. 394 (Exhibit US-35).

⁶² World Health Organization, Avian Influenza in Humans, available at <u>http://www.who.int/influenza/human_animal_interface/avian_influenza/en/</u> (last accessed March 31, 2013) (Exhibit US-36).

close contact with infected birds or heavily contaminated environments.⁶⁶ There is no evidence to suggest that human could be infected by avian influenza through consumption of properly cooked poultry meat or eggs.⁶⁷ Indeed, even India in its official government action plan on avian influenza notes that public awareness should emphasize that "it is absolutely safe to consume properly cooked poultry meat and eggs."⁶⁸

44. Second, the nature of human infections has varied depending on whether the strain is LPAI or HPAI. The number of LPAI infections in humans is very small and precludes analytical risk factor studies.⁶⁹ For the handful of infections that have been documented, the impact of the disease in humans appears to be limited:

Illness from infection with LPAI viruses generally has been mild clinically without serious complications or fatal cases reported, and has ranged from focal mild signs and symptoms (e.g., conjunctivitis) to more acute systemic illness (fever and upper respiratory trace disease) with full recovery.⁷⁰

In short, the experience thus far is that humans catch LPAI extremely rarely and when they do, they seem to recover well.

45. With respect to HPAI, the infections have varied from causing mild symptoms to becoming fatal. An outbreak of HPAI H7N7 in the Netherlands resulted in 89 cases of infection. Eighty-eight percent only developed conjunctivitis while one individual developed pneumonia and subsequently died.⁷¹ The strain of HPAI that has gathered the most media attention in recent

Applications of Research and Vaccine Design," AVIAN INFLUENZA, Eds. H.-D. Klenk et al., (2008) (Exhibit US-38).

⁶⁶ Alexander, p 331 ("Transmission between humans appears to have occurred only on very rare, exceptional occasions and in nearly all reported cases of human infection with AI viruses there has been close association with infected birds or infective carcasses.") (Exhibit US-11); OIE, Disease Card, p. 2 ("AI viruses are highly species-specific, but have, on rare occasions, crossed the species barrier to infect humans. Transmission to humans has occurred when there is close contact with infected birds or heavily contaminated environments.") (Exhibit US-23).

⁶⁷ Id.; *see also* European Commission, Key Facts About Avian Influenza, available at <u>http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/ten_key_facts_about_avian_influenza07_en.pdf</u>, p.5 (Exhibit US-39).

⁶⁸ India, Avian Influenza Action Plan (2012), p. 23 (Exhibit US-40).

- ⁶⁹ Cox & Uyeki, p. 463 (Exhibit US-37).
- ⁷⁰ *Id.*, p. 453 (Exhibit US-37).
- ⁷¹ *Id.* at 465 (Exhibit US-37); Klenk & Matrosovich, p. 259-260 (Exhibit US-5).

years is HPAI H5N1. Although cases of human infection remain rare, the case fatality rate is high. However, the transmission of H5N1 to humans remains rare. A tripartite document issued by the World Health Organization, the OIE, and the Food and Agriculture Organization of the United Nation issued on September 7, 2011, noted the following:

- Based on available information, there is currently no increased public health risk posed by any circulating H5N1 virus.
- Human cases of H5N1 infection are rare and sporadic events, occurring mostly in areas where the virus is circulating endemically in poultry. Human cases could occur wherever the viruses are present in poultry and when humans might be exposed to infected birds or contaminated environments. Therefore sporadic human cases could be expected to occur as long as the virus continues to circulate in poultry.⁷²
- As viruses spread more widely and intensively in poultry and wild birds, the likelihood of human exposures to infected birds increases. However, this does not increase the ability of the viruses to infect and transmit between people.⁷³

As the tripartite document explains, HPAI H5N1 infections of humans, like other avian influenza infections, remain rare and are typically the result of exposure to poultry.

⁷² FAO-OIE-WHO Technical Update: Current evolution of avian influenza H5N1 viruses (September 7, 2011) (Exhibit US-41).

⁷³ *Id.*, p. 5 (Exhibit US-41).

C. Parties' Avian Influenza Situations

46. The following map, derived from the OIE, reflects all reported H5 and H7 LPAI outbreaks in poultry from January 1, 2006 to January 1, 2013.⁷⁴



As is evident from the map, the United States has detected H5 and H7 outbreaks of LPAI in poultry, as have other countries that all seem to have surveillance policies in place for detecting LPAI. India, however, has not notified a single outbreak of H5 of H7 LPAI.

47. The situations, however, are flipped when it comes to HPAI. The following map notes all HPAI outbreaks during that interval, including outbreaks in wild birds.⁷⁵

⁷⁴ Generated through the OIE's website (WAHID Interface), available at <u>http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Diseaseoutbreakmaps</u>.

⁷⁵ Generated through the OIE's website (WAHID Interface), available at http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Diseaseoutbreakmaps. India – Measures Concerning the Importation of Certain Agricultural Products from the United States (DS430)



Many, if not most, of these outbreaks appears to be HPAI H5N1. From the end of 2003 to March this year, India has had over 90 HPAI H5N1 outbreaks.⁷⁶

⁷⁶ The following graphic is taken from the OIE's website. It is available at <u>http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/graph_avian_influenza/g</u> raphs_HPAI_12_03_2013.pdf (last accessed April 9, 2013).





Moreover, India's HPAI outbreaks have consistently occurred over an extended period of time. As the following timeline confirms, India's HPAI outbreaks were not clustered during a particular time period, but have occurred each year since 2006.

Key to colours														
There is no information a	vailable o	on this di	sease											
Never reported	Never reported													
Disease not reported dur	not reported during this period													
Disease suspected but n	Disease suspected but not confirmed													
Confirmed infection but r	Confirmed infection but no clinical disease													
Disease presence	Disease presence													
Disease limited to one or	Disease limited to one or more zones													
Infection/Infestation in or	Infection/Infestation in one or more zones													
Disease suspected but n	Disease suspected but not confirmed limited to one or more zones													
- The upper part indicate - The lower part indicate <u>N</u> Note NA Not applicable India														
India														
	Status for six month periods													
Disease	2006		2007		2008		2009		2010		2011		20	12
	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jur	n Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Ju
Highly pathogenic avian influenza														
														7

An FAO report from 2011 discussing H5N1 outbreaks noted the following with respect to India:

The outbreaks in state and research (parent stock) farms were not associated with disease in backyard poultry as there were no confirmation of infection in nearby households. The absence of reports of disease in backyard poultry suggests that outbreak detection in this sector is poor. The occurrence of disease in state and research farms indicates that biosecurity measures are insufficient. Although these outbreaks appear to be isolated sporadic incidents, their frequency and widespread nature, and the detection of infection in crows suggests that areas of India are endemically infected.⁷⁸

Thus, per the empirical results, India's policies since 2006 have not successfully stopped the persistent outbreaks of HPAI.

⁷⁷ Generated from the OIE website, available at <u>http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Diseasetimelines.</u>

⁷⁸ Food and Agriculture Organization of the United Nations, H5N1 Global Overview, Issue 31 (January to March 2012) p. 6.

IV. INTERNATIONAL STANDARDS FOR AVIAN INFLUENZA CONTROL

A. The OIE Terrestrial Animal Health Code's Recommendations for Avian Influenza

48. As the United States explained *supra* in Section III.A., avian influenza is not a homogenous disease. There are significant, meaningful distinctions between HPAI and LPAI. It is not the position, nor the actual practice of the United States to treat LPAI, particularly H5 and H7 subtypes, as irrelevant, but to recognize that because they are *different* than HPAI strains, they warrant *different* control measures. The OIE Code does so as well. Specifically, it recognizes that distinctions between HPAI and LPAI should be made and that control measures will need to be adjusted depending upon the specific product at issue.

49. The OIE Code's system for the control of avian influenza can be roughly divided into five components for the purpose of this dispute: (i) proper reporting; (ii) classifying a territory; (iii) applying the appropriate control measure based on the classification of that territory; (iv) zoning to ensure the impact of restrictions is appropriately tailored; and (v) surveillance. The fifth component is essential to ensuring the prior four mechanisms function properly.

1. Reporting of Outbreaks

50. With respect to the first component, notification, Articles 10.4.1.1 and 10.4.1.2 delineate which strains of avian influenza must be reported to the OIE.

General provisions

- 1) Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in *poultry*, as defined below, should be notified in accordance with the *Terrestrial Code*.
- 2) For the purposes of the *Terrestrial Code*, notifiable avian influenza (NAI) is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75 percent mortality) as described below. NAI viruses can be divided into highly pathogenic notifiable avian influenza (HPNAI) and low pathogenicity notifiable avian influenza (LPNAI):
 - a) HPNAI viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75 percent mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75 percent mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present

at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other HPNAI isolates, the isolate being tested should be considered as HPNAI;

LPNAI are all influenza A viruses of H5 and H7 subtype that are not HPNAI viruses.

Article 10.4.1.2 establishes the nomenclature of NAI, LPNAI, and HPNAI. HPNAI is the same as HPAI. It encompasses H5 and H7 viruses that have high lethality in chickens.⁷⁹ LPNAI consists of the H5 and H7 subtypes of LPAI. In other words, LPNAI is a subset of LPAI that consists only of those LPAI subtypes that may mutate in HPAI. LPNAI thus excludes all other LPAI subtypes. HPNAI and LPNAI collectively are Notifiable Avian Influenza.

51. Article 10.4.1 provides the current notification obligation. All HPNAI outbreaks in birds, including wild birds,⁸⁰ should be reported to the OIE. LPNAI, the H5 and H7 subtypes of LPAI, should be reported if found in poultry.⁸¹ Historically, OIE standards only called for the reporting of HPAI detections. It was only in recent years that the OIE also called for the reporting of H5 and H7 strains of LPAI.⁸² As noted by avian influenza experts at the time, reporting LPAI H5 and H& detections could be beneficial in controlling avian influenza, *provided that Members did not use them as a pretext for imposing trade barriers*:

The development and implementation of new control programmes for 'reportable AI' will require courageous steps by all countries that are members of OIE. The addition of H5 and H7 LPAI to the list of 'reportable' should reduce the number

⁷⁹ An intravenous pathogenicity index (IVPI) is determined from the number of healthy, sick, paralysed and dead birds observed each day for 10 days post inoculation. FAO, Epidemiology (Exhibit US-12).

⁸⁰ OIE, Report Of The Meeting Of The OIE Working Group On Wildlife Diseases, 78 SG/13/GT (February 2010), p. 4 ("Unrelated to trade status, the Working Group saw high value in surveillance for AI viruses in wild birds since this furnishes the background information required to understand transmission, and the basis for understanding actual risk to poultry and to wild bird populations.") (Exhibit US-46).

⁸¹ Article 10.4.3 contains the relevant definition for poultry. The definition captures "all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products" (Exhibit US-1).

⁸² See C. Bruschke & B. Vallat, "OIE Standards and Guidelines Related to Trade and Poultry Disease," *Rev. sci. tech. Off. int. Epiz.*, 2008, p. 628 ("The new chapter has several significant changes compared to the previous one, such as differentiating between low pathogenic avian influenza and HPAI, and stating that only cases of HPAI in poultry should be taken into account for the purposes of international trade (cases in wild birds cannot be used as justification for blocking trade)." [hereinafter "Bruschke & Vallat"] (Exhibit US-47).

of HPAI outbreaks in the future by providing governments with incentives to control LPAI before it mutates to HP. *However, if trading partners use the addition of H5 and H7 LPAI as a non-tariff barrier, this will have the opposite of the intended effect by encouraging nations not to report but to hide LPAI, and this could possible [sic] lead to increased HPAI outbreaks in the future.⁸³*

Accordingly, the nomenclature and notification of outbreaks in and of themselves do not have any immediate trade implications under the OIE Code save one: the OIE Code expressly provides that detections of HPAI and LPAI in birds other than poultry should not give rise to trade bans. Article 10.4.1.10 provides:

A Member should not impose immediate bans on the trade in poultry commodities in response to a notification, according to Article 1.1.3. of the Terrestrial Code, of infection with HPAI and LPAI virus in birds other than poultry, including wild birds.

The provision is notable because it addresses a situation that should not arise. Specifically, the provision provides that notification of HPAI *and LPAI in birds other than poultry* should not be a basis to impose bans. Article 10.4.1.1, however, does not require a country to notify anything other than LPNAI outbreaks in poultry.⁸⁴ Therefore, it addresses a trade action in response to a notification that is not called for under the OIE Code. The reason this provision is necessary is because, as explained below, of conduct by Members such as India that justified their import prohibitions by asserting exporting countries have detected LPAI in their wild birds.⁸⁵ In short, how notification is to be treated with respect to trade measures must be considered in the full context of the OIE Code, which entails recognizing that notification is simply the start, not the end, of deciding what the appropriate control measure is.⁸⁶

⁸³ D.E. Swayne and B.L. Akey, "Avian Influenza Control Strategies in the United States of America, AVIAN INFLUENZA, Eds. Remco S. Schrijver and G. Koch (2005), p. 127 (emphasis added) (Exhibit US-48).

⁸⁴ The language also encompasses HPNAI outbreaks in wild birds that are to be notified under the OIE Code, but confirms that such notifications cannot serve as a basis to impose import prohibitions.

⁸⁵ Two OIE officials have explained that the OIE Code is cognizant of the fact that all countries would have avian influenza in their wild birds and have noted that 10.4.1.10 is intended to address that situation. Petrini & Vallat, p. 29 ("The presence of AI viruses in wild birds creates a particular problem. In essence, no country can declare itself free from AI carried in wild birds. However, the definition of NAI refers to infection in poultry only and that 'for the purposes of international trade, a country should not impose immediate trade bans in response to a notification of infection with HPAI and LPAI virus in birds other than poultry." (Exhibit US-25).

⁸⁶ See Note by the Secretariat, Summary Of The Meeting Of 18-19 October 2007, G/SPS/R/46 (January 2, 2008), para. 32 ("The representative of the OIE clarified the recommendations of the OIE and how they should be put in practice. The listing of diseases such as high pathogenic avian influenza

2. Classification of a Territory

52. The second component of the Code is how to determine and classify NAI status of a territory. Articles 10.4.2, 10.4.3, and 10.4.4 of the OIE Code address this question.

Article 10.4.2

Determination of the NAI status of a country, zone or compartment

The NAI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) NAI is notifiable in the whole country, an on-going NAI awareness programme is in place, and all notified suspect occurrences of NAI are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the risk posed by birds other than *poultry*; this may be achieved through a NAI *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for NAI occurrence and their historical perspective.

(HPAI) and low pathogenic notifiable avian influenza (LPNAI) was first and foremost for disease reporting purposes and related to the question of transparency. Findings of AI in wild birds and of LPNAI should not lead to import bans. She emphasized that there needed to be a distinction drawn between reporting and the imposition of measures.")

Article 10.4.3

NAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from NAI when it has been shown that neither HPNAI nor LPNAI *infection* in *poultry* has been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, NAI free status can be regained:

- 1) In the case of HPNAI *infections*, three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
- 2) In the case of LPNAI *infections*, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, three months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

HPNAI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from HPNAI when:

- 1) it has been shown that HPNAI *infection* in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its LPNAI status may be unknown; or
- 2) when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from NAI but any NAI virus detected has not been identified as HPNAI virus.

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, HPNAI free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles

10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.2 imposes the threshold requirements that must be satisfied before any assessment regarding the NAI classification of a territory can be performed. Those factors are that NAI is in fact reported and notified in the country; that there is a surveillance program in place; and there is a consideration of the epidemiology for NAI outbreaks in the territory. If those factors are in place, then a determination can be made as to whether the territory should be classified as NAI free or HPNAI free.

53. A NAI free territory is one where *surveillance is practiced* and there have been no detections of LPNAI or HPNAI in the prior 12 months. If a territory has been previously considered to be NAI free and an outbreak of LPNAI or HPNAI occurs, the status can be regained. The Code treats the situations differently though. For an HPNAI outbreak, the poultry must be stamped out (killed) and surveillance must find no further evidence of HPNAI for 3 months. With respect to LPNAI, the poultry does not need to be stamped out; it can be alternatively slaughtered for consumption. Whichever scenario, once the poultry have been disposed of and three months have passed with an effective surveillance system detecting any further evidence of infection, NAI status can be regained.

54. If a territory cannot be considered NAI free, it can still be considered HPNAI free. Article 10.4.4 addresses that scenario. Essentially, if there is surveillance consistent with the OIE Code, and HPNAI has not been detected for the prior 12 months, the territory can be considered HPNAI free.

3. Appropriate Control Measures

55. The third component is the applicable control measure for trade in a particular product.⁸⁷ Which control measure is applicable is contingent on the status of the particular territory the product is being imported from as well as what the particular product is. The recommendation for the appropriate control measure may be tailored for an NAI free territory, an HPNAI free territory, or for any territory at all.

56. To illustrate how the OIE Code's recommendations operate – and properly distinguish between different scenarios – the United States will address three different situations under the OIE Code: (1) eggs and day-old live poultry, (2) poultry meat, and (3) live birds.

⁸⁷ It should be noted that in devising these control measures, OIE officials considered protection of human health as well. Brusche & Vallat, p. 629 ("The main goal is to reduce the virus load and circulation in poultry and limit the spread to unaffected areas or countries, thereby decreasing the risk of human infections and the development of a human pandemic virus."). (Exhibit US-47).

a. Eggs

57. The OIE Code provides separate recommendations regarding the import of eggs for human consumption, day-old live poultry, and hatching eggs of poultry depending on whether they are being imported from a territory that is NAI free or HPNAI free.

Article 10.4.13.

Recommendations for importation from a NAI free country, zone or compartment

For eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the eggs were produced and packed in a NAI free country, *zone* or *compartment*;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a HPNAI free country, zone or compartment

For eggs for human consumption

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the eggs were produced and packed in a HPNAI free country, *zone* or *compartment*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 1.1.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.7.

Recommendations for importation from a NAI free country, zone or compartment

For day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1)	the poultry were kept in a NAI free country, <i>zone or compartment</i> since they were hatched;
2)	the poultry were derived from parent <i>flocks</i> which had been kept in a NAI free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
3)	the <i>poultry</i> are transported in new or appropriately sanitized containers;
4)	if the <i>poultry</i> or the parent flocks have been vaccinated against NAI, it has been done in accordance with the provisions of the <i>Terrestrial Manual</i> and the nature of the vaccine used and the date of <i>vaccination</i> have been attached to the <i>certificate</i> .

Article 10.4.8.

Recommendations for importation from a HPNAI free country, zone or compartment

For day-old live poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *poultry* were kept in a HPNAI free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in a NAI free *establishment* for at least
- 3) 21 days prior to and at the time of the collection of the eggs;
- 4) the *poultry* are transported in new or appropriately sanitized *containers*;

if the *poultry* or the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a NAI free country, zone or compartment

For hatching eggs of poultry

Veterinary Authorities should require the presentation of an international veterinary certificate

attesting that:

- 1) the eggs came from a NAI free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in a NAI free country, *zone* or *compartment*
- 3) for at least 21 days prior to and at the time of the collection of the eggs;
- 4) the eggs are transported in new or appropriately sanitized packaging materials;
- 5) if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a HPNAI free country, zone or compartment

For hatching eggs of poultry

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the eggs came from a HPNAI free country, zone or compartment;
- 2) the eggs were derived from parent flocks which had been kept in a NAI free establishment for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs have had their surfaces sanitized (in accordance with Chapter 1.1.);
- 4) the eggs are transported in new or appropriately sanitized packaging materials;
- 5) if the parent flocks have been vaccinated against NAI, it has been done in accordance with the provisions of the Terrestrial Manual and the nature of the vaccine used and the date of vaccination have been attached to the certificate.

To summarize, for these products, the OIE Code provides they can be imported from either an HPNAI or NAI free country. The Code simply requires a veterinary certificate, for both NAI and HPNAI free territories, that certain control measures were in fact applied.

58. These recommendations are a clear example of the scientific evidence being applied rationally to ensure safety and permit trade. As noted in the prior section, LPAI viruses do not

transmit to the inside of poultry eggs and such eggs that are infected with HPAI do not hatch.⁸⁸ Accordingly, there is no need to prohibit these products from a territory that only has LPAI. Instead, the appropriate precaution is to ensure sanitization of the surface because that may be the only potential vehicle that might have any virus on it.⁸⁹

b. Poultry Meat

59. Poultry meat provides another clear example of the OIE Code corresponding to the relevant science. Article 10.4.19 provides that poultry meat can be imported from countries free of HPNAI.

Article 10.4.19.

Recommendations for importation from either a NAI or HPNAI free country, zone or compartment

For fresh meat of poultry

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of fresh meat comes from poultry:

- 1) which have been kept in a country, zone or compartment free from HPNAI since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved abattoir in a country, zone or compartment free from HPNAI and have been subjected to ante- and post-mortem inspections in accordance with Chapter 1.1. and have been found free of any signs suggestive of NAI.

As LPAI viruses do not replicate to poultry meat, the recommendation rightly focuses on ensuring that the source bird has not been in a HPNAI territory or at least outside it for the relevant incubation period (21 days). If so, and the bird is slaughtered appropriately with the proper inspection, then a certificate attesting as much is sufficient to allow trade.

⁸⁸ Swayne & Thomas, p. 55 (Exhibit US-31); Swayne & Halvorson, p. 166 (Exhibit US-6).

⁸⁹ OIE, Report Of The Meeting Of The OIE Terrestrial Animal Health Standards Commission (March 2006), p.7 ("The Terrestrial Code Commission took into account information provided by the EU (an EFSA opinion, http://www.efsa.eu.int/science/ahaw/ahaw_opinions/1145_en.html) that there was no evidence that natural low pathogenicity avian influenza (LPAI) infections in layers had resulted in eggs containing virus internally. However, as LPAI virus was excreted in the faeces, surface sanitation was considered necessary. As a result, it proposed the deletion of paragraph 2 in Article 2.7.12.12.") (Exhibit US-49).

c. Live Birds

60. In some instances, the OIE Code's recommendation calls for control measures to be applied regardless of the territory's avian influenza situation. An example of this policy can be seen with respect to live birds other than poultry and day-old live birds other than poultry.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the NAI status of the country of origin, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of infection with a virus which would be considered NAI in poultry;
- 2) the birds were kept in isolation approved by the Veterinary Services since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of infection with a virus which would be considered NAI in poultry during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from infection with a virus which would be considered NAI in poultry;
- 4) the birds are transported in new or appropriately sanitized containers;
- 5) if the birds have been vaccinated against NAI, it has been done in accordance with the provisions of the Terrestrial Manual and the nature of the vaccine used and the date of vaccination have been attached to the certificate.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry*;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;

- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;
- 4) the birds are transported in new or appropriately sanitized *containers*;
- 5) if the birds or parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with NAIV;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 1.1.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials;
- 4) if the parent *flocks* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Here, the OIE Code recommends that, regardless of whether the territory is affected or free of HPNAI or LPNAI, precautions be taken including diagnostic testing, sanitized transfer and clinical examination. As is evident, the OIE Code, consistent with the science noted above, is not ignoring LPNAI. Rather, it is prescribing particularized control measures.

d. Other Products

61. In the interests of completeness, the United States provides in Annex 1 of this submission additional recommendations in the OIE Code that allow for the safe import of poultry products. The United States notes that for every product – save live pigs – listed in India's most recent publication of its measures, the OIE Code provides a relevant recommendation. Moreover, these recommendations, with the exception of live poultry (other than day old poultry), explicitly provides that the products are safe for import from HPNAI free territories provided the proper control measures are in place.

4. Regionalization

62. As was evident in the preceding section, the OIE Code's recommendations often refer to an NAI free or HPNAI free "country, zone or compartment." This reference reflects the principle of zoning or regionalization that is contained within the OIE Code. Specifically, the OIE Code, particularly Chapters 4.3 and 4.4, allows for a Member to establish distinct health statuses for different parts of its territory.⁹⁰ In other words, an outbreak in one area of a Member's territory does not necessarily require all products from the Member's territory to be subject to the same control measures. The OIE Code recommends processes are in place to ensure that regionalization is effective to contain any outbreak. Per the OIE Code, importing countries should recognize zoning provided the recommendations of the Code are in place:

An importing country should recognise the existence of this zone or compartment when the appropriate measures recommended in the Terrestrial Code are applied and the Veterinary Authority of the exporting country certifies that this is the case.⁹¹

63. India has not found fault with any particular aspect of U.S. zoning measures or that of any other country. Instead, India rejects zoning in principle and insists that a country be completely free of avian influenza. As confirmed by the various veterinary certificates that DAHD requires for the import of products into India, India insists on this condition before imports are permitted:

- Veterinary Certificate for Import of Chicken/Quail Meat into India, clause 5(a): "Country is free from Avian Influenza (Highly Pathogenic Avian Influenza and Low Pathogenic Avian Influenza)"⁹²
- Veterinary Certificate for Import of Turkey Meat into India, clause 5(a): "Country is free from Avian Influenza (Highly Pathogenic Avian Influenza and Low Pathogenic Avian Influenza)."⁹³

⁹³ India, Department of Animal Husbandry, Dairying, and Fisheries, Veterinary Certificate for Import of Turkey Meat into India, available at <u>http://www.dahd.nic.in/dahd/upload/healthProtocolssanitryconditions/Turkey%20meat.pdf</u> (last accessed April 1, 2013) (Exhibit US-53).

⁹⁰ See generally OIE Code, Chapters 4.3 and 4.4 (Exhibits US-50 & US-51).

⁹¹ OIE Code, Article 4.3.2 (Exhibit US-50).

⁹² India, Department of Animal Husbandry, Dairying, and Fisheries, Veterinary Certificate For Import Of Chicken/Quail Meat Into India, available at <u>http://www.dahd.nic.in/dahd/upload/healthProtocolssanitryconditions/Chicken%20and%20quail%20meat</u>.<u>pdf</u> (last accessed April 1, 2013) (Exhibit US-52).

- Veterinary Certificate for Import of Hatching Eggs, clause 1: "The country is free from Notifiable Avian Influenza (both Highly Pathogenic and Low Pathogenic Avian Influenza)".⁹⁴
- Veterinary Certificate for Import Of Captive Birds (other than poultry), clause 1: "The country is free from Avian Influenza (Both Highly Pathogenic Avian Influenza and Low Avian Influenza)".⁹⁵

In short, whereas the OIE Code recommends countries permit zoning when the relevant conditions are satisfied, India's position, *ab initio*, is not to engage in that dialogue and demand categorical country freedom.

5. Surveillance

64. As was self-evident in many of the OIE Code recommendations noted above, proper surveillance is critical to fulfilling the Code's recommendations, and to detecting outbreaks of avian influenza.⁹⁶ OIE Code Chapter 1.4 lays out general principles of animal health surveillance. Article 10.4, however, also contains detailed disease-specific recommendations on how to conduct surveillance for avian influenza.

65. Article 10.4.29 lays out basic principles for effective avian influenza surveillance. It explains that "[t]he target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*" (emphasis in original). Moreover, "[a]ctive and passive *surveillance* for NAI should be ongoing." (emphasis in original).⁹⁷

66. Crucially, with respect to avian influenza, "[s]*urveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods" (emphasis in original). Moreover, the OIE Code emphasizes the need to align the type of

⁹⁵ India, Department of Animal Husbandry, Dairying, and Fisheries , Veterinary Certificate For Import Of Captive Birds (other than poultry) into India, available at <u>http://www.dahd.nic.in/dahd/upload/healthProtocolssanitryconditions/Captive%20birds.pdf</u> (last accessed April 1, 2013) (Exhibit US-55).

⁹⁶ See also, OIE Code Art. 1.4.1(1) ("In general, surveillance is aimed at demonstrating the absence of disease or infection, determining the occurrence or distribution of disease or infection, while also detecting as early as possible exotic or emerging diseases.") (Exhibit US-56).

⁹⁷ OIE Code, (Exhibit US-1).

⁹⁴ India, Department of Animal Husbandry, Dairying, and Fisheries, Veterinary Certificate For Import Of Hatching Eggs Of Chicken, Turkey, And Other Avian Species Into India, available at <u>http://www.dahd.nic.in/dahd/upload/healthProtocolssanitryconditions/Hatching%20Chicken%20Eggs.pdf</u> (last accessed April 1, 2013) (Exhibit US-54).

surveillance activity being conducted with prevailing characteristics of the epidemiological situation under consideration. Hence, because chickens can show clinical signs of NAI (when infected with HPAI) but ducks will not show clinical signs when infected with any form of NAI,⁹⁸ it would be appropriate to direct clinical surveillance efforts towards chickens but not ducks. The OIE emphasizes, however, that "[t]he results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, *zone* or *compartment*."⁹⁹

67. The Code prescribes further surveillance requirements that countries, zones, or compartments must follow in order to regain NAI or HPNAI-free status following an NAI detection or HPNAI outbreak. These requirements include "surveillance incorporating virus detection and antibody tests described in the Terrestrial Manual."¹⁰⁰ Such testing is similarly required in order to document that a particular establishment within an HPNAI-free compartment is NAI free.¹⁰¹

68. The OIE Code thus recognizes that detection of NAI, and the demonstration of an absence of NAI in a particular country, zone or compartment, hinges on the maintenance of effective surveillance programs, and that such programs include laboratory testing such as serological testing and virological testing (which can be sued to confirm the presence of disease following positive serological results or clinical signs). Countries that do not conduct such testing on a routine basis may, in particular, miss NAI in situations where its presence may not have clearly identifiable clinical signs—such as HPNAI or LPNAI infections in ducks, and LPNAI infections in chickens. As discussed *infra* in Section VI, India does not conduct such testing on a routine basis. This fact likely explains India's highly anomalous NAI reporting history, consisting of 95 reported HPNAI outbreaks, but zero LPNAI detections, over the period between the end of 2006 and March 2013.¹⁰²

6. Risk assessment

69. The OIE has promulgated standards regarding how to conduct a risk assessment in the OIE Code.¹⁰³ Additionally, the OIE has also issued a *Handbook on Import Risk Analysis* for

¹⁰⁰ OIE Code, Art. 10.4.31 (Exhibit US-1). The relevant tests are described in Chapter 2.3.4 of the Terrestrial Manual (Exhibit US-57).

- ¹⁰¹ OIE Code, Art. 10.4.32 (Exhibit US-1).
- ¹⁰² See Section III.C.
- ¹⁰³ OIE Code, Chapter 2.1 (Exhibit US-58).

⁹⁸ *See* Swayne & Jackwood-Pantin, p. 87. 92 ("but such viruses typically do not cause illness in ducks and geese.") (Exhibit US-18); CFSPH, p. 1 (Exhibit US-32).

⁹⁹ Article 10.4.29(4) (Exhibit US-1).

Animals and Animal Products that expands upon these standards and provides further guidance. As detailed below, India lacks a risk assessment. Accordingly there can be no dispute that India could not have accounted for these principles.

7. India's invocation of the OIE Code with respect to its exports

70. When it comes to its own exports, India invokes the OIE Code to justify their safety. First, after it has suffered an outbreak of HPAI, India routinely argues that it has regained NAI freedom. Second, India recognizes compartments within its own territory that it holds out as being entitled to take advantage of the OIE's recommendations regarding zoning.

71. With respect to the first point, as referenced above, OIE Code Article 10.4.3 provides in pertinent part:

If infection has occurred in poultry in a previously free country, zone or compartment, NAI free status can be regained:

1. In the case of HPNAI infections, three months after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Indian officials have asserted that India is entitled to "regain" its status as NAI-free once three months have elapsed after an HPAI outbreak.¹⁰⁴

• There has been no outbreak of avian influenza or bird flu in this country for more than three months. On August 10, India will seek certification from the International Animal Disease Agency, OIE, to declare the country free from bird flu.

Minister of Agriculture, Sharad Pawar¹⁰⁵

In particular, India has issued declarations of freedom from avian influenza, on a country basis in 2008,¹⁰⁶ 2009,¹⁰⁷ 2010,¹⁰⁸ 2011,¹⁰⁹ and 2013¹¹⁰ and the freedom of particular localities in 2012.¹¹¹

¹⁰⁴ According to at least one media report, it appears India has even denied that its own report of an outbreak of HPAI necessitated a ban on its exports. Gargia Parsai, Bangladesh Border Seale, The Hindu (Jan. 17, 2008) ("According to Union Agriculture Minister Sharad Pawar, the France-based OIE (World Organisation of Animal Health) had been informed of the outbreak, as per the international protocol. He denied that India had received any advisory to ban poultry exports.") (Exhibit US-59).

¹⁰⁵ Mahendra Gaur, INDIAN AFFAIRS ANNUAL 2007 288 (2007) (Exhibit US-60).

72. With respect to zoning, India, as noted in the veterinary certificates above, demands that a country be completely free of avian influenza. However, India apparently believes its trading partners should be willing to consider its application to exports from India. Specifically, Indian authorities have certified compartments for the purposes of avian influenza outbreaks.¹¹² Thus, India, which argues zoning is irrelevant for purposes of imports, is fully prepared to recognize its significance when it comes to its own products.

V. INDIA'S MEASURES

A. History

73. There are three themes in the United States' experience with India's measures that merit particular attention. First, at most times, but not all, India's prohibitions are reflected through a notice published by India's Department of Animal Husbandry, Dairying, and Fisheries ("DAHD") in the Gazette of India Extraordinary.¹¹³ Even where there is no notice in force,

¹⁰⁶ Letter from Arvind Kaushal to Chief Secretaries, dated November 6, 2008, re: Declaration of Avian Influenza Free Status (Exhibit US-61).

¹⁰⁷ Letter from Arvind Kaushal to Chief Secretaries, dated October 22, 2009, re: Declaration of Avian Influenza Free Status (Exhibit US-62).

¹⁰⁸ Letter from Arvind Kaushal to Chief Secretaries, dated June 2, 2010, re: Declaration of Avian Influenza Free Status (Exhibit US-63).

¹⁰⁹ Letter from R.S. Rana to Chief Secretaries, dated July 4, 2011, re: Declaration of Avian Influenza Free Status (Exhibit US-64).

¹¹⁰ Letter from R.S. Rana to the Chief Secretaries, dated February 13, 2013, re: Declaration of Avian Influenza Free Status (Exhibit US-65).

¹¹¹ Letter from R.S. Rana to the Chief Secretaries, date June 7, 2012, re: Declaration of freedom from Avian Influenza at epicenter Wilimnagar Block Samanda (Exhibit US-66); Letter from R.S. Rana to Chief Secretaries, dated June 19, 2012, re: Declaration of freedom from Avian Influenza at epicenters Kerange and Nayapalli in Odisha (Exhibit US-67); Letter from R.S. Rana, dated July 11, 2012, re: Declaration of freedom from Avian Influenza at epicenter Bahanada in Odisha (Exhibit US-68).

¹¹² India, Department of Animal Husbandry, Dairying, and Fisheries, Letter from B. Prashant Kuman to Commissioner, re: Recognition of Venco Research and Breeding Farms Ltd,. Sngvi, Talukia Khandala, Distric Stara as a notified compartment against Avian Influenza (June 6, 2010) (Exhibit US-69); India, Department of Animal Husbandry, Dairying, and Fisheries, Letter from B. Prashant Kuman to Commissioner, re: Recognition of establishments of M/s C&M Farming Limited, Nasik as notified compartment against Avian Influenza (Sept. 13, 2010) (Exhibit US-70).

¹¹³ The title of these notices begins with the letters "S.O." followed by a number. India in its preliminary ruling request professes confusion as the United States called them "orders" in its Panel Request. The reason the United States did so it that based on conversations by the United States with

however, the United States understands that India continues to apply import prohibitions on account of avian influenza. Indeed, when the United States first discovered that India was prohibiting its products on account of LPAI detections, there was no instrument in place by India that even referenced LPAI. Second, the history of the U.S. experience provides important context as to the positions of the parties. The United States and other trading partners have consistently argued that India's measures are not in accord with the OIE Code. In contrast, India's position has been anything but consistent, including most critically regarding whether it had a risk assessment in support of its measures or not. Finally, the history of this matter confirms that India has frustrated efforts by its trading partners to understand its measures, including what, if any, scientific evidence India is considering in maintaining these measures.

1. India starts imposing import prohibitions on account of LPAI (Fall 2006 to early 2007)

74. In the fall of 2006 - without prior warning – India proceeded to prohibit the import of various U.S. poultry and pork products. The United States was aware that in August of 2006, India had notified a new measure to the WTO regarding avian influenza. That measure, notified after it had already entered into force, prohibited various imports from countries that reported outbreaks of HPAI and was scheduled to expire on February 3, 2006.¹¹⁴ But the United States had not reported an outbreak HPAI – not in the prohibited products, not in its poultry flocks, not anywhere – and has not since. India's response was that the United States had detected *LPAI* in *wild birds*.¹¹⁵

75. As noted *supra* in Section III.A.1, wild birds are the natural reservoir for LPAI viruses and the United States tests wild birds as part of its surveillance programs. During the relevant

Indian officials, the United States understood "S.O" to stand for "special order." In any event, it is perfectly clear from India's Preliminary Ruling Request that India understands precisely what the United States was referring to.

¹¹⁴ India, Notification of Emergency Measures, G/SPS/N/IND/46. (US-). The measure was titled in the notification form as "Notification no. S.O. 1256(E)." A copy of that measure is attached as (Exhibit US-). Besides prohibiting certain products from countries reporting HPAI, the measure also prohibited three products from all countries regardless of their avian influenza situation: (i) domestic and wild birds including captive birds (excluding poultry); (ii) unprocessed meat and meat products from avian species including wild birds; and (iii) semen of domestic and wild birds.

¹¹⁵ Besides the oral representations made by Indian government officials, mutually agreed minutes to a trade policy forum held in April 2007 memorialize that India's position was to impose prohibitions on account of LPAI. The minutes noted that "[t]he Indian side stated that United States had reported an outbreak of low-pathogenic Avian Influenza in April 2007 in poultry (H5N2, which was notifiable to the OIE) and had also reported several outbreaks of low pathogenic Avian Influenza in migratory birds in 2006. Therefore, import of certain specified products from the United States was restricted in accordance with regulation adopted in India" surveillance season at that time (April 1, 2006 to March 31, 2007), the United States tested over 60,000 wild birds in all 50 U.S. states as well as American Samoa, Guam, the Marshall Islands, Midway Islands, Palau and Puerto Rico.¹¹⁶ The United States' program was well known and recorded in a subsequent OIE report.¹¹⁷ Therefore, the United States' detections of a virus that was endemic to these birds was consistent with the scientific understanding of avian influenza. Indeed, the OIE has noted the following:

Since avian influenza viruses occur regularly in wild birds, it is expected that wild bird surveillance efforts will detect these viruses irrespective of any role wild birds may play in local epidemiological events involving poultry. It is not justified to attribute the source of avian influenza virus infection in poultry to wild birds unless complete investigations have been carried out and the results fully support such attribution. Response actions such as killing wild birds or destroying their habitat should be prohibited.¹¹⁸

76. Continuing through the fall of 2006 and early 2007, U.S. officials raised their concerns about the prohibitions on U.S. imports with Indian government officials, both in meetings and through written comments.¹¹⁹ The points made by U.S. officials included that avian influenza is found in wild birds populations throughout the world; that the United States maintains a robust surveillance and monitoring program; and that the U.S. position on the safety of its poultry products was consistent with OIE guidelines while India's position regarding prohibitions on account of LPAI findings in wild birds was not.¹²⁰

2. India starts publishing notices reflecting its avian influenza restrictions on account of LPAI (2007)

77. On February 2, 2007, months after U.S. imports have been subject to prohibitions and one day prior to when India's published HPAI measure was set to expire, India finally published in the Gazette of India Extraordinary a document that reflected the measures prohibiting U.S. imports on account of LPAI. That document was S.O. 102(E). Per the text of S.O. 102(E), India prohibited the import of three products from all countries regardless of whether they had reported outbreaks of avian influenza or not:

¹²⁰ Id.

¹¹⁶ OIE, Report of the OIE Working Group on Wildlife Diseases 12-15 February 2007. 75 SG/12/GT (Feb. 2013), p. 10.

¹¹⁷ *Id*.

¹¹⁸ OIE, Report Of The Meeting Of The OIE Working Group On Wildlife Diseases, 78 SG/13/GT (February 2010).

¹¹⁹ *See* Letter from U.S. Ambassador to Foreign Secretary (January 10, 2007).

- 1. domestic and wild birds including the captive birds (excluding poultry)
- 2. unprocessed meat and meat products from Avian species including wild birds (except poultry);
- 3. semen of domestic and wild birds

From those countries reporting HPAI and LPAI, S.O. 102(E) stated the following products were additionally prohibited:

- 1. live poultry;
- 2. day old chicks, ducks, turkey and other newly hatched avian species;
- 3. meat and meat products from avian species including wild birds;
- 4. hatching eggs;
- 5. eggs and egg products (except specific pathogen free eggs);
- 6. feathers;
- 7. live pig and pig meat products;
- 8. Pathological material and biological products from birds;
- 9. Product of animal origin (from birds) intended for use in animal feeding or for agricultural or industrial use.

S.O. 102(E) concluded by noting that the prohibition would remain in force for six months or until modified or withdrawn, whichever occurring earlier.

78. With respect to notification to the WTO, on February 19, 2007, India filed an addendum to its earlier HPAI notification that included the text, albeit not the name of S.O. 102(E). The notification, beside being made after the measures had already been in force, created new questions while preserving existing ambiguities. The original notification was made on the WTO notification template for emergency measures. The template requests the submitter to provide information on a series of topics, one of which is the "Nature of the urgent problem(s) and reasons for urgent action." In response, India answered:

Highly Pathogenic Avian Influenza Virus is not prevalent in India. The urgent action has been taken to prevent the ingress of this virus to protect the human health as well as the health of poultry in India.¹²¹

¹²¹ India, Notification of Emergency Measures, G/SPS/N/IND/46, p.2 (Q. 8).

The new publication though was imposing import prohibitions on account of LPAI.

79. Moreover, India has failed to provide all the requested information in the prior template. For example, Box 9 of the template asks the submitter to identify the International standard, guideline or recommendation and if one exists, to give the appropriate reference and briefly identify any deviation. India ticked the box for OIE in response to this question, but did not identify any deviations. The prohibitions in the new publication went further than the old one – and accordingly even more inconsistent with OIE Guidelines, but India was not providing any further information. Box 3 of the template asks for the products covered and for submitter to provide the tariff numbers. Although India provided in response to this query the listing of the relevant tariff numbers.¹²²

3. India's trading partners raise India's measures in the WTO SPS Committee (2007-2011)

80. From 2007 through 2011, the United States and other WTO Members regularly raised concerns regarding India's avian influenza measures in the WTO SPS Committee. One consistent them through these meetings was the U.S. request that India provide a risk assessment. After pressing this request for years, India, at the June 2010 Meeting of the WTO SPS Committee, asserted it had one:

India conducted a detailed risk analysis for the importation of animal and animal products, by a committee of experts, based on the existing global situation of AI, available scientific literature and the OIE standards.¹²³

Thus, per the Secretariat's notes, India asserted that it had in fact conducted a risk assessment that took into account scientific evidence and OIE standards. This position did not hold for long.

81. At a following WTO SPS Committee meeting in October of that year, India provided a document to the United States and the European Union. The document bears the title "India's Risk Assessment on Avian influenza for imposing ban on import of poultry and poultry products from Avian Influenza positive countries."¹²⁴ The minutes prepared by the WTO Secretariat for

¹²⁴ India, India's Risk Assessment on Avian Influenza for imposing ban on import of poultry and poultry products from Avian Influenza positive countries [hereinafter "Summary Document"] (Exhibit US-110).

¹²² G/SPS/N/IND/46.

¹²³ Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 17-18 March 2010, Note by the Secretariat (11 June 2010), G/SPS/R/61, para. 39.

that meeting record that "India had provided its risk assessment on avian influenza directly to the United States, and was willing to share it with other Members upon request."¹²⁵

82. At the following meeting of the SPS Committee, the United States, and other Members, criticized the document as inconsistent with the appropriate standards for a risk assessment and that it did not contain any scientific evidence that would justify India's import prohibitions.¹²⁶ India then noted that what it had provided "*was not the final risk assessment document, which would take some time.*" At this meeting, the OIE also noted that it had received a letter stating that the document was for "information purposes" and that it would be "happy to review India's risk assessment if so requested."¹²⁷ It bears noting that India asserted it would need more time to conduct a risk assessment even though the United States has been requesting a risk assessment from India since the inception of its measures.

83. In September of 2011, the United States requested the OIE to review the document provided by the representative of India.¹²⁸ A review was conducted that noted, *inter alia*, the following:

- "I have reviewed the document and have concluded that it is unstructured and repetitive. Its reasoning is unclear and it is poorly supported by reference to scientific literature.¹²⁹
- "'An evaluation of the likelihood of the risk, which may be expressed qualitatively or quantitatively, must be undertaken.' *India's risk assessment* fails to evaluate the likelihood of the risks arising."¹³⁰

Letter from Bernard Vallat to Dr. John Clifford & Dr. Bernard Von Goethen, dated Sept. 15,
2011.

¹²⁹ Dr. S.C. MacDiarmid, Critical Review of the Document "India's risk assessment on avian influenza for imposing ban on import of poultry and poultry products from avian influenza positive countries" (Sept. 30, 2011), p. 1 (Exhibit US-108).

¹³⁰ *Id.*, p. 2 (emphasis original).

¹²⁵ Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 20-21 October 2010, Note by the Secretariat (16 February 2011) G/SPS/R/61, para. 27.

¹²⁶ Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 30 June - 1 July 2011, Note by the Secretariat (12 September 2011) G/SPS/R/63, paras. 64-67.

¹²⁷ Id. at para. 67.

- "Article 2.1.3. of the Terrestrial Animal Health Code (OIE 2011a) states that "The risk assessment should be based on the best available information that is in accord with current scientific thinking." India's risk assessment is seriously deficient in this respect. … The most recent scientific reference cited in the bibliography is 14 years old and, given the great advances in scientific knowledge with respect to influenza viruses, this is a serious deficiency."¹³¹
- "Several passages in India's risk assessment are taken word for word, with no acknowledgment of source, from an import risk analysis conducted in New Zealand in 1999 (MAF Regulatory Authority 1999). … [W]hile India's risk assessment has concluded that chicken meat imports from "avian influenza positive countries" should be banned, the New Zealand import risk analysis from which text was reproduced reached different conclusions and concluded that, subject to the application of appropriate sanitary measures, chicken meat could be imported safely from countries or zones considered infected with highly pathogenic avian influenza."¹³²
- "A problem one experiences in approaching India's risk assessment is that it is not clear, precisely, what it is about. It lacks a clear statement of either its scope or its purpose."¹³³

The review can essentially be summed in its statement that India's "document does not constitute an import risk analysis"¹³⁴

84. At the next meeting of the SPS Committee, the United States asked that the OIE be given the floor in order to summarize its findings on India's document. India objected and noted that:

India clarified that it had not formally provided any scientific risk assessment to the OIE. In October 2010, India had provided a summary report on an informal basis to the European Union and the United States. India clarified that the document had also been provided to the OIE on an informal basis, and *that it was a summary document, not a full risk assessment*.¹³⁵

¹³⁴ *Id.*, p. 1.

¹³⁵ Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 19-20 October 2011, Note by the Secretariat (17 January 2012) G/SPS/R/64, para. 85 (emphasis added).

¹³¹ *Id.*, p. 2.

¹³² *Id.*, p. 2.

¹³³ *Id.*, p. 2.

The OIE representative was unable to share her views. Thus, in light of India's disavowal of the document provided in the SPS Committee and its failure to provide any other, the answer with whether India has carried out a risk assessment is no.

4. The United States submitted an article 5.8 request to india – and received no response (2012)

85. Before initiating this dispute, the United States made every reasonable effort to try and resolve its concerns with India. In addition to bilateral talks, discussions in the SPS Committee, offers for technical discussions, the United States also sought pursuant to Article 5.8 of the SPS Agreement for India to at least provide an explanation as the reasoning behind its measures.

86. Article 5.8 of the SPS Agreement states:

When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, *an explanation of the reasons* for such sanitary or phytosanitary measure *may be requested and shall be provided by the Member maintaining the measure*.¹³⁶

This provision thus contains a right and an obligation. The right is that of a WTO Member to seek answers regarding the SPS measures of other Members. The obligation, as noted by the use of the term "shall," is for the requested Member to actually provide the answers.¹³⁷ In *Japan – Apples*, the Appellate Body explained the implications if a Member failed in its obligation to respond to a request made under Article 5.8:

¹³⁶ Emphases added.

¹³⁷ The term "shall" signifies a sense of legal duty, compulsion, obligation, and that something "must" be done "according to command or instruction." *See, e.g.*, NEW SHORTER OXFORD ENGLISH DICTIONARY, p. 2808 (1993); MIRIAM-WEBSTER DICTIONARY Shall, 2b ("used in laws, regulations, or directives to express what is mandatory <it shall be unlawful to carry firearms>"); The definitions for "require" include "specify as compulsory." CONCISE OXFORD ENGLISH DICTIONARY, p. 1222 (2009).

Raising a presumption that there are no relevant studies or reports is not an impossible burden. The United States could have requested Japan, *pursuant to Article 5.8 of the SPS Agreement*, to provide "an explanation of the reasons" for its varietal testing requirement, in particular, as it applies to apricots, pears, plums and quince. Japan *would, in that case, be obliged to provide such explanation.* The failure of Japan to bring forward scientific studies or reports in support of its varietal testing requirement as it applies to apricots, pears, plums and quince, would have been a strong indication that there are no such studies or reports.¹³⁸

The Appellate Body has accordingly recognized that if a Member failed in its obligation to provide a response to a request made under Article 5.8, this is a strong indication that the Member adopting the measure did not have scientific support for its measure. On January 17, 2012, the United States submitted a request to India pursuant to Article 5.8 of the SPS Agreement ("5.8 request").¹³⁹ The 5.8 request sought an "explanation of the reasons for India's various avian influenza related import restrictions including the restrictions contained within S.O. 1663(E)" and posed specific questions regarding the basis for India's measures. The two page request asked the following questions:

- Q.1. Please confirm whether the import restrictions contained in S.O. 1663(E), published in the Gazette of India: Extraordinary, on July 20, 2011, apply to exports from the United States of America.
- Q.2. To the extent India maintains import restrictions on account of AI that are not reflected in S.O. 1663(E), please identify and provide copies of those measures.
- Q.3. If India considers that a measure is based on the relevant international standard, guideline, or recommendation, please indicate which one and in what manner the measure is based on that international standard, guideline or recommendation.
- Q.4. Please identify the scientific evidence upon which each import restriction in S.O. 1663(E), as well as any measure listed in response to question 2, is based and provide any scientific studies or reports that support each such restriction.
- Q.5. Please indicate for each measure whether it is based on a risk assessment, and if so, please provide a copy, including any appendices and any other documents the risk assessment references or relies upon. If the following information is not apparent in the risk assessment documentation itself, then we ask that India identify (i) the risk assessment's authors, (ii) the date of the risk assessment, (iii) and the names of any government agencies that reviewed the risk assessment.

¹³⁸ Japan – Apples (AB), para. 137 (emphasis added).

¹³⁹ United States, 5.8 Request (Exhibit US-4).

- Q.6. Please identify the level of protection that India has determined is appropriate in regards to AI and how restrictions of any particular exports from countries reporting outbreaks of LPAI achieve that level of protection. If this level of protection is specified in writing, please provide a copy of that document.
- Q.7. The United States understands that if a Member has experienced an outbreak of Low Pathogenic AI ("LPAI") or High Pathogenic AI ("HPAI"), then India will restrict imports of products, including the products specified in S.O. 1663(E), such as poultry meat and eggs, from that Member. Please confirm whether that understanding is accurate. If not, please explain why not. If so, please identify how long a Member must be free of any further outbreak of LPAI or HPAI before India will allow imports to resume. To the extent India's answer may vary according to specific conditions, India should identify those conditions and explain how they may impact the timeframe.
- Q.8. Please explain why the Government of India's AI import restrictions, to the extent they have been notified to the WTO SPS Committee,¹⁴⁰ have been notified as emergency measures even though India has had similar measures in place for over five years.
- Q.9. Please explain whether or not India's measures take into account the principle of regionalization in developing and applying the AI import restrictions. If the measures take into account the principle of regionalization, please explain how.

The United States requested that India reply by the following month (that is, by February 16, 2012).

87. In a letter dated February 15, 2012, India responded to the United States via a letter the body of which stated *in toto*:

This has reference to your letter dated 17 January, 2012, asking India to provide responses to the United States request under Article 5.8 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

2. [sic] This is to mention that India would require some more time to respond to the United States request.¹⁴¹

¹⁴⁰ See, e.g., G/SPS/N/IND/73, dated October 11, 2011, notifying NO.S.O. F.No.109-21/2007, dated July 20, 2011.

¹⁴¹ United States, 5.8 Request (Exhibit US-4).

Over 14 months has passed since the 5.8 request, yet India has not otherwise responded.

B. Instruments Reflecting the Measures

88. The measures at issue are those that constitute and support an import ban of various agricultural products, purportedly on account of NAI.¹⁴² As explained above, when India initially instituted these measures, there was no specific instrument in place that reflected the prohibitions. With the publication of S.O. 102(E) on February 2, 2007, there was finally a government document that reflected the prohibitions. S.O. 102(E) stated that the import prohibitions would remain in place for six months from the date of publication. India has subsequently published further notifications that continued to extend import prohibitions. Some of these notifications provide that fewer products are to be prohibited on account of NAI. Nonetheless, they continue to impose prohibitions that run afoul of the recommendations in the OIE Code.

89. In Section VIII.I., the United States addresses additional notifications issued by DAHD. The table also notes the corresponding notifications to the WTO as well their notification to the WTO. It appears there are periods of time when a notification expired by its terms, but no new notification was issued. The United States understands that India maintains its prohibitions during these intervals. Also evident is that India notified the WTO of these subsequent publications only after that had already entered into force.

90. The United States understands that these notifications are issued pursuant to the Indian Livestock Importation Act, 1898 (9 of 1898) ("Livestock Act"). It appears the relationship between the Livestock Act and a notification is akin to a grant of authority and the exercise thereof. The Livestock Act, specifically sections 3 and 3A, empowers the central government of India, through a notification in India's official gazette, to "regulate, restrict, or prohibit, in such manner and to such extent as it may think fit" the import of livestock and livestock products. A central government agency located within the Indian Ministry of Agriculture, the Department of Animal Husbandry, Dairying, and Fisheries ("DAHD"), is the central government body exercising that discretion.

91. The most recent notification issued by DAHD is S.O. 1663(E), which was published on July 19, 2011 and notified to the WTO SPS Committee on October 11, 2011.¹⁴³ Unlike prior notifications issued by DAHD, it has no set expiration date. S.O. 1663(E) bans the import "of

¹⁴² SPS Agreement, Annex A, para. 1 defines sanitary measure as "Paragraph 1 of Annex A of the SPS Agreement defines a sanitary measure as "all measures applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms."). The Panel in *Japan – Apples* noted that there is "no legal, logical, or factual obstacle" to treating various requirements as a single measure for purposes of the SPS Agreement. para. 8.17.

wild birds, except those reared in captivity" from all countries.¹⁴⁴ For those "countries reporting Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza)," S.O. 1663(E) bans the following products:

- (a) domestic and wild birds (including poultry and captive birds);
- (b) day old chicks, ducks, turkey, and other newly hatched avian species;
- (c) un-processed meat and meat products from Avian species, including domesticated, wild birds and poultry;
- (d) hatching eggs;
- (e) eggs and egg products (except Specific Pathogen Free eggs);
- (f) un-processed feathers;
- (g) live pigs;
- (h) pathological material and biological products from birds;
- (i) products of animal origin (from birds) intended for use in animal feeding or for agricultural or industrial use; and
- (j) semen of domestic and wild birds including poultry.¹⁴⁵

S.O. 1663(E) provides that the "Central Government may allow the import of processed poultry meat after satisfactory conformity assessment of the exporting country" and that its prohibitions are not applicable to the import of "processed pet food" and "pathological materials and biological products for use in research purposes exclusively by the National Referral Laboratories."¹⁴⁶

92. The United States also understands that there are other instruments that implement the avian influenza prohibitions reflected in these notices such as office memoranda instructing customs officials to ban the various products as well veterinary certificates issued by DAHD that must be satisfied before import of a product is allowed.

¹⁴⁴ S.O. 1663(E)(1)(i).

¹⁴⁵ S.O. 1663(E)(1)(ii)(a)-(j).

¹⁴⁶ S.O. 1663(E)(2).
VI. INDIA'S INTERNAL AVIAN INFLUENZA CONTROL MEASURES

93. As the preceding section demonstrated, India's position on imports is that LPAI is sufficiently dangerous that it merits import prohibitions that must be applied to a country *in toto*.¹⁴⁷ One would expect then that India would maintain aggressive surveillance policies for LPAI at home. Additionally, since India believes that avian influenza measures need to be applied country-wide, one would expect India to have extremely strict controls on the internal movement of products in the event of an outbreak. However, as the United States will explain in this section, India's policies with respect to domestic production are far different than with respect to imports. While, as noted, India's measures regarding imports go far beyond any control measures contemplated in the international OIE standard, India is willing to apply significantly less stringent policies domestically.

94. India's surveillance and control policies for avian influenza are set forth in DAHD's Action Plan of Animal Husbandry For Preparedness, Control, and Containment of Avian Influenza ("AI Action Plan").¹⁴⁸ As demonstrated below, India's AI Action Plan does not bother to check for LPAI and only imposes control measures that extend a few kilometers from the site of an HPAI outbreak.

A. India's Surveillance Program Ignores LPAI

95. The only reference to low pathogenic avian influenza in the AI Action Plan is at an annexure at the end that copies a Q&A created by the World Health Organization.¹⁴⁹ When it comes to the actual surveillance policies that are to be implemented, the AI Action plan is not merely silent regarding LPAI, it provides policies that essentially ignore it. For example, in the section that provides the "Guidelines for Collection, Packing and Transportation of Samples," India states the following:

The following guidelines are extremely important. States should adhere to these guidelines:

(i) The States/ UTs must distinguish at their level between unusual sickness/ mortality and normal incidences of sickness and mortality in poultry. Only in case of unusual sickness/ mortality raising suspicion of AI, forward the samples

¹⁴⁷ See e.g., Note by the Secretariat, Summary Of The April 2008 Meeting Of G/SPS/R/49, ("With respect to the OIE guidelines, India had voted against the resolution in the last annual session which proposed that low pathogenic AI was not a concern for international trade.").

¹⁴⁸ India's first action plan was issued in November 2006. In July 2012, a revised action plan was issued. For ease of reference, unless otherwise indicated, all references and quotations are to the 2012 plan.

¹⁴⁹ India's AI Action Plan (2012) (Exhibit US-90), p. 69.

immediately either to respective Regional Disease Diagnostic Laboratory or directly to HSADL, Bhopal through special messengers under intimation to the Joint Secretary (Livestock Health), in the Department of ADF, Government of India.

But, as India is fond of reminding its trading partners, LPAI is often asymptomatic. To the extent that noticeable symptoms occur at all, they are unlikely to be different from those caused by other diseases, and thus unlikely to trigger suspicions of AI.¹⁵⁰ By emphasizing reports from farmers of "unusual sickness" in their birds and making a distinction against "normal incidences of sickness and mortality," India's system is tailored *not* to detect LPAI outbreaks when they occur.¹⁵¹ Moreover, there is no mandatory testing under the AI Action Plan. Both the 2006 and 2012 versions of the plan provide, with respect to biological testing, that random sampling "may" be conducted on flocks.¹⁵²

B. India Imposes Limited Controls After Outbreaks of HPAI

96. Per the AI Action Plan, India imposes no restriction on the movement within India of any product from a location in the country more than ten kilometers from the site of an AI outbreak. Once avian influenza is detected, authorities designate an "infected zone" with a radius of one kilometer from the AI detection.¹⁵³ The plan prohibits movement of live birds to and from the infected zone, and calls for the stamping out of live birds within that zone and subsequent disinfection of premises where they had been located.¹⁵⁴ In addition to providing for designation of an "infected area," India's AI Action Plan calls for the creation of a "surveillance area" of ten kilometers around the AI detection. The plan requires closure of "shops and markets dealing with poultry products and eggs" within the surveillance area while authorities conduct stamping out operations in the infected zone.¹⁵⁵ Once these operations are complete, India allows the reopening of poultry shops and markets and the resumption of "inward trade" of "eggs and processed poultry / products [sic.]" within the surveillance area.¹⁵⁶ Following three

¹⁵⁰ Statement of Rebecca Jones, para. 4(a)

¹⁵¹ Statement of Emi Saito, para. 3(e).

¹⁵² India's AI Action Plan (2012) (Exhibit US-90), p.4; India's AI Action Plan (2006) (Exhibit US-89), p.4.

¹⁵³ India's AI Action Plan (2012) (Exhibit US-90), p.13.

¹⁵⁴ India's AI Action Plan (2012) (Exhibit US-90), pp.13-19.

¹⁵⁵ India's AI Action Plan (2012) (Exhibit US-90), p.15.

¹⁵⁶ India's AI Action Plan (2012) (Exhibit US-90), p.15.

additional months with no positive AI tests, outward trade can resume.¹⁵⁷ India's AI Action Plan calls for no other restrictions on the movement of animals or of poultry and egg products as a result of AI detections within India. This was true under the 2006 version of the Action Plan as well: Outside of an "alert zone" having a ten-kilometer radius from an AI detection,¹⁵⁸ the Plan called for no restriction on the movement of poultry or poultry products following an AI detection within India. Thus, while India argues that country wide bans on imports from countries reporting LPAI is appropriate, a detection of HPAI in India results in no restrictions on products that originate a mere ten kilometers from the site of the outbreak.

VII. STANDARD OF REVIEW

A. Deciding SPS Claims

97. The Appellate Body has found that "Article 11 of the DSU 'articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels'¹⁵⁹ reviewing the assessment of facts under the SPS Agreement."¹⁶⁰ Article 11 of the DSU states in pertinent part that:

[A] panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements.

Under this standard, while panels should not engage in a *de novo* review, they must equally avoid "total deference to the findings of the national authorities."¹⁶¹

B. The Review Here Does Not Require The Assistance of Experts

170. The United States recognizes that in some SPS disputes, experts can play a valuable role. In this dispute, however, the United States submits that the adoption of an expert procedure would delay the outcome of the dispute without resulting in any appreciable assistance to the Panel on the legal matters at issue in this dispute. The role of an expert is to assist a panel with respect to assessing scientific evidence. That role is contingent though on the respondent have some scientific evidence to actually assess, specifically that set forth in a risk assessment:

¹⁵⁷ India's AI Action Plan (2012) (Exhibit US-90), p.21.

¹⁵⁸ See India's AI Action Plan (2006) (Exhibit US-89), p.17.

¹⁵⁹ *EC* – *Hormones (AB)*, paras. 115 -116.

¹⁶⁰ US – Continued Suspension (AB).

¹⁶¹ US – Continued Suspension (AB), para. 589, quoting EC – Hormones (AB), para. 117.

[U]nder Article 5.1 of the SPS Agreement, the Appellate Body identified two aspects of a panel's scrutiny of a risk assessment, namely, scrutiny of the underlying scientific basis and scrutiny of the reasoning of the risk assessor based upon such underlying science. With respect to the first aspect, the Appellate Body saw the panel's role as limited to reviewing whether the scientific basis constitutes 'legitimate science according to the standards of the relevant scientific community'. The Appellate Body perceived the second aspect of a panel's review as involving an assessment of whether the reasoning of the risk assessor is objective and coherent, that is, whether the conclusions find sufficient support in the scientific evidence relied upon. Having done so, the panel must determine whether the results of the risk assessment sufficiently warrant the challenged SPS measures.¹⁶²

Here, there is no risk assessment and therefore, no scientific evidence that needs scrutiny with the assistance of experts. To be sure, the United States has referred extensively to scientific evidence in this submission. But the United States has provided this information not because there is any scientific dispute with India, but rather to provide factual context on avian influenza. In short, this is not a complicated case of competing scientific claims, but rather one where experts – including the OIE – have spoken – and India has cited to no risk assessment in support of its measure.¹⁶³

VIII. LEGAL CLAIMS

A. India's Measures Are Subject To The SPS Agreement

171. The SPS Agreement applies to India's measures. Article 1.1 of the SPS Agreement provides that it "applies to all sanitary and phytosantiary measures which may, directly or indirectly, affect international trade." Accordingly, the SPS Agreement governs when (1) the measure at issue is a sanitary of phytosanitary measure and (2) the measure affects international trade.¹⁶⁴ India's avian influenza measures satisfy both requirements.

US - Poultry, para. 7.82 ("there are two conditions for the application of the SPS Agreement to a given measure; namely, (i) the measure must be an SPS measure as defined in Annex A of the SPS Agreement, and (ii) the measure has to directly or indirectly affect international trade.").

¹⁶² Australia – Apples (AB), para. 215, quoting US – Continued Suspension (AB), para. 591.

¹⁶³ Australia – Apples (AB), para. 384 ("Experts may assist a panel is assessing the level of risk associated with SPS measures and potential alternative measures, but whether or not an alternative measure's level of risk achieves a Member's appropriate level of protection is a question of legal characterization, the answer to which will determine the consistency or inconsistency of a Member's measure with its obligation under Article 5.6. Answering this question is not a task that can be delegated to scientific experts.")

172. With respect to the first requirement, Annex A, paragraph 1 of the SPS Agreement defines "sanitary measure" as any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods,
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments

The Appellate Body has explained that the list of instruments noted in the end paragraph are "both illustrative and expansive" meaning "that measures of a type not expressly listed may nevertheless constitute SPS measures when they are 'relevant', that is when they are applied for a purpose that corresponds to one of those listed in subparagraphs (a) through (d)."¹⁶⁵ In other words, the critical question of whether a measure is a sanitary measure is whether the purpose of the measure is one of the enumerated concerns in paragraph 1 of Annex A.

173. India's measures, both on their face and as described by India itself, have ostensible purposes corresponding to those in subparagraphs (a) through (c). India's Livestock Act, which India invokes as the authority for its import prohibitions, authorizes India's central government to regulate, restrict, or prohibit the import of "any live-stock product, which may be liable to affect *human or animal health*."¹⁶⁶ India, in one of its government publications, acknowledges that:

¹⁶⁵ Australia – Apples (AB), para. 175.

¹⁶⁶ The Live-stock Importation Act, 1898 (Exhibit US-114); The Live-stock Importation (Amendment) Act, 2001 (Exhibit US -115).

the objective of this Act and the notifications/orders issued therein is to regulate the import of livestock products in such a manner that these imports do not adversely affect the country's human and animal health population.¹⁶⁷

Additionally, the belated notifications made by India provide additional confirmation regarding the objectives of India's measures. India notified its most recent publication of avian influenza import prohibitions, S.O. 1663(E), to the SPS Committee, and in the notification ticked the following as its objectives and rationales: (1) food safety, (2) animal health, and (3) to protect humans from animal/plant pest or disease. India, in the same notification, also provided a narrative response for S.O. 1663(E)'s objective and rationale: "[t]o ensure food safety and protect domestic and wild birds from avian influenza (both from highly pathogenic notifiable avian influenza and low pathogenic avian influenza)."¹⁶⁸ Thus, there appears to be no dispute that India's measures are sanitary measures as defined under the SPS Agreement.

174. In respect to the second requirement, "affects international trade," India's measures prohibit the import of the relevant products. As the panel in EC – Hormones noted, "[i]t cannot be contested than an import ban affects international trade."¹⁶⁹ Thus, because India's measures are sanitary measures as defined under Annex A of the SPS Agreement (their objectives include those provided for in subparagraphs (a) through (c)), and because the measures affect international trade by imposing import prohibitions, the measures are subject to review for consistency under the SPS Agreement.

B. The OIE Code is Relevant to the Resolution of the Claims

98. At the outset, the United States notes that OIE Code's standards and recommendations are relevant to the resolution of the claims in this dispute for at least five reasons.

99. First, the SPS Agreement specifically designates the OIE as the authority that sets standards for diseases such as avian influenza. Specifically, paragraph 3(b) of Annex A provides that the international standards, guidelines, and recommendations for animal health and zoonoses are those developed under the auspices of the International Office of Epizootics (OIE), now called the World Organization for Animal Health.

100. Second, Article 3.1 of the SPS Agreement requires that Members base their sanitary measures "on a wide a basis as possible" on the applicable international standards absent scientific justification or a consequence of their appropriate level of protection as determined through a risk assessment.

¹⁶⁷ Ministry of Finance, Central Board of Excise & Customs, CUSTOMS MANUAL (2011).

¹⁶⁸ Notification of Emergency Measures, G/SPS/N/IND/73 (11 Oct. 2011), at Q. 7.

¹⁶⁹ *EC* – *Hormones*, para. 8.23.

101. Third, in conducting any risk assessment, Article 5.1 of the SPS Agreement requires that sanitary or phytosanitary measures take into account "risk assessment techniques developed by the relevant international organizations." The OIE has in fact promulgated techniques regarding how to conduct a proper risk assessment.

102. Fourth, Articles 5.2 and 2.2 of the SPS Agreement requires that a Member's measures take into account scientific evidence and not be maintained without sufficient scientific evidence. The OIE's standards reflect the prevailing scientific evidence for continued safe trade in commodities with respect to avian influenza.¹⁷⁰ This is evident in the process by which the OIE promulgates the OIE Code. Specifically, the OIE has established a Terrestrial Animal Health Standards Commission that is responsible for ensuring disease specific chapters in the OIE Code, such as those for avian influenza, "are maintained current with the latest scientific information"¹⁷¹ As explained by the OIE:

The Code Commission, which comprises six elected members experienced in regulatory veterinary science drawn from all OIE regions, ... works with internationally renowned specialists to prepare draft texts for new articles of the Terrestrial Code and to revise existing articles in light of advances in veterinary science. As well, the Code Commission collaborates closely with the Aquatic Animal Health Standards Commission on issues needing a harmonised approach, and with the Biological Standards Commission and the Scientific Commission for Animal Diseases to ensure the Code Commission is utilising the latest scientific information in its work.

The views of the Delegates of Member Countries are routinely sought through the circulation of draft and revised texts and, at each General Session, the Delegates discuss and formally adopt the draft texts as OIE standards. These texts are then incorporated into the next edition of the Terrestrial Code.¹⁷²

The OIE Code is thus comprised of the best and latest science available.

103. Finally, the SPS Agreement provides that a Member's standards that conform to the applicable international standards enjoy a presumption of consistency with the SPS Agreement. Article 3.2 of the SPS Agreement provides that:

¹⁷⁰ Bruschke & Vallat, p. 628 ("The OIE continually updates its disease standards, taking into account the latest scientific information on diseases.").

¹⁷¹ OIE Terrestrial Animal Health Standards Commission, Overview, Terms of Reference, para. 4(b) (Exhibit **Error! Reference source not found.**).

¹⁷² OIE, Overview of the Terrestrial Animal Health Standards Commission, available at <u>http://www.oie.int/international-standard-setting/specialists-commissions-groups/code-commission-reports/</u> (last accessed March 31, 2013) (Exhibit **Error! Reference source not found.**).

Sanitary or phytosanitary measures which *conform* to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994. (emphasis added)

Accordingly, a Member whose measures conform to an international standard is entitled to "a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the SPS Agreement and of the GATT 1994."¹⁷³ Central to this provision is the use of the term "conform."¹⁷⁴ As the Appellate Body has explained, the use of the term "conform" means that the Member's measure must match the international standard "completely:"

[A] measure may adopt some, not necessarily all, of the elements of the international standard. The Member imposing this measure does not benefit from the presumption of consistency set up in Article 3.2; but, as earlier observed, the Member is not penalized by exemption of a complaining Member from the normal burden of showing a prima facie case of inconsistency ...¹⁷⁵

Therefore, a WTO Member that picks and chooses those standards and recommendations it prefers is not entitled to the presumption. As explained in Section ____, India's measures are not consistent, let alone conforming to, the OIE Code. Thus, India is unable to invoke Article 3.2 as a defense to U.S. claims.

C. India Breached Articles 5.1, 5.2, And 2.2 Of The SPS Agreement By Failing To Undertake A Risk Assessment And Considering The Relevant Scientific Evidence

104. The specific SPS provisions at issue regarding India's risk assessment – or rather the lack of one – are Articles 2.2, 5.1, paragraph 4 of Annex A, and 5.2. which provide as follows:

Article 2.2: Members shall ensure that any sanitary or phytosanitary measure is [1] applied only to the extent necessary to protect human, animal or plant life or health, [2] is based on scientific principles and [3] is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

¹⁷⁵ *EC* – *Hormones (AB)*, para. 170-171.

EC - Hormones (AB), para. 170 (parentheses original).

¹⁷⁴ Concise Oxford Dictionary, Conform at p. 302 (Conform means "to comply with rules, standards, or laws.")

Article 5.1: Members shall ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

Annex A, para. 4: Risk assessment - [1] The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or [2] the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

Article 5.2: In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

105. Per the Appellate Body, Article 2.2 provides interpretative guidance to Article 5.1:

Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1.¹⁷⁶

Article 2.2 thus clarifies at least two issues. First, Article 2.2 provides that measures must be based on scientific principles. Therefore, the fact that a certain degree of scientific uncertainty may exist does not necessarily mean a Member is excused from its obligations under Article 5.1 and 5.2.¹⁷⁷ Second, Article 2.2 requires that measures be maintained with "sufficient scientific evidence." Accordingly, in assessing a risk assessment under Article 5.1 it is important to determine whether the risk assessment is relying on sufficient scientific evidence. Fundamentally, a risk assessment is not an exercise to gather evidence to fit a pre-ordained conclusion, but rather an impartial, scientific exercise to determine whether a measure should be adopted to protect against a particular risk.

106. Under Article 5.1, a Member must ensure its measures are "based" on a risk assessment. Paragraph 4 of Annex A defines two types of risk assessment. The first (the "Pest Risk Assessment") concerns assessing the risk of the entry, establishment, or spread of pests and diseases. The second (the "Food Safety Risk Assessment") concerns assessing the risk of harm

¹⁷⁶ EC – Hormones (AB), para. 180.

¹⁷⁷ Australia – Salmon (AB), para. 130.

present in foodstuffs.¹⁷⁸ Additionally, Article 5.1 provides that an appropriate risk assessment "tak[es] into account risk assessment techniques developed by the relevant international organizations." ¹⁷⁹ As explained in Section ___, the OIE has promulgated standards regarding a risk assessment both in the OIE Code (Chapter 2.1) and in its *Handbook on Import Risk Analysis*. Accordingly, a proper risk assessment for avian influenza under the SPS Agreement would, at a minimum, consider and address the OIE's risk assessment techniques.

1. India Breached Articles 5.1 and 5.2 because its measures are not based on a risk assessment

107. Because India has stated that its measures were adopted to address risks associated with both diseases and food safety, the SPS Agreement obliges India to base its measures on both types of risk assessment -- a Pest Risk Assessment and a Food Safety Risk Assessment.¹⁸⁰ In its most recent notification to the WTO of its measures, India explained why it enacted its measures:

To ensure food safety and protect domestic and wild birds from avian influenza (both from highly pathogenic notifiable avian influenza and low pathogenic notifiable avian influenza).

Urgent action has been taken to prevent the ingress of this virus to protect human health as well as health of poultry in India.¹⁸¹

Thus, per India's own pronouncement, it seeks to prevent entry and establishment of disease and to ensure food safety and must accordingly perform both types of risk assessments.

108. India, however, has done neither. For years now, the United States and other Members have been waiting for India to provide a risk assessment on which it bases its measures in

 $^{^{178}}$ *Australia* – *Salmon (AB)*, paras. 8.68-8.69 (the "first set of definitions deals with risks arising from the entry, establishment or spread of pests or diseases [while] [t]he second addresses risks arising from specific substances in food, beverages or feedstuffs.").

¹⁷⁹ Shorter Oxford Dictionary, p. 15 (The definition for "take into account" includes "take into consideration, notice, turn to.").

EC - Hormones (AB), para. 182 (applying risk assessment defined in the second part of Annex A, paragraph 4 to measures applied to protect human life or health from risks arising from contaminants in foods (according to paragraph 1(b) of Annex A))' *Australia – Salmon*, paras. 8.68-8.69. (the "first set of definitions deals with risks arising from the entry, establishment or spread of pests or diseases [while] [t]he second addresses risks arising from specific substances in food, beverages or feedstuffs.").

accordance with its obligations. With respect to the U.S. experience, the United States has requested India bilaterally, in the SPS Committee, and through its 5.8 request to provide one. However, six years after it imposed import prohibitions, India still lacks a risk assessment on which it bases its measures. Thus, India's measures are not based on a risk assessment in contravention of Article 5.1. Additionally, without a risk assessment, India could not have taken into account the factors noted in Article 5.2 thereby breaching that provision as well.

109. In the interests of completeness, however, the United States will address the document referenced in Section V.A. that India provided at the October 2010 meeting of the SPS Committee (the "Summary Document").¹⁸² As noted previously, India's position regarding this document has changed in the past. India's more recent pronouncements are that the Summary Document is in fact not intended to serve as its risk assessment. However, in the event that India asserts in this proceeding that the document qualifies as a risk assessment, the United States demonstrates below why the Summary Document fails to satisfy the requirements of the SPS Agreement.

a. The Summary Document is Not a Pest Risk Assessment

110. Having proclaimed that its measures are intended to protect human and animal health from disease, India is required to perform a Pest Risk Assessment. A Pest Risk Assessment must: "(1) *identify* the diseases [or pests] whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases [or pests]; (2) *evaluate the likelihood* of entry, establishment or spread of these diseases [or pests], as well as the associated potential biological and economic consequences; and (3) evaluate the likelihood of entry, establishment or spread of these diseases [or pests] according to *the SPS measures which might be applied*."¹⁸³ This evaluation may be expressed in either "quantitative" or "qualitative" terms.

111. With respect to each of these requirements, the Summary Document is lacking.¹⁸⁵ As an initial matter, it does not bother to make any attempt to truly identify avian influenza. As explained in the statement of facts, avian influenza is not a single or homogenous disease. This point is illustrated well by the fact that the summary document makes no real attempt to explain what LPAI is and or what distinguishes it from HPAI. At most, the document simply notes that LPAI in poultry is reportable to the OIE and that LPAI may potentially mutate. To the extent India asserts that identification of the disease at issue can be inferred by reference to the OIE

¹⁸² Exhibit US-110

¹⁸³ Australia – Salmon (AB), para. 121 (emphasis in original).

¹⁸⁴ Australia – Salmon (AB), para. 124.

¹⁸⁵ India, Summary Document (Exhibit US-110).

Code, there is the problem that India's interpretation of the Code in this document is simply wrong. For example, the document fails to note that only H5 and H7 strains of LPAI in poultry are notifiable to the OIE. Additionally, the document, wrongly again, asserts that the OIE Code prohibits trade in poultry from LPAI positive countries. To the contrary, as explained above, the OIE Code explicitly allows for trade of poultry products such as poultry meat, even from countries reporting outbreaks of H5 and H7 strains of LPAI provided the proper precautions are taken.

112. With respect to the second element, likelihood, India's risk assessment should provide an "*evaluation of the likelihood* of entry, establishment or spread of … [the disease] *and* of the associated potential biological and economic consequences."¹⁸⁶ Although India bans numerous products, the only two products referenced are poultry meat and eggs, presumably for human consumption. The majority of products that India prohibits, such as hatching eggs, poultry semen, feathers, etc., are not referenced at all. Even with respect to poultry meat and eggs, the Summary Document fails to note any actual likelihood of transmission, including with respect to LPNAI. In fact, the Summary Document seems to suggest that transmission with respect to these products would be difficult if not extremely unlikely. For example, it notes that "raw scraps or the imported carcass tissue would have to be fed" to cause transmission to poultry and that cooking inactivates the virus.

113. Finally, regarding the last element, the SPS measures that might be applied, India's document fails to evaluate any other potential options including the use of the OIE Code.¹⁸⁷ India's failure to note alternatives is striking for at least two reasons. First, the document notes in passing that there are options other than a country wide ban, such as "accepting compartment freedom and zonal freedom."¹⁸⁸ Accordingly, the drafter of the document was at least cognizant of these options, yet saw no need to examine whether they could address any concerns. Second, although the document does not note it, it appears the author of the Summary Document was very likely aware of another alternative option. Specifically, the OIE official who reviewed the document noted that:

Several passages in India's risk assessment are taken word for word, with no acknowledgment of source, from an import risk analysis conducted in New Zealand in 1999 (MAF Regulatory Authority 1999). Such extensive reproduction from another publication, without acknowledgment, . . . seriously undermines the credibility of India's risk assessment. Interestingly, while India's risk assessment has concluded that chicken meat imports from "avian influenza positive"

¹⁸⁶ Australia – Salmon (AB), para. 127 (emphases original).

¹⁸⁷ The OIE official who reviewed the documented noted that it only considered the option of an import ban. MacDiarmid, p. 4.

¹⁸⁸ India, Summary Document, p. 5.

countries" should be banned, the New Zealand import risk analysis from which text was reproduced reached different conclusions and concluded that, subject to the application of appropriate sanitary measures, chicken meat could be imported safely from countries or zones considered infected with *highly* pathogenic avian influenza.¹⁸⁹ (emphasis added)

114. Apparently, the Summary Document was aware that another country's risk assessment had concluded that imports, with the proper precautions, could be permitted from countries even reporting HPAI outbreaks. The Summary Document fails completely to describe these precautions and why they would be inadequate for India. Thus, because India's Summary Document does not identify threats including LPNAI, evaluate them, or consider genuine options to address any particular threats, it cannot be considered a Pest Risk Assessment under the SPS Agreement.

b. The Summary Document is Not a Food Safety Risk Assessment

115. Since India has proclaimed an objective of its measure to be food safety, it is also required to perform a Food Safety Risk Assessment. A Food Safety Risk Assessment must (1) "identify the adverse effects on human health (if any)" arising from the presence of the additives, contaminants, toxins, or disease-causing organisms in food, beverages, or feedstuffs at issue; and (2) "if any such adverse effects exist, evaluate the potential . . . occurrence of such effects."¹⁹⁰ This type of risk assessment requires the party to address "the specific risk at issue."¹⁹¹ A risk assessor is not excused "from evaluating whether there is a connection between the particular substance being evaluated and the possibility that adverse health effects may arise."¹⁹²

116. The fundamental problem with the Summary Document serving as a Food Safety Risk Assessment is that is does not address most of the products India bans. Beyond that, there is no discussion of what adverse impacts on human health would arise by consumption of poultry meat and eggs, particularly with respect to LPNAI, and the potential occurrence of those adverse impacts. If anything, the Summary Document notes that there is no evidence to suggest transmission is possible if the products have been properly cooked. In short, having failed to identify any adverse effects and their possible occurrence, India cannot claim the Summary Document is a food safety risk assessment either.

¹⁸⁹ MacDiarmid, p. 2 (Exhibit US-108).

¹⁹⁰ EC – Hormones (AB), para. 183.

¹⁹¹ US – Continued Suspension (AB), para. 559.

¹⁹² US – Continued Suspension (AB), para. 562.

c. The Summary Document Does Not Take Into Account the OIE Techniques for a Risk Assessment or Relevant Scientific Evidence

117. Although the failures above are more than sufficient to disqualify the Summary Document as a risk assessment under the SPS Agreement, the United States briefly notes two other deficiencies. First, Article 5.1 requires a risk assessment take into account the risk assessment techniques developed by relevant international organizations. The Summary Document does not. The document does not even reference the OIE's standards for a risk assessment such as Chapter 2.1 of the OIE Code or the Handbook on Import Risk Analysis.¹⁹³ By failing to consider the techniques promulgated by the OIE, the Summary Document runs afoul of Article 5.1's requirement that a risk assessment at least take into account the risk assessment techniques of relevant international organizations.

118. The second deficiency related to Article 5.2's obligation to take into account available scientific evidence. Here too, the Summary Document fails on its face. The most recent scientific authority cited is over 14 years old. Moreover, there is not even a cursory reference to the available scientific evidence explaining that LPAI does not replicate systemically and the corresponding implications for the safety of poultry meat and eggs. Accordingly, the Summary Document cannot be said to take available scientific evidence into account.

2. India's Failure to Conduct a Risk Assessment Results in a Breach of Article 2.2

119. Article 2.2 sets forth fundamental obligations applicable to all SPS measures including that measures be based on scientific principles and sufficient scientific evidence. Articles 5.1 and 5.2 serve as a specific application of these basic principles by requiring Members to undertake a risk assessment. Specifically, Article 5.1 imposes the obligation on Members to base their measures on a risk assessment while Article 5.2 confirms that the risk assessment *must* take into account factors including scientific evidence. Accordingly, the relationship, as confirmed by the Appellate Body, is that a proper risk assessment is a constituent component of ensuring measures are based on scientific principles and not maintained without sufficient scientific evidence:

... Articles 5.1 and 5.2 ... "may be seen to be marking out and elaborating a particular route leading to the same destination set out in" Article 2.2. Indeed, in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence. We conclude, therefore, that if we find a violation of the more specific Article 5.1 or 5.2 such finding can be presumed to imply a violation of the more

¹⁹³ Exhibit US-108.

general provisions of Article 2.2. We do recognize, at the same time, that given the more general character of Article 2.2 not all violations of Article 2.2 are covered by Articles 5.1 and 5.2.¹⁹⁴

Because of this relationship, a finding that Article 5.1 or 5.2 has been breached means a violation of Article 2.2 has occurred as well. Therefore, in the absence of *any* risk assessment, and, thus, in the absence of sufficient scientific evidence, supporting India's measures, India is also in breach of Article 2.2. India's imposition of a ban on the identified avian products, moreover, is not maintained with sufficient scientific evidence because there is no scientific evidence that these products may not be safely traded under any circumstances. To the contrary, the scientific evidence establishes that LPAI virus is not present in poultry meat or inside eggs and thus LPAI cannot be transmitted through these products.¹⁹⁵

3. India May Not Rely on the Exception in Article 5.7 of the SPS Agreement

120. As a final matter, India may not invoke Article 5.7 in order to avoid its obligations under Articles 5.1 and 5.2. Although it is India's burden to establish such a defense, the facts here are sufficiently defined as to confirm the unavailability of Article 5.7 with respect to India's measures. In *Japan – Agriculture Products II*, the Appellate Body found that Article 5.7 permits a Member to institute provisional measures provided the measure is:

- (1) imposed in respect of a situation where 'relevant scientific information is insufficient'; and
- (2) adopted 'on the basis of available pertinent information'

[and the Member]

- (1) 'seek[s] to obtain the additional information necessary for a more objective assessment of risk'; and
- (2) 'review[s] the ... measure accordingly within a reasonable period of time'.

An absence of any of these elements precludes a Member from successfully relying on Article $5.7.^{196}$ Here, India cannot establish the first element because relevant scientific evidence exists – and it does not support the imposition of import prohibitions. The clearest demonstration of this

¹⁹⁴ *Australia – Salmon (AB)*, paras. 137-138, quoting panel report, para. 8.52.

¹⁹⁵ Statement of David Swayne, p. 1 (Exhibit US-97).

¹⁹⁶ Japan - Agriculture II (AB), para. 89.

point is the OIE Code. The OIE Code, based on the latest available science, has found that the very products India bans can be safely traded. Moreover, there is no reason to believe that India could satisfy the other three requirements. There is no indication that India's measures are based on pertinent available information, that it has ever in over six years sought additional information for an objective assessment of risk, or that it proceeded to engage in a legitimate review of its measure. Accordingly, , India cannot rely on Article 5.7

D. India Breached Article 3.1 By Failing to Base Its Measures on the OIE Code

121. Article 3.1 of the SPS Agreement provides that:

Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

122. Article 3.1 thus imposes a positive obligation on a Member to base its measures on international standards unless the Member's measure is justified through another provision of the SPS Agreement. As already noted, the relevant international standards in this dispute, per Annex A of the SPS Agreement, is the OIE Code.

1. India's Measures Are Not Based on the OIE Code

123. A defining characteristic of the OIE Code is that it distinguishes between HPNAI and LPNAI with respect to trade:

The new chapter has several significant changes compared to the previous one, such as differentiating between low pathogenic avian influenza and HPAI, and stating that only cases of HPAI in poultry should be taken into account for the purposes of international trade (cases in wild birds cannot be used as justification for blocking trade).¹⁹⁷

India's measures refuse to make such a distinction and impose a complete ban for certain products regardless of whether the country is reporting HPNAI and LPNAI. As noted above, the OIE allows trade to occur from countries reporting LPNAI – and even HPNAI – with respect to a particular product if the appropriate control measure is applied. For every product banned by India, there is either an applicable OIE recommendation explaining how trade can be facilitated or no recommendation at all.

S.O. 1663: Bans from all countries	OIE Code
reporting NAI (including LPNAI and	

¹⁹⁷ Bruscheke & Vallat, p. 628 (Exhibit US-47).

HPNAI)	
domestic and wild birds (including poultry and captive birds);	Articles 10.4.5 and 10.4.6
day old chicks, ducks, turkey, and other newly hatched avian species;	Articles 10.4.7 and 10.4.8
un-processed meat and meat products from Avian species, including domesticated, wild birds and poultry;	Articles 10.4.19 and 10.4.20
hatching eggs;	Articles 10.4.10, 10.4.11, and 10.4.12
eggs and egg products (except Specific Pathogen Free eggs);	Articles 10.4.13, 10.4.14, and 10.4.15
un-processed feathers;	Article 10.4.22 and Article 10.4.23
live pigs;	No recommendation
pathological material and biological products from birds;	No recommendation
products of animal origin (from birds) intended for use in animal feeding or for agricultural or industrial use; and	Articles 10.4.21
semen of domestic and wild birds including poultry.	Articles 10.4.17 and 10.4.18

At no point in the OIE Code is there any suggestion that the relevant product should be categorically prohibited from trade. In short, the OIE Code allows trade; India's measures do not. Under these circumstances, there can be no dispute that India's measures are not based on the OIE Code.

2. India's Failure to Base Its Measures on International Standards is Not Justified Under Article 3.3

124. Article 3.1, per its terms, provides that a Member *shall* base its measures on international standards unless another provision of the SPS Agreement provides otherwise. In particular, the provision references Article 3.3, which provides:

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if [1] there is a scientific justification, or [2] as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[footnote] Notwithstanding the above, all measures which result in a level of sanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

[footnote:] For the purposes of paragraph 3 of Article 3, there is scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

India cannot avail itself of this provision because it lacks a risk assessment. At first glance, the use of the term "or" in Article 3.3 suggests that two conditions are available: (1) scientific justification or (2) as a consequence of a level of sanitary protection derived through paragraph 1 through 8 of Article 5. The reference to Article in the second condition makes explicit that this option is contingent on a Member basing its measures on a proper risk assessment under the SPS Agreement. While perhaps not as explicit, a close reading confirms a risk assessment is also required for the first option. As explained by the Appellate Body in EC - Hormones:

The use of the disjunctive "or" does indicate that two situations are intended to be covered. These are the introduction or maintenance of SPS measures which result in a higher level of protection:

(a) "if there is a scientific justification"; or

(b) "as a consequence of the level of ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5".

It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that "all measures which result in a [higher] level of ... protection", that is to say, measures falling within situation (a) as well as those falling within

situation (b), be "not inconsistent with any other provision of [the SPS] Agreement". "Any other provision of this Agreement" textually includes Article 5. Secondly, the footnote to Article 3.3, while attached to the end of the first sentence, defines "scientific justification" as an "examination and evaluation of available scientific information in conformity with relevant provisions of this Agreement ...". This examination and evaluation would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the *SPS Agreement*.¹⁹⁸

In other words, a full reading of the provision confirms that a risk assessment is just as essential for the first condition in Article 3.3. As India lacks a risk assessment consistent with Article 5.1 and 5.2, it cannot invoke Article 3.3 and is thus in breach of Article 3.1.

125. Even absent the failure to conduct a risk assessment here, India would be unable to invoke Article 3.3 as a result of its appropriate level of protection. Although India, despite the US 5.8 request, has not elucidated it ALOP, it may be possible to infer India's ALOP from measures that it is applying.¹⁹⁹ As detailed with greater specificity below, India's AI Action Plan imposes only limited controls on products in response to domestic AI detections. Essentially, a 1 kilometer "infected zone" is established from the center of the outbreak.²⁰⁰ Per the Action Plan, the movement of live birds to and from the infected zone is prohibited and live birds within that zone are stamped out.²⁰¹ India's Action Plan also calls for the creation of a "surveillance area" of ten kilometers around the AI detection. Following three additional months with no positive AI tests, outward trade can resume.²⁰² The Action Plan calls for no other restrictions on the movement of animals or of poultry and egg products as a result of AI detections within India. Accordingly, India's level of protection is sufficiently satisfied at home, even with respect to the more dangerous HPAI, by a simple quarantine zone of a few kilometers.

126. Viewed together with the minimal restrictions on movement of domestic products that India imposes following domestic HPAI outbreaks, it is clear that measures based on the OIE international standard would achieve India's ALOP. Accordingly, while India's failure to base its measures on a risk assessment provides a clear reason why India cannot invoke Article 3.3, it

- ²⁰⁰ India's AI Action Plan (2012), p.13.
- ²⁰¹ India's AI Action Plan (2012), p.13-19.
- ²⁰² India's AI Action Plan (2012), p.21.

¹⁹⁸ *EC – Hormones (AB)*, para. 175.

¹⁹⁹ Appellate Body Report, *Australia – Measures Affecting the Importation of Salmon*, WT/DS18/AB/R, 20 Oct. 1998, para. 207.

is additionally the case that India cannot make any claim under Article 3.3 because of its relatively low ALOP.

E. India Breached Articles 5.6 and 2.2 By Maintaining Sanitary Measures That Are More Trade Restrictive than Required to Achieve its Appropriate Level of Protection

127. Article 5.6 of the SPS Agreement requires a Member not to establish or maintain sanitary or phytosanitary measures that are more trade-restrictive than required to achieve its appropriate level of protection. The provision states:

Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

The footnote to Article 5.6 clarifies:

For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

128. In *Australia – Salmon*, the Appellate Body agreed with the panel that, reading Article 5.6 together with its footnote, a complainant needed to establish three cumulative elements for a breach of Article 5.6. First, there must be an alternative measure that "is reasonably available taking into account technical and economic feasibility." Second, the measure must achieve "the Member's appropriate level of sanitary or phytosanitary protection." Finally, the measure must be "significantly less restrictive to trade than the SPS measure contested." ²⁰³ Here, all three elements are satisfied and India is in breach of Article 5.6 as a result.

a. The OIE Code is Reasonably Available

129. There is a clear, scientifically based alternative to India's prohibitions that is reasonably available: measures based on the OIE Code. This alternative is technically feasible because the OIE Code is developed and indeed in use around the world. Additionally, the OIE Code was

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Australia – Salmon (AB), para. 194; see Australia – Salmon, (Panel), para. 8.167

formulated through the expertise of veterinary authorities around the world who are familiar with real world practicalities.

130. Adoption of the OIE Code's prescriptions poses no economic barrier to India either. Specifically, since the OIE Code provides for the application of control measures by *the exporting country*. Thus, this expense of control measures is not incurred by an importing country such as India. To the extent India insists it would bear a burden in reviewing the veterinary certificates that the OIE Code recommends it accept, that argument is unpersuasive because India already requires sanitary import permits that require various conditions be attested to.²⁰⁴ Adoption of measures based on the OIE Code would simply mean that Indian officials, instead of reviewing certificates for the conditions they currently require – such as countrywide freedom from NAI – would instead confirm that the conditions of the OIE Code have been satisfied.

b. Measures Based on the OIE Code Would Achieve India's ALOP

131. India has not stated its Appropriate Level of Protection. However, as explained *infra*, after an examination of its domestic surveillance and control measures, India's ALOP appears to be quite low. Assuming *arguendo* though that the ALOP was extremely high – to prevent any infection by LPNAI subtypes – the control measures in the OIE Code are sufficient to achieve it. Specifically, three points need to be kept in mind.

132. First, India's ban extends to products such as poultry meat and eggs that are not vehicles for LPAI transmission. The virus is simply not found in those products.²⁰⁵ Accordingly, these products absent contamination – which the OIE Code confirms – will not transmit disease.²⁰⁶

133. Second, the OIE Code's provision for containment of AI, and trade in products originating outside the area where AI was detected, through the zoning and compartmentalization, is consistent with India's measures with respect to domestic products, which impose controls and restrictions on movement of products only within a limited area following an AI outbreak. Establishment of a zone or compartment in accordance with the OIE Code necessarily entails establishment of surveillance, control, and biosecurity measures to ensure that trade in products from outside the zone or compartment is safe, and allows for application of distinct requirements (or no requirements) for products coming from outside the zone or compartment than are applied to products coming from inside it.

²⁰⁴ *See e.g.*, India, Veterinary Certificates (Exhibits US-52-55).

²⁰⁵ Statement of David Swayne, p. 1 (Exhibit US-97).

²⁰⁶ OIE, Code Article 10.4.19 (ante- and postmortem inspectons); OIE Code, Article 10.4.14 (surface sanitation on eggs).

134. Third, the control measures have proven effective over an extended period sustained period of time. The United States is one of the world's largest exporters of poultry commodities. Yet, there is no evidence that any country has suffered LPNAI – or HPNAI – infections as a result of U.S. exports. The prescriptions of the OIE Code have thus proven, in real world conditions, more than sufficient to prevent transmission of LPNAI.

c. The OIE Code is Significantly Less Trade Restrictive

135. As the OIE Code allows for trade from countries reporting outbreaks of LPNAI – and India's measures do not – the OIE Code is inherently less trade restrictive. Additionally, the OIE Code recognizes that zoning can be an appropriate method to control for avian influenza risks. In contrast, India rejects any consideration of regional conditions and would impose a country wide ban even if the outbreak is geographically isolated and thousands of kilometers away from the exporting facility.

1. India's Breach of Article 5.6 Results in a Consequential Breach of Article 2.2

136. The Appellate Body has recognized that Article 2.2 informs the interpretation of Article 5.6^{207} Indeed, the Appellate Body has suggested it may be the case that a breach of Article 5.6 results in a consequential breach of Article 2.2:

In this connection, we take particular note of the similarities between the requirement in Article 2.2 that Members apply their SPS measures "only to the extent necessary to protect", and the requirement in Article 5.6 that SPS measures be "no more trade-restrictive than required to achieve" the relevant objectives.

Thus, the Appellate Body has ruled that a violation of Article 5.1 or Article 5.2 can be presumed to imply a violation of Article 2.2, but that the reverse does not hold true—that is, a violation of Article 2.2 does not imply a violation of Article 5.1 or Article 5.2. Whether a similar relationship exists between Article 2.2 and Article 5.6 has not yet been squarely decided, and is not an issue that is raised in this appeal, although it has been suggested that just such a relationship does exist.

A breach of Article 5.6 may then indicate a breach of Article 2.2 as well. The first component of Article 2.2 is that a measure be "applied only to the extent necessary to protect human, animal or plant life or health..." A finding under Article 5.6 necessitates a determination that a viable alternative measure that achieves a Member's appropriate level of protection exists and is less trade restrictive than the Member's measure. The existence of such an alternative measure – and

²⁰⁷ Australia – Apples (AB), para. 339.

the concomitant finding that the Member has declined to adopt it - may lead to the conclusion necessary that a Member has adopted a measure that is applied to a greater extent than necessary and is accordingly inconsistent with Article 2.2 as well.

F. India Has Acted Inconsistently With Its Obligations Under Article 6 of the SPS Agreement

137. India's measures explicitly ban poultry from all parts of a country whenever NAI is detected anywhere in the country. Their wording leaves no room for deviation. This precludes the application of AI restrictions on a regionalized basis, as provided for in the OIE's Terrestrial Animal Health Code, and as required under Article 6 of the SPS Agreement.

138. Articles 6.1 and 6.2 of the SPS Agreement lay out the WTO requirements with respect to a member's obligation to ensure that its SPS measures are adopted to regional conditions. Article 6.1 provides that:

Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether all of a country, part of a country, or all or parts of several countries — from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

139. Article 6.2 provides that:

Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

140. India's AI measures preclude India from taking regional conditions (sanitary or phytosanitary characteristics) into account. They explicitly require a ban on covered imports from all parts of a country whenever there is a detection of HPAI or notifiable LPAI anywhere in the country. Thus, S.O. 1663(E) "prohibits, with effect from the date of publication ... the import into India from the countries reporting Notifiable Avian Influenza (both Highly Pathogenic and Low Pathogenic Notifiable Avian Influenza), the [listed] livestock and livestock products." Predecessor instruments likewise explicitly applied AI restrictions on a country-wide basis.²⁰⁸

²⁰⁸ S.O. 102(E) (Exhibit . US-73); S.O. 228(E) (Exhibit. US-74); S.O. 1892(E) (Exhibit US-75); S.O. 419(E) (Exhibit US-76); S.O. 2208(E) (Exhibit US-77); S.O. 616(E) (Exhibit US-78); S.O. 2976(E) (Exhibit US-79).

141. In addition, India requires veterinary certifications for the importation of poultry and poultry products to contain declarations about the AI status of the entire country of origin. Thus, the required veterinary certificates for import of chicken meat, duck meat, and turkey meat into India each require an attestation from an Official Veterinarian that the "Country [of origin] is free from Avian Influenza (Highly Pathogenic Avian Influenza and Low Pathogenic Avian Influenza)."²⁰⁹ Likewise, a consignment of processed poultry meat imported into India must be accompanied by "a Sanitary Certificate from an Official Veterinarian of the exporting country indicating that … the country of export is free from Avian Influenza (Highly Pathogenic Avian Influenza)."²¹⁰

142. The requirement that official veterinarians certify that the entire exporting country is disease-free for a particular consignment of poultry meat is contrary to India's obligations under Article 6.1 because the requirement is not adopted to the characteristics of the area from which the product originated, but rather relates to the country of exportation as a whole. The requirement is doubly problematic, however, because India's certificates do not just refer to notifiable forms of avian influenza. Veterinarians must certify nationwide freedom from all forms of avian influenza, including non-notifiable forms of LPAI, such as LPAI in wild birds. Because avian influenza is endemic in wild birds, no veterinarian could make this certification if wild birds fly over any part of the country.

143. India has required country-level certification despite requests by the United States dating back to at least 2006 that India adjust its required certification to recognize the concept of disease free regions or zones. India has also been asked to regionalize its AI-related import restrictions at numerous meetings of the WTO's SPS Committee.²¹¹ India has explained its refusal to alter its requirement for country-level certification on the grounds that the requirement is "uniform," and that it has a "uniform" policy of requiring country-level certification. Consistent with that approach, moreover, at the May 2012 meeting of the OIE, the Indian delegate criticized the OIE Code's avian influenza chapter, asserting that for India "the concept of zoning looked irrelevant as far as avian influenza was concerned."²¹²

²⁰⁹ Indian Veterinary Certificate, Chicken/Quail Meat into India, (Exhibit US-52); Indian Veterinary Certificate, Duck Meat (Exhibit US-71); Indian Veterinary Certificate, Turkey Meat (Exhibit US-53).

²¹⁰ Requirements for Sanitary Certificate, processed poultry meat (Exhibit US-72).

²¹¹ G/SPS/R/63 (Exhibit US-81), para. 64; G/SPS/R/62 (Exhibit US-82), para. 37; G/SPS/R/61 (Exhibit US-83), para. 26; G/SPS/R/59 (Exhibit US-84), para. 39; G/SPS/R/58 (Exhibit US-85), para. 38; G/SPS/R/56 (Exhibit US-86), para. 40; G/SPS/R/55 (Exhibit US-87), para. 43.

²¹² OIE, 80th General Session FR (Exhibit US-80), para. 231.

144. India's measures thus are not adapted to the sanitary characteristics of the areas from which covered products originate, contrary to the first sentence of Article 6.1 of the SPS Agreement. Even if there has been no detection of notifiable avian influenza within thousands of kilometers of the area from which covered products originate, and regardless of how rigorous a country's AI-control mechanisms are, India bans the shipment of those products based on a single detection of NAI anywhere in the country of origin.

145. Moreover, by banning products from areas thousands of kilometers from an AI detection, India appears not to have taken account of "the level of prevalence" (i.e., the lack of prevalence) of AI in those areas, contrary to the second sentence of Article 6.1. By banning imports from all parts of an exporting country, India also does not appear to have accounted for "the existence of [an AI] eradication or control program" that an exporting country uses to limit the spread of AI once it has been detected, also contrary to the second sentence of Article 6.1.

146. Also contrary to the second sentence of Article 6.1, India has not taken into account the relevant international guidelines on AI, here, Chapter 10 of the OIE's Terrestrial Code, which provide for the application of AI-related trade restrictions at the zone or compartment level when appropriate surveillance, control, and biosecurity measures are in place. In its chapter on AI, the OIE code lays out surveillance requirements for "Members declaring freedom from NAI or HPNAI for [a] country, zone or compartment"²¹³ and for "[c]ountries, zones or compartments declaring that they have regained freedom from NAI or HPNAI following an outbreak,"²¹⁴ as well as standards for when a "country, zone or compartment may be considered" HPNAI free or NAI free.²¹⁵

147. The Code's discussion of AI-related requirements that a country may permissibly impose in connection with the importation of different products also shows that AI is a disease for which it is appropriate to consider the sanitary characteristics of a region in establishing sanitary measures. For each product, the recommended requirements apply either a) "for importation from an HPNAI free country, zone, or compartment," b) "for importation from an NAI free country, zone, or compartment," or c) "[r]egardless of the NAI status of the country of origin." Thus, the OIE Code is clear that AI-related requirements should be applied on a zone or compartmental basis where possible. India, however, has not taken into account the sanitary characteristics of the area from which the product is exported (whether a zone or a compartment) at all, and therefore has not taken into account the pertinent OIE guidelines.

148. India's measures are also contrary to Article 6.2 of the SPS Agreement. The first sentence of Article 6.2 requires Members to recognize the concept of disease-free areas. Yet

²¹³ OIE Code, Article 10.4.30 (Exhibit US-1).

²¹⁴ OIE Code, Article 10.4.31 (Exhibit US-1).

²¹⁵ OIE Code, Articles 10.4.3 & 10.4.4 (Exhibit US-1).

India's measures explicitly preclude recognition of such areas upon notification of a detection of NAI anywhere in the territory of a Member.

149. The second sentence of Article 6.2 requires countries to determine disease-free areas "based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls." By precluding recognition of disease-free areas with respect to AI, India's measures preclude it from determining AI-free areas based on these factors, contrary to Article 6.2's second sentence.

1. India's Failure to Adopt Measures based on Regional SPS Characteristics Is Also Contrary to Article 3.1 of the SPS Agreement

150. India's application of its measures on a countrywide basis breaches Article 3.1, which provides that "Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3."

151. As noted above, India's country-based application of its AI-based import bans is not based on international standards, guidelines or recommendations, which provide for the application of AI-related trade restrictions at the zone or compartment level when appropriate surveillance, control, and biosecurity measures are in place. Therefore, India's measures must comport with Paragraph 3 of Article 3 of the SPS Agreement in order to be consistent with Article 3.1. Paragraph 3 of Article 3 provides that:

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.

This provision does not provide a safe harbor for India's measures because, in addition to lacking a scientific basis for not basing those measures on the relevant international standards, India's rejection of regionalization cannot be justified by its appropriate level of protection.

152. A Member is obliged under the SPS Agreement to determine the ALOP that its measures will try to achieve, and to do so with sufficient precision so that the application of relevant provisions of the SPS Agreement is possible.²¹⁶ However, where, as here, a Member has not disclosed its ALOP (despite repeated requests to do so), it may be possible in some

²¹⁶ Australia – Salmon (AB), paras 205-206.

circumstances to infer a Member's ALOP from measures that the Member is applying.²¹⁷ Here, the disease in question—AI—already exists in the territory of the responding Member, and that Member has measures aimed at preventing the spread of the disease within its territory. In this situation, the Member's ALOP should logically be inferred from *those* measures, which would not be influenced by concerns related to international trade.²¹⁸

India's measures aimed at preventing the spread of AI outbreaks occurring within India 153. show that India's ALOP could be achieved by measures based on the relevant international standard since India's own measures with respect to domestic products reflect the idea that AI can be contained to limited areas, allowing normal trade of products from outside those areas. India's AI Action Plan sets out its response to domestic AI detections. Under the 2012 Action Plan, if a case of AI is suspected, an "alert zone" of ten kilometers surrounding the detection is established, and movement of "poultry, eggs, dead carcasses, manure, used litter, farm machinery, [and] equipment" to and from the "alert zone" is prohibited pending confirmation of whether or not a case of AI has in fact occurred.²¹⁹ The plan also provides for extra surveillance in the "alert zone."²²⁰ After a detection is confirmed, the plan calls for the maintenance of two zones: an "infected zone" and a "surveillance area." The "infected zone" has a radius of one kilometer from the AI detection.²²¹ This zone may be extended to a maximum of three kilometers from the detection.²²² The Action Plan prohibits movement of live birds to and from the infected zone, and calls for the stamping out of live birds within that zone.²²³ Birds may not be reintroduced into disinfected premises for thirty days following disinfection, at which point "farmers may restart poultry production."²²⁴ The "surveillance area" is the ten kilometer area surrounding the AI detection. The Action Plan requires closure of "shops and markets dealing with poultry products and eggs" within the surveillance area while authorities conduct stamping

²¹⁷ *Australia –Salmon (AB)*, para. 207. However, this needs to be approached with caution otherwise, for example, the disciplines in Art. 5.6 could be undermined since if it is assumed that a Member's measures are precisely achieving the Member's ALOP, it would appear difficult to find that there is an alternative, less-restrictive measure that could achieve that ALOP.

²¹⁸ Indeed, if India were to attempt to state a level of protection in excess of that reflected in its measures addressing domestic AI detections, that statement should be rejected as manifestly untrue.

²¹⁹ India's AI Action Plan (2012) (Exhibit US-90), p.9.

²²⁰ India's AI Action Plan (2012) (Exhibit US-90), p.9.

²²¹ India's AI Action Plan (2012) (Exhibit US-90), p.13.

²²² India's AI Action Plan (2012) (Exhibit US-90), pp. 13-14.

²²³ India's AI Action Plan (2012) (Exhibit US-90), p.13-19.

²²⁴ India's AI Action Plan (2012) (Exhibit US-90), p.19.

out operations in the infected zone.²²⁵ Once these operations are complete, India allows the reopening of poultry shops and markets and the resumption of "inward trade" of "eggs and processed poultry / products [sic.]" within the surveillance area.²²⁶ Following three additional months with no positive AI tests, outward trade can resume.²²⁷ India's AI Action Plan thus calls for detections of AI in India to result in no restrictions on the movement of products beyond the area within ten kilometers of the detection. This was true under the 2006 version of the Action Plan as well.

154. Thus, India imposes no restrictions on the domestic movement of products in response to either an LPNAI detection or an HPAI outbreak, so long as the items are moving from an area more than ten kilometers from the detection or outbreak. Countrywide application of a ban on covered imports from all HPAI positive countries—let alone from all LPNAI positive countries—is grossly disproportionate to the ALOP that can be inferred from these domestic measures. Based on India's own measures with respect to its domestic products, measures regarding imported products that were based on regionalization and compartmentalization would also achieve India's ALOP. Accordingly, India cannot claim that its ALOP justifies its failure to base its measures on the relevant international standards.

G. India Has Acted Inconsistently With Its Obligations Under Article 2.3 of the SPS Agreement by Treating Imported Products Differently from Indian Products Without Justification

155. When it comes to regulating its trade in its own products on account of AI, India takes a diametrically different approach from that which it applies to imported products. As this section explains, India's measures therefore serve, not as a buffer against AI, but as a means of arbitrarily or unjustifiably discriminating against imported products and applying a disguised restriction on trade. In so doing, India breaches Article 2.3 of the SPS Agreement.

156. India's discrimination against imports takes two key forms. First, as discussed above, India imposes a ban on all imports of covered products from an exporting country whenever there is a detection of avian influenza anywhere in the country. By contrast, when India detects AI within its own borders, it imposes no controls on the movement of these products within its own borders, aside from a ban on the movement of such products from the area within ten kilometers from the AI outbreak.

157. Second, India bans products from countries that report detections of low pathogenic avian influenza to the OIE. Yet India has not put in place mechanisms that would serve to detect

²²⁵ India's AI Action Plan (2012) (Exhibit US-90), p.15.

²²⁶ India's AI Action Plan (2012) (Exhibit US-90), p.15.

²²⁷ India's AI Action Plan (2012) (Exhibit US-90), p.21.

LPNAI outbreaks within its own territory effectively. As a result, despite having had over ninety outbreaks of the far rarer HPAI since 2006, India has never reported an outbreak of LPAI. India's reliance on the detection of LPNAI thus only affects imported products. India's measures only serve to block imports from countries that do have in place the LPNAI detection mechanisms that India itself has failed to implement.

1. Article 2.3's Protections Against Discrimination and Disguised Restrictions on Trade

158. Article 2.3 of the SPS Agreement provides that:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

159. The first sentence of Article 2.3 prohibits SPS measures that arbitrarily and unjustifiably discriminate between different Members, whether between two different exporting Members that ship the same product to the Member imposing the measure, or between the Member imposing the measure and another Member. One panel has found that a breach of Article 2.3, first sentence, exists if:

(1) the measure discriminates between the territories of Members other than the Member imposing the measure, or between the territory of the Member imposing the measure and that of another Member;

(2) the discrimination is arbitrary or unjustifiable; and

(3) identical or similar conditions prevail in the territory of the Members compared. 228

160. The second sentence of Article 2.3 prohibits application of measures in a way that constitutes a disguised restriction on international trade whether or not the measures embody arbitrary or unjustifiable discrimination.

2. Arbitrary or Unjustifiable Discrimination Between Members with Identical or Similar Conditions

a. First Form of Discrimination: Total Ban on Imports vs. Only Banning Domestic Products from a Limited 10 km Zone

²²⁸ Australia – Salmon (21.5), para. 7.111.

161. India arbitrarily and unjustifiably discriminates against imported products in the treatment of those products following an AI outbreak somewhere in the exporting country. In so doing, India breaches the first sentence of Article 2.3.

162. Under S.O. 1663(E), if there is an NAI outbreak anywhere in the exporting country, the covered product is not permitted to be imported into India. By contrast, under India's domestic AI-control regime, domestic products may still be sold in India following an NAI outbreak within India, so long as the product originates outside a zone within ten kilometers of an NAI detection.

163. India's AI Action Plan sets out its response to domestic AI detections.²²⁹ Under the 2012 Action Plan, if a case of AI is suspected, an "alert zone" of ten kilometers surrounding the detection is established, and movement of "poultry, eggs, dead carcasses, manure, used litter, farm machinery, [and] equipment" to and from the "alert zone" is prohibited pending confirmation of whether or not a case of AI has in fact occurred.²³⁰ The plan also provides for extra surveillance in the "alert zone."²³¹

164. After a detection is confirmed, the plan calls for the maintenance of two zones: an "infected zone" and a "surveillance area." The "infected zone" has a radius of one kilometer from the AI detection.²³² This zone may be extended to a maximum of three kilometers from the detection.²³³ The Action Plan prohibits movement of live birds to and from the infected zone, and calls for the stamping out of live birds within that zone.²³⁴ Birds may not be reintroduced into disinfected premises for thirty days following disinfection, at which point "farmers may restart poultry production."²³⁵

165. The "surveillance area" is the ten kilometer area surrounding the AI detection. The Action Plan requires closure of "shops and markets dealing with poultry products and eggs" within the surveillance area while authorities conduct stamping out operations in the infected zone.²³⁶ Once these operations are complete, India allows the reopening of poultry shops and

- ²³¹ India's AI Action Plan (2012) (Exhibit US-90), p.9.
- ²³² India's AI Action Plan (2012) (Exhibit US-90), p.13.
- ²³³ India's AI Action Plan (2012) (Exhibit US-90), pp. 13-14.
- ²³⁴ India's AI Action Plan (2012) (Exhibit US-90), p.13-19.
- ²³⁵ India's AI Action Plan (2012) (Exhibit US-90), p.19.
- ²³⁶ India's AI Action Plan (2012) (Exhibit US-90), p.15.

²²⁹ India's AI Action Plan (2012) (Exhibit US-90), p.1.

²³⁰ India's AI Action Plan (2012) (Exhibit US-90), p.9.

markets and the resumption of "inward trade" of "eggs and processed poultry / products [sic]" within the surveillance area.²³⁷ Following three additional months with no positive AI tests, outward trade can resume.²³⁸

166. India's AI Action Plan thus calls for detections of AI in India to result in no restrictions or conditions on the movement of products originating outside the ten kilometer area surrounding the detection. This was true under the 2006 version of the Action Plan as well. By contrast, India's measures treat imported products differently and less favorably. The import ban is imposed on products from anywhere in a country where there has been even a single detection of avian influenza. It does not matter if the detection was 3,000 kilometers away from where the product originated, or whether strict biosecurity measures were established in the zone surrounding the detection to prevent its spread outside the zone – the product is banned. India has offered no justification for this disparate treatment of imported products, and therefore India's measures arbitrarily or unjustifiably discriminate against imported products.²³⁹

167. India's differential treatment of imported products and domestic products is not a function of any differences in conditions prevailing in India and other countries, or in countries' measures or procedures for control of avian influenza. As discussed earlier, India's measures, including S.O. 1663(E), explicitly require a nationwide ban regardless of the conditions prevailing in the exporting country, including that exporting country's policies for AI containment. The measures offer no room for India to provide different treatment for another country based on the conditions prevailing in that country.

168. India applies one set of rules for domestic products and another, less favorable set for identical imported products. This difference in treatment has no SPS justification. In sum,

²³⁹ The extent of India's discrimination is highlighted by the fact that, although India proclaimed "the concept of zoning ... irrelevant as far as avian influenza was concerned" in the OIE (OIE, 80th General Session FR (Exhibit US-88), para. 231), Indian authorities have certified facilities in India as compartments for the purposes of avian influenza outbreaks. India, Department of Animal Husbandry, Dairying, and Fisheries, Letter from B. Prashant Kuman to Commissioner, re: Recognition of Venco Research and Breeding Farms Ltd, Sngvi, Talukia Khandala, Distric Stara as a notified compartment against Avian Influenza (June 6, 2010) (Exhibit US-69); India, Department of Animal Husbandry, Dairying, and Fisheries, Letter from B. Prashant Kuman to Commissioner, re: Recognition of establishments of M/s C&M Farming Limited, Nasik as notified compartment against Avian Influenza (Sept. 13, 2010) (Exhibit US-70).

²³⁷ India's AI Action Plan (2012) (Exhibit US-90), p.15.

²³⁸ India's AI Action Plan (2012) (Exhibit US-90), p.21. India's AI Action plan does not address the effect of a domestic AI detection on domestic trade in live pigs—one of the products covered under S.O. 1663(E). However, DAHD has issued a circular telling Indian states to institute a "strict check on movement of pigs from suspected/confirmed area having Avian Influenza to non-infected area." The circular also told states to conduct a "culling of all pigs found positive for Avian Influenza." See DAHD D.O. 53-53/2006-LDT (Exhibit US-111),

India's measures breach Article 2.3 of the SPS Agreement by arbitrarily and unjustifiably discriminating against imported products.

b. Second Form of Discrimination: Imposition of Bans on Imported Products on Account of Notifiable Low Pathogenic Avian Influenza.

169. India's measures unjustifiably discriminate against imported products by banning them from India following detections of LPAI in the exporting country while India does not even maintain surveillance requirements that would result in detection of LPNAI cases occurring in India's domestic poultry flocks.

170. In the time that the OIE has had a notification requirement for some types of low pathogenic avian influenza India has never once notified a detection of LPNAI in India. India thus represents that it has never during this period—i.e., since May 2005—had an outbreak of LPNAI even though it has had over ninety outbreaks of the far rarer highly pathogenic avian influenza during the same period.²⁴⁰ In fact, India asserts that it did not have LPNAI before this period either.²⁴¹ By contrast, since 2007 the United States has detected and notified nine incidents of LPNAI and no incidents of HPAI. Indeed, the United States last had an HPAI outbreak in 2004, and has had only three such outbreaks over the past century.

171. As explained in the statements of veterinarians Saito and Jones, it is simply not plausible that, during a period when India had over ninety HPNAI outbreaks, there were no cases of LPNAI in India.²⁴² In fact, as explained below, India does not require use of surveillance procedures that would effectively detect LPNAI. India's contrasting LPNAI-based import ban thus constitutes unjustifiable discrimination in breach of Article 2.3 of the SPS Agreement. India's measures merely serve to exclude imports from countries, like the United States, that do have in place the surveillance mechanisms necessary to detect, and subsequently contain, LPNAI.

172. India maintains no requirement that its poultry flocks receive any form of routine testing—i.e., collection and laboratory analysis of samples—for avian influenza. The 2012 version of India's avian influenza action plan provides, with respect to routine testing, that sampling "may" be conducted on flocks, and that one particular type of testing (virological) should occur "where possible."²⁴³ However, routine testing is not required. The 2006 version

²⁴⁰ See Graph, Outbreaks of Highly Pathoegenic Avian Influenza (subtype H5N1) in poultry, (Exhibit US-91). This graph covers the period from 2004 until May 2012. However, India asserts, on page 1 of its 2006 AI Action Plan (Exhibit US-89), that it was free of all AI until 2006.

²⁴¹ India's AI Action Plan (2006) (Exhibit US-89), p.1.

²⁴² Saito Statement (Exhibit US-92), para. 3(e), 5; Jones Statement (Exhibit US-106), para. 6.

²⁴³ India's AI Action Plan (2012) (Exhibit US-90), pp. 2, 4.

of India's AI Action plan likewise provided that testing "may" be conducted, but included no requirement that such testing occur.²⁴⁴

173. Under its AI Action plan, India's principal frontline method of detecting AI appears to be visual observation. The 2012 version of the plan, which the Indian government posted to the internet on August 14, 2012, calls for poultry owners and others involved in poultry production to be required to "report unusual sickness/mortality in domestic or wild birds immediately."²⁴⁵ Similarly, as a frontline means of detecting AI, the 2006 version of the plan relied upon mandatory reports by those involved in poultry production of "unusual mortality and sickness."²⁴⁶ However, LPAI, including notifiable strands, is typically asymptomatic or causes only mild respiratory disease or decreased egg production.²⁴⁷ Any illness caused is unlikely to be different from that caused by other diseases and unlikely to strike a poultry producer as an unusual event requiring reporting of possible AI.²⁴⁸ Relying on visual observation of "unusual sickness" in birds, India's system therefore is not conducive to successful detection of LPNAI.²⁴⁹ HPAI outbreaks, by contrast, produce significant unusual and noticeable mortality. It should thus come as no surprise that India detects HPAI but not LPNAI.²⁵⁰

174. The inadequacy of reliance on visual observation, and the resulting importance of laboratory testing, is reflected in the OIE Code chapter on NAI, which explains the surveillance

²⁴⁷ Dennis J. Alexander, A Review of Avian Influenza in Different Bird Species, 3-13 VETERINARY MICROBIOLOGY 74 (2000) (Exhibit US-107).

²⁴⁸ Jones Statement (Exhibit US-106), para. 4(a).

²⁴⁹ Saito Statement (Exhibit US-92), paras. 3-4, 6; Jones Statement (Exhibit US-106), paras. 3-4.

²⁵⁰ Saito Statement (Exhibit US-92), para. 3, 6. The consequences of an LPAI detection for Indian poultry owners likely compound India's inability to identify the disease by deterring reporting in the unlikely event that a farmer does have reason to suspect that a flock is infected with LPAI. Under India's AI Action Plan, the government would stamp out the farmer's flocks—and those of the farmer's neighbors in the "infected zone." *See* India's AI Action Plan (2012) (Exhibit US-90), p.15. While the government would pay compensation for birds that are destroyed (*see* India's AI Action Plan (2012) (Exhibit US-90), pp.21-22), the farmers would be out of business for a significant period of time while disinfection occurs. *See* India's AI Action Plan (2012) (Exhibit US-90), p.19. So too would local vendors of birds and poultry products. *See* India's AI Action Plan (2012) (Exhibit US-90), p.15. This could provide a strong incentive to ignore any unusual illness that a farmer suspects. Only large-scale mortality, like that caused by HPAI, would be likely to raise a level of concern sufficient to prompt reporting.

²⁴⁴ India's AI Action Plan (2006) (Exhibit US-89), p. 4.

²⁴⁵ India's AI Action Plan (2012) (Exhibit US-90), p.3.

²⁴⁶ India's AI Action Plan (2006) (Exhibit US-89), p.3.

necessary to establish, maintain, and re-establish the NAI or HPNAI-free status of a country, zone, or compartment. Article 10.4.29(1) explains that "[s]urveillance should be composed of random and targeted approaches using molecular, virological, serological and clinical methods." "Random surveillance is conducted using serological tests described in the Terrestrial Manual."²⁵¹ When conducting targeted surveillance, "[v]irological and serological methods should be used concurrently to define the NAI status of high risk populations."²⁵² "Virological surveillance," in particular, "using tests described in the Terrestrial Manual should be conducted: a. to monitor at risk populations; ... [and] d. to test 'normal' daily mortality[.]"²⁵³ The OIE Code also explains that "[t]he results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, zone, or compartment. It is therefore essential that the survey be thoroughly documented."²⁵⁴ The Code is also clear that, regaining NAI or HPNAI-free status following an NAI detection or HPNAI outbreak "require[s] surveillance incorporating virus detection and antibody tests described in the Terrestrial Manual."²⁵⁵

175. What this means in practice is that while India relies on the detection of LPAI to ban the sale of products, India in fact applies LPAI-based bans only to imported products. Indeed, India has failed to put in place measures that would effectively detect LPAI, and so India is not taking steps necessary to restrict domestic products on account of LPAI. India's imposition of a ban on specified imports following LPAI detections in the exporting country therefore constitutes arbitrary or unjustifiable discrimination in breach of the first sentence of Article 2.3.

176. We note further that India seeks to protect against risks posed by AI, but the risks presented by foreign and domestic products in relation to LPAI are the same. There is no justification for imposing different measures on products presenting the same risk. Ironically, the countries that face import prohibitions under India's measures because they have reported LPAI are likely to have better conditions than India with respect to LPNAI risk: while India is almost certain to have regular LPNAI cases that go undetected, the countries facing product restrictions are those that have the capacity to detect LPNAI and that therefore are able to take steps to contain the LPNAI.

3. Disguised Restriction on International Trade

- ²⁵³ OIE Code, Art. 10.4.29(3) (Exhibit US-1).
- ²⁵⁴ OIE Code, Art. 10.4.29(4) (Exhibit US-1).

²⁵⁵ OIE Code, Art. 10.4.31 (Exhibit US-1). The relevant tests are described in Chapter 2.3.4 of the Terrestrial Manual, which has been submitted as U.S. Exhibit US-112.

²⁵¹ OIE Code, Art. 10.4.29(1) (Exhibit US-1).

²⁵² OIE Code, Art. 10.4.29(1) (Exhibit US-1).

In this dispute, a variety of facts, taken together, indicate that India's measures amount to a disguised restriction on international trade. Most significantly, India's application of drastically more stringent measures to foreign products than to domestic products demonstrate that, under the guise of SPS measures, India has drawn an arbitrary and unjustifiable distinction between products that present the same risk. Additional relevant facts include: India's shifting position on whether its measures are justified by OIE guidelines or a risk assessment; and India's failure, in the end, to offer either a risk assessment or scientific evidence that would justify LPAI-based import bans or India's application of AI measures to entire countries, without any possibility for recognition of zones, regions or compartments with distinct AI status. The manner in which India conducted its aborted attempt to construct a risk assessment further demonstrates that India's measure is a trade restriction, not an attempt to prevent the spread of avian influenza. In response to numerous inquiries in the SPS Committee about the justification for its AI measures, in October 2010 India provided to the United States, and offered to circulate to SPS Committee delegates, a document entitled "India's Risk Assessment on Avian Influenza for imposing ban on import of poultry and poultry products from Avian Influenza positive countries."²⁵⁶ At the time, India asserted that this was a risk assessment justifying its measures,²⁵⁷ although India later clarified to the SPS Committee that this was not in fact a finalized risk assessment.²⁵⁸

177. A review of this document conducted by a Member of the OIE Terrestrial Animal Health Standards Commission, Dr. Stuart MacDiarmid, at the request of the Director General of the OIE, concluded that:

Several passages in *India's risk assessment* are taken word for word, with no acknowledgement of source, from an import risk analysis conducted in New Zealand in 1999 (MAF Regulatory Authority 1999). Interestingly, while *India's risk assessment* has concluded that chicken meat imports from 'avian influenza positive countries' should be banned, the New Zealand import risk analysis from which the text was reproduced reached different conclusions and concluded that, subject to the application of appropriate sanitary measures, chicken meat could be imported safely from countries considered infected with highly pathogenic avian influenza (underline added).²⁵⁹

India thus took analysis from New Zealand's risk assessment for chicken meat finding no basis for an import ban even after outbreaks of HPAI, eliminated that conclusion, and for a time held

²⁵⁶ G/SPS/R/61 (Exhibit US-83), para. 27.

²⁵⁷ G/SPS/R/61 (Exhibit US-83), para. 27.

²⁵⁸ G/SPS/R/61 (Exhibit US-83), para. 68.

²⁵⁹ Critical Review of India's Risk Assessment (Exhibit US-108). A copy of the avian-influenzarelated portion of New Zealand's 1999 import risk analysis for chicken meat and chicken meat products is attached as Exhibit US-109.

its document forward as a justification for measures imposing not just a regionalized ban, but a nationwide ban on imports from countries reporting outbreaks of *either* HPAI or LPNAI. In *Australia – Salmon*, the panel found that changes in a risk assessment's conclusion between the preliminary and final draft pointed to the possibility that the final measure was a disguised restriction on trade.²⁶⁰ Here, India's failure to adhere to the conclusions of the assessment from which it copied analysis demonstrates that its measure is a disguised restriction on trade.

178. As a disguised restriction on trade, India's application of its import ban on a countrybasis is contrary to the second sentence of Article 2.3.

H. In the Alternative, India Could be Viewed as Having Breached Its Obligations Under Article 5.5 of the SPS Agreement with a Resulting Consequential Breach of Article 2.3

179. The United States believes that India's application of discriminatory treatment to imported products through its measures results in a breach of Article 2.3 of the SPS Agreement. As discussed above, moreover, in the absence of a statement from India of its level of protection, that level of protection should be inferred from the measures that India applies to domestically produced products.

180. However, to the extent that transmission of avian influenza through domesticallyproduced products and through foreign products are viewed as distinct situations, then India has breached Article 5.5 of the SPS Agreement by applying drastically different levels of protection to these situations without justification. This breach of Article 5.5 in turn would result in a consequential breach of Article 2.3.

181. Article 5.5 provides in relevant part that:

With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

182. India's avian influenza measures with respect to imported products are far more restrictive than those applied with respect to domestic products, the level of protection that would be inferred from the measures applied to imported products would far exceed that which would be inferred from India's measures for domestic products. The maintenance of different levels of protection based on whether products presenting the same risks are imported or

Australia – Salmon (Panel), para. 2.28, 2.30, 8.154. The Appellate Body upheld the panel's consideration of this switch in position. Australia – Salmon (AB), paras 170-173.
domestic would be unjustifiable. In the circumstances at issue here, moreover, where in the absence of a valid risk assessment or scientific evidence, India applies country-based, LPAI-based bans on imports but no similar bans on the circulation of domestic products even following HPAI outbreaks, the measures at issue should be considered to amount to a disguised restriction on trade.

183. Thus, if India's treatment of foreign and domestic products with respect to regionalization and with respect to prohibition on account of LPNAI detection were viewed as different situations for purposes of Article 5.5, then India's measures would be contrary to that Article. Moreover, the Appellate Body has held that "a finding of violation of Article 5.5 will necessarily imply a violation of Article 2.3, first sentence, or Article 2.3, second sentence."²⁶¹ Accordingly, that breach of Article 5.5 would result in a consequential breach of Article 2.3.

I. India Has Acted Inconsistently With Its Obligations Under Article 7 and Annex B of the SPS Agreement By Failing to Notify Properly Its AI Restrictions

184. The SPS Agreement contains notification and publication-related requirements with respect to SPS measures. India has not complied with these requirements. India's failure to abide by these obligations has made it more difficult for WTO Members to understand and assess India's measures.

185. Article 7 of the SPS Agreement provides that "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B." Paragraph 5 of Annex B applies where:

(a) a relevant international standard does not exist or the content of the proposed measure is not substantially the same as the content of an international standard, guideline or recommendation, and

(b) if the regulation 262 may have a significant effect on trade of other Members.

Here, the two conditions are met. As explained above, India's measures do not correspond to the OIE guidelines. Moreover, by imposing a ban that precludes members from shipping covered products to India, the measures clearly have a significant impact on international trade.

186. Under paragraph 5 of Annex B, a Member must:

²⁶¹ Australia – Salmon (AB), para. 252.

²⁶² For purposes of Annex B, "regulations" refers to "[s]anitary and psytosanitary measures, such as laws, decrees or ordinances which are applicable generally." *See* SPS Agreement, Annex B, para. 1, fn.5.

notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account.²⁶³

The requirement that notifications occur "when amendments can still be introduced," the reference to provision of information about the "proposed regulation," and use of the future tense in requiring notification of the products "*to be* covered" (emphasis added), makes clear that the notification must occur before the measure takes effect.

187. So too does the chapeau to paragraph 5, which makes clear that the requirements of paragraph 5 apply to proposed measures: "Whenever ... the content of *a proposed* sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall...." (emphasis added). Paragraph 6 makes it clear that Members must follow paragraph 5 except where there are "urgent problems."

188. To provide context and background, the United States notes that India has habitually notified avian influenza measures after they have gone into effect and without an indication of their objective or rationale. In some instances, India appears to have failed entirely to notify the measures:

- India issued S.O. 102(E), its first S.O. imposing for six months an LPAI-based import ban on February 2, 2007.²⁶⁴ It did not notify S.O. 102(E), however, until February 15, 2007.²⁶⁵ India's notification to the WTO of S.O. 102(E) was styled as an addendum to notification of a prior measure, S.O. 1256(E) that imposed HPAI-based import restrictions. However, India provided no indication of the objective and rationale of S.O. 102(E)'s LPAI-based import restrictions.
- India appears to have extended the prohibitions in S.O. 102(E), as subsequently amended, ²⁶⁷ for a period of six months by means of S.O. 1311(E), dated august 1,

- ²⁶⁵ G/SPS/N/IND/46/Add.1.
- ²⁶⁶ *Id.*

²⁶⁷ India appears to have made two amendments to S.O. 102(E): S.O. 367(E) and a second amendment expanding the scope of covered pig products from "pig meat products" to all "pig products (including pig bristles)" (*see* G/SPS/N/IND/46/Add.3).

²⁶³ SPS Agreement, Annex B, para. 5(b).

²⁶⁴ S.O. 102(E) (Exhibit US-73).

2007.²⁶⁸ India did not notify an extension to the WTO until August 27, 2007.²⁶⁹ Styled as a further addendum to the prior WTO notification of S.O. 1256(E), India's notification to the WTO of S.O. 102(E) provided no indication of the objective and rationale of India's measures.²⁷⁰

- On January 31, 2008, India issued S.O. 228(E),²⁷¹ which imposed for six months an LPAI-based import ban on a variety of listed products. India did not notify S.O. 228(E) to the WTO until February 12, 2008.²⁷² Styled as a further addendum to the prior WTO notification of S.O. 1256(E), India's notification to the WTO of S.O. 228(E) provided no indication of the objective and rationale of India's measures.²⁷³
- On July 30, 2008, India issued S.O. 1892(E),²⁷⁴ which imposed for six months an LPAI-based import ban on a variety of listed products. India did not notify S.O. 1892(E) to the WTO until August 11, 2008.²⁷⁵ Styled as a further addendum to the prior WTO notification of S.O. 1256(E), India's notification to the WTO of S.O. 1892(E) provided no indication of the objective and rationale of India's measures.²⁷⁶
- On February 9, 2009, India issued S.O. 419(E),²⁷⁷ which imposed for six months an LPAI-based import ban on a variety of listed products. India did not notify S.O. 419(E) to the WTO until March 27, 2009.²⁷⁸ Styled as a further addendum to the prior WTO notification of S.O. 1256(E), India's notification to the WTO of

- ²⁷⁰ *Id*.
- ²⁷¹ S.O. 228(E) (Exhibit US-74).
- ²⁷² G/SPS/N/IND/46/Add.5.
- ²⁷³ *Id.*
- ²⁷⁴ S.O. 1892(e) (Exhibit US-75).
- ²⁷⁵ G/SPS/N/IND/46/Add.6.
- ²⁷⁶ *Id*.
- ²⁷⁷ S.O. 419(E) (Exhibit US-76).
- ²⁷⁸ G/SPS/N/IND/46/Add.7.

²⁶⁸ S.O. 1859(E) (Exhibit US-113); G/SPS/N/IND/46/Add.4.

²⁶⁹ G/SPS/N/IND/46/Add.4.

S.O. 419(E) provided no indication of the objective and rationale of India's measures.²⁷⁹ Further, India's notification to the WTO of S.O. 419(E) cast S.O. 419(E) as a six-month extension, with amendments, of the ban initially notified on February 19, 2007, even though India's last six-month extension had technically expired over a week before India issued S.O. 419(E).

- On August 28, 2009, India issued S.O. 2208(E),²⁸⁰ which imposed for six months an LPAI-based import ban on a variety of listed products. India does not appear to have ever notified S.O. 2208(E) to the WTO. India issued S.O. 2208(E) several weeks after the end of the six month period during which S.O. 419(E) applied.
- On March 18, 2010, India issued S.O. 616(E),²⁸¹ which imposed for six months an LPAI-based import ban on a variety of listed products. India does not appear to have ever notified S.O. 616(E) to the WTO. India issued S.O. 616(E) several weeks after the end of the six month period during which S.O.2208(E) applied.
- On December 10, 2010, India issued S.O. 2976(E),²⁸² which imposed for six months an LPAI-based import ban on a variety of listed products. India does not appear to have ever notified S.O. 2976(E) to the WTO.
- On July 19, 2011, India issued S.O. 1663(E),²⁸³ which imposed an LPAI-based import ban of indefinite duration on a variety of listed products. India did not notify S.O. 1663 (E) to the WTO until October 11, 2011.²⁸⁴ India issued S.O. 1663 (E) over a month after the end of the six month period during which S.O. 2976(E) applied.

By failing to notify properly, before they go into effect, measures changing the scope of and extending the term of its avian influenza restrictions, and by failing to include in its notices information on the objective and rationale of the measures, India has again-and-again acted inconsistently with Article 7 and Annex B, paragraph 5(b) of the SPS Agreement.

- ²⁸⁰ S.O. 2208(E) (Exhibit U.S.77).
- ²⁸¹ S.O. 616(E) (Exhibit US-78).
- ²⁸² S.O. 2976(E) (Exhibit US-79).
- ²⁸³ S.O. 1663(E) (Exhibit US-80).
- ²⁸⁴ G/SPS/N/IND/73.

²⁷⁹ *Id*.

189. India's failure to publish its measures properly, if at all, has resulted in additional breaches of Article 7 and Annex B. First, paragraph 5(a) of Annex B requires Members issuing a covered measure to "publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation." The fact that this requirement aims to make Members aware of a "*proposal to introduce* a regulation" (emphasis added) makes clear that it requires publication *before* the measure is to take effect. The Indian measures listed above, however, all took effect *on* the date of publication.

190. India has also breached paragraph 5(d) of Annex B, a provision closely related to paragraph 5(a). Paragraph 5(d) requires Members issuing a covered measure to "allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account." The early-stage publication requirement in paragraph 5(a) serves to enable Members to offer the comments envisioned in paragraph 5(d).²⁸⁵ At no point when issuing the Notifications discussed above did India allow reasonable time for comments because India did not publish a notice of any proposed regulation for any of these measures.

191. India has also breached Annex B, paragraph 2. This paragraph provides, *inter alia* that "[e]xcept in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force." As discussed, India has never provided for any interval of time between publication of the Notifications at issue here and their entry into force.

192. By maintaining its LPAI-based import ban, India has on numerous occasions breached Article 7 and Annex B, paragraphs 2, 5(a), 5(b), and 5(d) for an additional reason. Prior to issuance, S.O. 1663(E), the Notification currently in force, whenever India published or issued a Notification imposing or extending its LPAI-based ban, it stated that the Notification would remain in force for a period of six months. As this chronology noted above demonstrates, however, the Notifications were not always renewed within six months of when India issued its previous Notification. India's ban on imports from LPAI-positive countries nonetheless continued unabated even when six months passed and no additional Notification was issued. During the gap periods, India maintained the ban on imports from LPAI-positive countries without any published measure providing for that ban. The measure was, during these gap periods, an unpublished SPS measure.

193. By maintaining an unpublished LPAI-based import ban India breached the publication provisions of Annex B: paragraph 2 and paragraph 5(a). India did not allow "a reasonable interval between the publication [of its extension of the import ban] and its entry into force," as required by paragraph 2, because during these gap periods, India entirely failed to publish the fact that the ban would be continuing. Paragraph 2 of Annex B explains that advance publication aims to provide producers with a chance to adjust their production to the coming regulatory

²⁸⁵ *EC* – *Biotech*, para. 7.47.

environment. Similarly, paragraph 5(a) requires Members to "publish a notice [of a proposed regulation] at an early stage" so as to enable Members "to become acquainted with the proposal." India did not publish notice at an early stage or even after these unwritten extensions took effect, thereby preventing producers from taking the extension of the measures into account when making production decisions, and the United States from becoming acquainted with the fact that the measures would not expire as previously stated.

194. India's extension of its LPAI-based import ban without any published regulation breached paragraph 5(d) of Annex B as well, as India failed to "allow reasonable time for other Members to make comments in writing." Finally, India breached the notification requirement in Article 7 and paragraph 5(b) of Annex B by failing to provide an "early stage" notification that the ban on imports from countries notifying LPAI would be extended beyond the previouslyscheduled expiration. Indeed, due to India's failure to publish or notify the fact that the import ban was continuing, during the gap periods other Members and producers in those Members had no reason at all to think that India maintained measures restricting imports on account of LPAI.

195. India is not exempt from any of the requirements of Annex B, paragraph 5, because, as discussed above, no urgent problem of health protection has arisen or threatened to arise for India in relation to avian influenza. India, moreover, has not complied with the requirements of paragraph 6(a) of Annex B, as required to bypass the requirements of paragraph 5 in the event of urgent actual or threatened health problems. Paragraph 6(a) provides that when, on account of urgent actual or threatened health problems, a Member omits steps otherwise required under paragraph 5, the Member must "immediately notif[y] other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s)." As discussed above, however, India frequently provided either no notification to the WTO or delayed notification of its Notifications—including S.O. 1663(E), which India did not notify to the WTO for almost three months after it was issued.

196. In sum, India has repeatedly breached the obligations on Article 7 and Annex B with respect to its measures prohibiting the importation of products on account of avian influenza. India remains in breach of these obligations today, as S.O. 1663(E), through which India currently maintains those restrictions, was not notified to the WTO or published in advance of its entry into force, thereby precluding WTO Members such as the United States from commenting in writing on this measure.

J. India Has Breached Article XI of the GATT 1994

197. Article XI:1 of the GATT 1994 states, in pertinent part, "[n]o prohibitions or restrictions other than duties, taxes or other charges . . . shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party." India's measures are clearly import prohibitions and they are not justified under the SPS Agreement. Accordingly, India's measures breach Article XI of the GATT 1994.

IX. INDIA'S PRELIMINARY RULING REQUEST IS WITHOUT MERIT

198. India makes a number of allegations concerning the identification of the measures at issue and the legal basis of the complaint in the U.S. panel request. However, even a quick review of the U.S. panel request makes clear that these allegations are not valid. India's allegations overlook the actual content of the U.S. panel request, which not only satisfies, but goes beyond, the minimum required to establish that the claims and measures addressed in this submission are within the Panel's terms of reference, and to notify clearly both India and other Members that these would constitute the matter at issue in the dispute.

199. The U.S. panel request clearly explains that this dispute challenges Indian measures restricting the importation of agricultural products from countries reporting Highly Pathogenic Avian Influenza and Low Pathogenic Avian Influenza. The panel request lists the products currently covered by these measures. It also explains not only the articles of the SPS Agreement and the GATT 1994 that India's measures breach, but also how the measures breach specific disciplines in those articles. And with respect to some disciplines, the panel request goes further, providing illustrative examples of how the United States would argue that India is in breach.

200. Accordingly, the text of the panel request is sufficient to present clearly both the measures and claims at issue in this dispute. Yet while the panel request must on its own offer a sufficient statement of both, the Panel may consider certain attendant circumstances.²⁸⁶

201. The attendant circumstances of this panel request include India's failure to respond to the request submitted to it by the United States pursuant to Article 5.8 of the SPS Agreement. That request sought additional information on some of the subjects that India now suggests the panel request should have discussed in extraordinary detail. While the panel request fully satisfies Article 6.2 of the DSU standing on its own, it is also relevant to consider whether India should profit from its own non-compliance with the transparency obligation contained in Article 5.8 of the SPS Agreement.

A. The Panel Request Clearly and Sufficiently Identifies the Measures at Issue

1. The Panel Request Clearly Identifies S.O. 1663(E) As a Measure At Issue

202. Contrary to India's assertion in the PRR, the panel request makes clear that India's import restrictions due to avian influenza maintained through S.O. 1663(E) is the measure at issue in this dispute. The request states that "India maintains its avian influenza measures

²⁸⁶ United States – Carbon Steel (AB), para. 127. Demonstrating the relationship between the panel request and the First Written Submission, the Appellate Body in United States – Corrosion-Resistant Carbon Steel went on to explain that the First Written Submission supported the complaining Member's assertion that it had raised an as such challenge to U.S. laws and regulations governing sunset reviews. *Id.*, para.132.

through the following legal instruments ... orders issued by India's Department of Animal Husbandry, Dairying, and Fisheries ("DAHD") pursuant to the Livestock Act, most recently S.O. 1663(E)[.]" Consequently, the panel request identifies S.O. 1663(E) as a measure at issue. India's arguments essentially all consist of a request for a preview of the U.S. arguments as to <u>how</u> S.O. 1663(E) is WTO inconsistent. India cannot argue that S.O. 1663(E) was not identified in the panel request.

203. After identifying S.O. 1663(E), the panel request then makes the factual statement that "S.O. 1663(E) imposes import restrictions on the following products: ..." On its face, this factual listing does not modify the measure identified -- S.O. 1663(E).

204. The PRR displays no uncertainty about the fact that the United States has challenged S.O. 1663(E)'s prohibition on the import into India from countries reporting any form of NAI of the products listed in paragraph (1)(ii) of S.O. 1663(E).²⁸⁷²⁸⁸ The PRR suggests that India is uncertain only whether a) S.O. 1663(E)'s complete ban on the import of wild birds into India, and b) conformity assessment requirements for the import of processed poultry meat from countries reporting NAI form a part of the dispute.

205. Because the U.S. panel request identified the import restrictions imposed through S.O. 1663(E), India's ban on the importation of wild birds, and its requirement of a "conformity assessment" for the importation of processed poultry meat, imposed through that instrument fall within the Panel's terms of reference. Indeed, the panel request specifically notes that "wild birds" are a product subjected to import restrictions pursuant to S.O. 1663(E). Likewise, the panel request notes that S.O. 1663(E) "imposes import restrictions" on "meat products from Avian species."

2. The Panel Request Properly Uses the Terms "Related Measures" and "Implementing Measures" to Explain the Scope of the Dispute

206. India's suggestion that there is something ambiguous about the terms "related measures" and "implementing measures" lacks merit. The U.S. panel request clearly identified the measures at issue both in narrative form and by citation to particular legal instruments. As the panel request states: "India's avian influenza measures prohibit the importation of various agricultural products into India from those countries reporting Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian

²⁸⁷ India, PRR, paras 25-27.

²⁸⁸ The PRR states that S.O. 1663(E) is a "notification" and not an "order." PRR, para 37. As explained above the United States referred to this document as an order because, based on conversations by the United States with Indian officials, the United States understood "S.O" to stand for "special order." In any event, it is perfectly clear from India's Preliminary Ruling Request that India understands precisely what the United States was referring to when it referred to S.O. 1663(E) or to "orders" generically. *See, e.g.*, para. 38.

Influenza)." Accordingly, any reference to measures "related" to, or "implementing" one of the cited legal instruments is to be understood in the context of this overall identification of the measures at issue.

207. For example, S.O. 1663(E) imposes a variety of import restrictions ostensibly on account of avian influenza. India may be using orders, "notifications," procedures, guidelines, or other instruments to give effect to the import prohibitions laid out in S.O. 1663(E). For instance, India requires that shipments of certain imported poultry and poultry products be accompanied by a veterinary certificate attesting that the country of origin is free of notifiable avian influenza. As the narrative identification of the measures at issue makes clear, the measures at issue include S.O. 1663(E) and measures related to or implementing S.O. 1663(E) that prohibit the importation of various agricultural products into India from those countries reporting Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza), not just the "notification" S.O. 1663(E) itself. Accordingly, other Indian documents or instruments that relate to or implement some or all aspects of these prohibitions or restrictions likewise fall within the Panel's terms of reference.

208. Further, to the extent that there is any ambiguity about whether other Indian laws, regulations, orders, "notifications," guidelines, or other instruments implement or are related to the prohibitions or restrictions spelled out in S.O. 1663(E), that ambiguity stems from India's own failure to provide the response called for under Article 5.8 of the SPS Agreement. Well over a year ago, and before seeking consultations in this dispute, the United States requested India pursuant to Article 5.8, among other things "[t]o the extent India maintains import restrictions on account of AI that are not reflected in S.O. 1663(E), please identify and provide copies of those measures."²⁸⁹ India has never responded to the United States' Article 5.8 request.

209. In any event, the Appellate Body has already confirmed the appropriateness and sufficiency of the approach used in the U.S. panel request to capture other instruments that implement, repeat, or elaborate on the restrictions spelled out in S.O. 1663(E). In *EC* – *Bananas III*, the panel found that the inclusion of the following language – "subsequent EC legislation, regulations, and administrative measures . . . which implement, supplement and amend [the bananas] regime" – satisfied the specificity requirement of Article 6.2 of the DSU as it "adequately identified" the measures at issue, although those measures were not explicitly listed in the panel request.²⁹⁰ The Appellate Body:

agree[d] with the Panel that the request in this case, WT/DS27/6, dated 12 April 1996, which refers to "a regime for the importation, sale and distribution of bananas established by Regulation 404/93 (O.J. L 47 of 25 February 1993, p. 1),

Exhibit US-4.

²⁹⁰ EC – Bananas III (Panel), para.7.27.

and <u>subsequent EC legislation</u>, regulations and administrative measures, including those reflecting the provisions of the Framework Agreement on bananas, <u>which</u> <u>implement</u>, <u>supplement and amend that regime</u>", contains sufficient identification of the specific measures at issue to fulfil [sic.] the requirements of Article 6.2 of the DSU.²⁹¹ (emphasis added)

Similarly, the Appellate Body has cited with approval a panel's examination of "related measures" where that term was used in the panel request.²⁹²

By contrast, EC - Customs Matters, which India cites in its PRR,²⁹³ involved factual 210. questions and a panel request that starkly distinguish that dispute from this one. In that dispute, the United States challenged the lack of uniformity in the administration of the EC's customs classification and valuation system. The Appellate Body reversed the panel's finding that the U.S. panel request only stated a challenge to the administration of each listed Council or Commission Regulation individually, concluding instead that the United States had adequately specified a challenge to the administration of the listed regulations collectively.²⁹⁴ The Appellate Body indicated in a footnote that in that dispute, the terms "implementing measures" and "related measures" could not be used to expand the scope of measures whose administration was at issue in that dispute.²⁹⁵ But given the nature of listed regulations—the EC's entire Customs Code, implementing regulations, and statistical nomenclature²⁹⁶—the terms "implementing measures" and "related measures" could have covered the administration of any aspect of the ECs customs procedures. These terms terms clearly do not create the same uncertainty or ambiguity here, where they merely capture instruments that implement or relate to the specific AI-related import restrictions or prohibitions set out in a one-page instrument: S.O. 1663(E).

211. In *China – Raw Materials*, the panel found that in accordance with the terminology of the panel request, it could consider "implementing measures" to those specifically listed.²⁹⁷ While the panel found that it could not consider "related measures" to those specifically listed, that

²⁹⁵ *EC-Selected Customs Matters (AB)*, para. 152, fn. 369.

²⁹⁶ Request for Establishment of a Panel by the United States, *EC-Selected Customs Matters*, WT/DS315/8.

²⁹⁷ Communication from the Panel, *China – Raw Materials*, WT/DS/394/9WT/DS395/9, WT/DS/398/8, para. 20.

²⁹¹ *EC* – *Bananas III (AB)*, para. 140.

²⁹² *Brazil – Tyres (AB)*, para. 128.

²⁹³ India, PRR, paras 32-33.

²⁹⁴ *EC-Selected Customs Matters (AB)*, para. 154.

dispute, like EC - Customs Matters, involved numerous broad laws, regulations, rules, and measures touching on the export of the products that China was subjecting to restraint.²⁹⁸ In any event, here, all instruments addressed in this submission that are used by India to restrict the importation of agricultural products ostensibly on account of avian influenza, and that are not specifically mentioned in the panel request—including requirements for the inclusion of particular attestations on veterinary certificates required for the importation of agricultural products—constitute measures that implement the prohibitions laid out in S.O. 1663(E).

212. The U.S. panel request thus clearly identifies the measures at issue, and put both India and other Members on notice that the dispute would encompass all measures that have been discussed in this First Written Submission.²⁹⁹

B. The United States' Panel Request Clearly and Sufficiently Presents the Legal Basis of the Complaint

213. India's preliminary ruling request asserts that the U.S. panel request failed to present the legal basis for certain claims. India, however, confuses the concept of "the legal basis of the complaint"—that is, the 'claims' being asserted,"³⁰⁰ with "the arguments put forth by [a] party in support of its claims."³⁰¹ The United States clearly set forth the claims that it is raising, and had no obligation to set forth in its panel request the arguments in support of those claims.

214. As the Appellate Body explained in *Korea Dairy*, "a claim of violation must ... be distinguished from the arguments adduced by a complaining party to demonstrate that the responding party's measure does indeed infringe upon the identified treaty provision."³⁰² "Article 6.2 demands only a summary – and it may be a brief one – of the legal basis of the complaint."³⁰³ It imposes no obligation to set out "detailed arguments as to which specific

²⁹⁹ India's PRR also expresses confusion as to whether the United States aims to challenge expired special orders. As the panel request explains, the United States challenges only measures in force as of the date of the panel request. The U.S. panel request refers to "orders" (plural) to ensure that it captured new, replacement, or additional orders or notifications in force as of that time of which the United States was not aware. This inclusive phrasing was particularly necessary in the present case given India's failure to respond to the United States' request pursuant to Article 5.8 of the SPS Agreement for a statement of the measures through which India maintains import restrictions based ostensibly on avian influenza and India's practice of not notifying measures and not publishing measures.

³⁰⁰ *US – OCTG (AB)*, para. 162 (citing *Korea – Dairy (AB)*, para. 139).

²⁹⁸ China – Raw Materials (AB), annexes I-III, paras. 147-176.

³⁰¹ US - OCTG (AB), para. 162.

³⁰² *Korea – Dairy (AB)*, para. 139.

³⁰³ *Korea – Dairy (AB)*, para. 120.

aspects of the measures at issue relate to which specific provisions of those agreements."³⁰⁴ Moreover, the Appellate Body has elaborated, in the context of an SPS dispute, that "Article 6.2 of the DSU does not impose any additional requirement ... that a complainant must, in its request for establishment of a panel, demonstrate that the identified measure at issue causes the violation of, or can violate, the relevant obligation."³⁰⁵

215. In *Australia – Apples*, the panel applied these principles in the context of an SPS dispute. In its panel request, the complaining Member, New Zealand, after listing seventeen specific measures at issue, simply listed in a single sentence the Articles of the SPS Agreement under which it was raising claims in the dispute. The panel found that in light of "the language used in the panel request *and the specific content of the provisions of the SPS Agreement cited*, the … panel request contains enough information to adequately inform the responding party and other WTO Members on the nature of the complaint and to allow the responding party to begin preparing its defence" (emphasis added). 306 Among the provisions cited in that panel request were Articles 2.3, 5.5, and 5.6 of the SPS Agreement.³⁰⁷ The claims under these Articles in the present dispute are precisely the ones that India contends the panel request was required to elaborate on even more than it did.

216. The U.S. panel request in the present dispute not only satisfies Article 6.2, it provides more detail than New Zealand did in *Australia – Apples*. For each cited paragraph of the SPS Agreement and its Annex B, as well as for Article XI of the GATT 1994, the panel request here describes how India's avian influenza measures breach the cited provision. Where India's AI-related import prohibitions or restrictions breach more than one obligation in one of the cited paragraphs, the panel request explains the specific obligations that these measures breach. While not required in a panel request, with respect to some obligations, the United States even previewed key arguments that it would make in support of its claims that India's measures breach the obligation. Ironically, two of the claims for which the United States provided this extra information are ones for which India claims the panel request failed to provide sufficient explanation.

2. Articles 2.3 and 5.5

217. India's "[u]ncertainty as to whether the United States intends to raise claims on only one distinct obligation or multiple distinct obligations contained in Article 2.3^{308} is baffling. As

³⁰⁴ *EC* – *Bananas III (AB)*, para. 141.

³⁰⁵ Australia – Apples (AB), para. 423.

³⁰⁶ Preliminary Ruling by the Panel, *Australia – Apples*, para. 11 (footnote omitted).

³⁰⁷ Request for the Establishment of a Panel by New Zealand, *Australia – Apples*.

³⁰⁸ India, PRR, para. 48.

discussed above, a measure can breach Article 2.3 either because it arbitrarily or unjustifiably discriminates between Members where similar conditions prevail, including between its own territory and that of other Members (Article 2.3, first sentence), or because the measure constitutes a disguised restriction on international trade (Article 2.3, second sentence).³⁰⁹ The United States has argued in this submission that India's measures breach both of these obligations. The panel request made clear that the United States considered the measures breached both obligations. The request states that India's measures breach:

Article 2.3, because India's avian influenza measures arbitrarily or unjustifiably discriminate between Members where similar conditions prevail, including between India's own territory and that of other Members. For example, while India applies the avian influenza measures at issue here to imported products, India does not apply similar avian influenza related controls with respect to like domestic products and their internal movement within India. Further, India has applied its measures in a manner that constitutes a disguised restriction on international trade.

India and other Members were thus on notice that both Article 2.3's non-discrimination discipline and the discipline against imposition of disguised restrictions on trade were at issue, and both claims are within the Panel's terms of reference.

218. The fact that the United States provided an illustrative example of why it considered India's measures to breach the first sentence of Article 2.3 cannot, contrary to what India suggests,³¹⁰ plausibly be read to suggest that the second sentence was not at issue. Not only did the United States preface the example with the words "for example," clearly indicating that this was just one way in which India's measures breach Article 2.3, but after providing the example, the United States expressly stated that India had breached the Article's second sentence.

219. The Appellate Body confronted a similar argument in EC – Selected Customs Matters, which addressed non-uniform customs administration among different member States of the European Union. The U.S. panel request in that dispute provided a brief, six bullet list of ways in which the EC's Customs administration was not uniform.³¹¹ With respect to this list, the Appellate Body explained that:

Article 6.2 of the DSU requires that the *claims*—not the *arguments*—be set out in a panel request in a way that is sufficient to present the problem clearly. Nothing in Article 6.2 prevents a complainant from making statements in the panel request that foreshadow its arguments in substantiating the claim. If the complainant

³⁰⁹ See Australia – Salmon (AB), para. 252.

³¹⁰ India, PRR, paras. 51-52.

³¹¹ Request for Establishment of a Panel by the United States, *EC-Selected Customs Matters*.

chooses to do so, these arguments should not be interpreted to narrow the scope of the measures or the claims. Accordingly, we are of the opinion that the Panel erred when it found that the list of areas of customs administration in the third paragraph of the panel request limits the scope of the "specific measures at issue."³¹² (footnote omitted)

Like its assertion that the panel request contains ambiguity with respect to which Article 2.3 obligations are at issue, there is no merit in India's assertion³¹³ that use of the words "for example" in the explanation of the Article 2.3 and Article 5.5 claims generates improper ambiguity in the panel request's statement of these claims. Even without the examples provided when stating the claims under these articles, the United States satisfies its duty to state clearly which claims it considered to be at issue.³¹⁴ The U.S. decision to preview arguments under these articles merely provided India with additional information about the U.S. view of the dispute. As the Appellate Body explained in *EC* – *Selected Customs Matters* with respect to the panel request's brief, six bullet list of ways in which the EC's Customs administration was not uniform:

We read the third paragraph of the panel request as an illustrative list of areas where the United States considers European Communities customs law is not administered in a uniform way. Thus, the substance of the third paragraph of the panel request should be viewed as an anticipation of the United States' arguments. In this paragraph, the United States explains—briefly and in general terms—why it considers that the legal instruments listed in the first paragraph of the panel request are administered in a manner that is inconsistent with the uniformity requirement in Article X:3(a).³¹⁵

In any event, the examples given in the panel request here clearly put India and other Members on notice as to the U.S. view with respect to these arguments. India's PRR displays no uncertainty on this point.³¹⁶ Indeed, the plain meaning of the phrase "for example" indicates that the following language provides only one illustration of why India's measures give rise to the claim to which the example is connected. With respect to each claim, the argument previewed in

³¹⁶ India, PRR, paras 55-62.

³¹² EC-Selected Customs Matters (AB), para. 153.

³¹³ India, PRR, paras. 55-62.

³¹⁴ Preliminary Ruling by the Panel, *Australia – Apples*, paras. 10-11; *EC – Bananas III (AB)*, para. 141.

³¹⁵ *EC-Selected Customs Matters (AB)*, para. 153.

the panel request is at the core of the argument that the United States has advanced and elaborated on in this submission.³¹⁷

220. Further, contrary to India's assertions, the wording of the examples provided in the Article 2.3 and Article 5.5 paragraphs of the panel request hardly lacks precision. The panel request's paragraph on Article 2.3 explains that India's avian influenza restrictions arbitrarily or unjustifiably discriminate between its own territory and the territories of other Members with identical conditions, because:

While India applies the avian influenza measures at issue here to imported products, India does not apply similar avian influenza related controls with respect to like domestic products and their internal movement within India.

India faults this description for not specifying "whether the United States is challenging treatment of imports vis a vis [sic.] domestic like products in a situation of high pathogenic avian influenza."³¹⁸ Article 6.2 of the DSU calls for an identification of the measures at issue, and as discussed above the panel request here does so. Article 6.2 does not call for a listing of the particular aspects of those measures that give rise to the dispute or that may be the focus of the complaining party's arguments.³¹⁹ In any event, India's measures impose import restrictions on countries reporting "Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza)"³²⁰ and the panel request makes clear that India does not apply similar controls with respect to domestic products. Thus, although the United States did not need to specify whether it would raise claims with respect to the treatment of products following detections of highly

³¹⁷ India's PRR makes repeated reference to a purported obligation to "freely" disclose "facts relating to [a complaining Member's] claims." *E.g.*, India, PRR, para. 59 (quoting *India – Patents (AB)*, paras 94). In context, the passage of the Appellate Body Report cited in the PRR is referring to the obligation of the *responding Member* to freely disclose facts during *consultations*, a disclosure which enables accurate formulation of legal claims if the dispute proceeds to the panel formation stage. *See India – Patents (AB)*, paras 93-94. The United States had no obligation to lay out the facts supporting its claims in its panel request. By contrast, India has acted inconsistently with the admonition it cites by failing to respond to the U.S. request under Article 5.8 of the SPS Agreement—a provision designed to help enable the resolution of SPS issues.

³¹⁸ India, PRR, para. 64.

³¹⁹ See EC – Bananas III (AB), para. 141 (Article 6.2 of the DSU imposes no obligation to set out "detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements.")

³²⁰ S.O. 1663(E) (Exhibit US-80). In addition, S.O. 1663(E) imposes some import restrictions on all countries "in view of Notifiable Avian Influenza (both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza)."

pathogenic avian influenza, low pathogenicity avian influenza, or both,³²¹ the plain language of the panel request did in fact put India on notice that both situations could be at issue. The arguments in this submission confirm that the panel request's reference to "avian influenza measures" and not "low pathogenicity avian influenza measures" or "high pathogenicity avian influenza measures" should be read as an indication that the Article 2.3 claims encompass both.

India also complains that this phrasing did not specify whether the U.S. discriminatory 221. treatment claim under Article 2.3 relates to some or all of the products listed in the panel request.³²² This argument, too, lacks foundation in both fact and law. As a legal matter, the United States did not need to specify in the panel request the specific products for which India's avian-influenza-related import restrictions result in discriminatory treatment—the United States needed only to specify the measure and that it breaches Article 2.3 of the SPS Agreement. Indeed, as the Appellate Body has explained, Article 6.2 of the DSU imposes no obligation to set out "detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements."³²³ As a factual matter, the panel request does make clear that the claim of discriminatory treatment refers to all products covered by the measures. The panel request notes that India's "avian influenza measures," which apply to the products listed in the panel request, impose controls not applied under domestic law "with respect to like domestic products." A plain reading of the panel request therefore shows that the claim relates to discriminatory treatment of foreign and domestic shipments of all of the listed products following detections of notifiable avian influenza, and is not limited to any subset of the products mentioned in S.O. 1663(E) or the panel request. This reading is confirmed by the U.S. argument in this submission, which relates to measures that under S.O. 1663(E) govern the importation of all of the products mentioned in the panel request.

222. India's arguments with respect to the claim under Article 5.5 of the SPS Agreement similarly confuse claims themselves, which must be stated in a panel request, and the facts and arguments supporting those claims, which a complaining Member need not present until it makes submissions to the panel.

223. As under the Article 2.3 claims, the panel request leaves no basis for doubt that all products mentioned in S.O. 1663(E) or the panel request are at issue in the Article 5.5 claim. The panel request explained that India does not impose on like domestic products the same AI-related controls that it imposes through the measures at issue, which impose import restrictions on the listed products. In this context, the panel request's explanation that India's measures treat

³²¹ See EC – Bananas III (AB), para. 141 (Article 6.2 of the DSU imposes no obligation to set out "detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements."); Preliminary Ruling by the Panel, *Australia – Apples*, paras. 10-11.

³²² India, PRR, para. 64.

³²³ *EC* – *Bananas III (AB)*, para. 141; *see also* Preliminary Ruling by the Panel, *Australia* – *Apples*, paras. 10-11.

transmission of avian influenza through domestic and imported agricultural products as different situations to which different levels of protection apply unambiguously presents a claim that is not limited to any subset of the products mentioned in S.O. 1663(E) or the panel request. Moreover, as noted above, Article 6.2 imposes no obligation to set out "detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements."³²⁴ While the Article 5.5 claim leaves no ambiguity with respect to product coverage, such clarity is unnecessary.

224. Further, contrary to India's baffling assertion, there is no ambiguity as to whether the phrase "transmission of avian influenza" refers to transmission of low pathogenic avian influenza, high pathogenic avian influenza, or both. "[T]ransmission of avian influenza" means just that—transmission of avian influenza of any form. Indeed, S.O. 1663(E), the central document laying out the import prohibitions or restrictions at issue in this dispute, itself defines the term "notifiable avian influenza" as encompassing "both Highly Pathogenic Notifiable Avian Influenza and Low Pathogenic Notifiable Avian Influenza," and the restrictions that it imposes apply equally following detections of either.

225. India additionally appears to assert³²⁵ that the panel request was required to state the level of protection that India maintains with respect to the transmission of avian influenza through foreign products and through domestic products. This assertion is particularly ironic given India's own failure to identify, in response to the U.S. request pursuant to Article 5.8 of the SPS Agreement, "the level of protection that India has determined is appropriate in regards to AI."³²⁶ In any event, the specific levels of protection maintained by a responding Member are facts that need not be set out in a panel request—indeed, levels of protection were not stated in the Article 5.5 claim found to be adequately stated in the *Australia – Apples* panel request.³²⁷ In fact, even to prove a claim under Article 5.5, a complaining Member need not identify what those levels are with precision. The complaining Member must only establish that the levels applied with respect to two situations are different. While the maintenance of different levels of protection in different situations is an element of a claim under Article 5.5, the panel request notes that such a difference exists.

226. Finally, as discussed above, there is no requirement for a panel request to explain what characteristics of a measure satisfy each element of a legal claim.³²⁸ Indeed, in *Australia* –

³²⁴ *EC* – *Bananas III (AB)*, para. 141; *see also* Preliminary Ruling by the Panel, *Australia* – *Apples*, paras. 10-11.

³²⁵ India, PRR, para. 66.

³²⁶ Article 5.8 Request (Exhibit US-4), question 6.

³²⁷ Preliminary Ruling by the Panel, *Australia – Apples*, paras. 10-11; Request for the Establishment of a Panel by New Zealand, *Australia – Apples*.

³²⁸ *EC* – *Bananas III (AB)*, para. 141.

Apples, where the panel found that New Zealand had adequately stated its claim under Article 5.5. the panel request offered no explanation of why Australia's measures constituted a disguised restriction on trade.³²⁹ In any event, the panel request here noted that India to the extent transmission of avian influenza by way of U.S. agricultural products is considered a "different situation" than the transmission of avian influenza by way of India's domestic agricultural products – India is maintains arbitrary or unjustifiable distinctions in its appropriate levels of sanitary protection in different situations. This leaves no uncertainty as to how the United States asserts that India's measure constitutes a disguised restriction on trade.

3. Article 5.6

227. India's complaints about the way the panel request lays out the Article 5.6 claim ignore the context surrounding that sentence as well as the nature of an Article 5.6 claim, and once again seek inclusion of argument in the panel request. Indeed, once the measures at issue have been described, an Article 5.6 claim needs no elaboration: the statement that less restrictive measures suffice to achieve the protection desired by the responding Member puts the responding Member on notice of what it will need to defend. Any explanation of how other measures satisfy the responding Member's ALOP would constitute argument that a complaining Member need not set out until its submissions. The panel in *Australia – Apples* confirmed that Article 6.2 of the DSU requires no elaboration in the panel request of how a responding Member's measures breach Article 5.6 of the SPS Agreement. New Zealand's panel request offered no such elaboration,³³⁰ and the panel found that the request adequately laid out the legal basis of the claim.

228. The Appellate Body's report in EC – *Bananas* also bears recalling. In that dispute, the complaining Members merely listed the articles of WTO agreements that they believed the measures at issue breached, providing no narrative explanation of how the measures at issue breached each provision, or which specific aspects of the measures at issue breached which provision. The Appellate Body concluded that this was sufficient, noting that:

there is a significant difference between the claims identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the arguments supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties.³³²

³²⁹ Preliminary Ruling by the Panel, *Australia – Apples*, paras. 10-11; Request for the Establishment of a Panel by New Zealand, *Australia – Apples*.

³³⁰ Request for the Establishment of a Panel by New Zealand, *Australia – Apples*.

³³¹ Preliminary Ruling by the Panel, *Australia – Apples*, paras. 10-11

³³² *EC* – *Bananas III (AB)*, para. 141.

Moreover, India is in no position to complain about the fact that the United States had no specifically-stated ALOP that it could point to in connection with this claim. As noted above, the United States submitted to India a request pursuant to Article 5.8 of the SPS Agreement for a statement of India's appropriate level of protection. India has never responded to that request, leaving the United States to infer India's ALOP from India's domestic measures for handling transmission of the same disease.³³³

229. In sum, the panel request put India and other Members clearly on notice of the legal basis of the complaint. A listing of articles of WTO agreements alleged to be breached by the measures at issue in a dispute may well be sufficient³³⁴ Here, even though it did not have to, the United States went much further than a mere listing of articles. The facts belie any assertion that the panel request failed to identify the specific measures at issue or provide a brief summary of the legal basis of the complaint, sufficient to present the problem clearly.

X. CONCLUSION

230. For the reasons set forth in this submission, the United States respectfully requests the Panel to find that India's measures, as set out above, are inconsistent with India's obligations under the GATT 1994 and the SPS Agreement. The United States further requests, pursuant to Article 19.1 of the DSU, that the Panel recommend that India bring its measures into conformity with the GATT 1994 and the SPS Agreement.

³³³ In its argument regarding the Article 5.6 claim, India again raises the arguments it made in the context of the Article 2.3 and 5.5 claims about product coverage and whether the claim's challenge to "avian influenza measures" challenges measures related to highly pathogenic avian influenza, low pathogenic avian influenza, or both. These arguments have been addressed above in the explanation of the panel request's sufficiency with respect to those claims. The U.S. previous responses to these arguments apply equally in the context of the Article 5.6 claim.

³³⁴ *Korea – Dairy (AB)*, para. 131.

Annex 1

Article 10.4.5.

Recommendations for importation from a NAI free country, zone or compartment

For live poultry (other than day-old poultry)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *poultry* showed no clinical sign of NAI on the day of shipment;
- 2) the *poultry* were kept in a NAI free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*;
- 4) if the *poultry* have been vaccinated against NAI, it has been done in accordance with the provisions of the *Terrestrial Manual* and the nature of the vaccine used and the date of *vaccination* have been attached to the *certificate*.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) The *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or
- 2) the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.25.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.16.

Recommendations for importation from a NAI free country, zone or compartment

For poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

- 1) showed no clinical sign of NAI on the day of semen collection;
- 2) were kept in a NAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a HPNAI free country, zone or compartment

For poultry semen

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the

donor *poultry*:

- 1) showed no clinical sign of HPNAI on the day of semen collection;
- 2) were kept in a HPNAI free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to semen collection;
- 2) showed no clinical sign of *infection* with a virus which would be considered NAI in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free of NAI *infection*.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the NAI status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from *fresh meat* which meet the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the destruction of NAI virus in accordance with Article 10.4.26.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the NAI status of the country of origin, Veterinary Authorities should

require the	presentation of an international veterinary certificate attesting that:
1)	these <i>commodities</i> were processed in a NAI free country, <i>zone</i> or <i>compartment</i> from <i>poultry</i> which were kept in a NAI free country, <i>zone</i> or <i>compartment</i> from the time they were hatched until the time of <i>slaughter</i> or for at least the 21 days preceding <i>slaughter</i> , or
2)	these <i>commodities</i> have been processed to ensure the destruction of NAI virus (under study);
	AND
3)	the necessary precautions were taken to avoid contact of the <i>commodity</i> with any source of NAI virus.
Article 10.4.22.	
Recommendations for the importation of feathers and down of poultry	
	s of the NAI status of the country of origin, Veterinary Authorities should presentation of an <i>international veterinary certificate</i> attesting that:
1)	these <i>commodities</i> originated from <i>poultry</i> as described in Article 10.4.19. and were processed in a NAI free country, <i>zone</i> or <i>compartment</i> , or
2)	these <i>commodities</i> have been processed to ensure the destruction of NAI virus (under study);
Article 10.4.23.	
Recommendations for the importation of feathers and down of birds other than poultry	
-	s of the NAI status of the country of origin, <i>Veterinary Authorities</i> should presentation of an <i>international veterinary certificate</i> attesting that:
1)	these <i>commodities</i> have been processed to ensure the destruction of NAI virus (under study); and
2)	the necessary precautions were taken to avoid contact of the <i>commodity</i> with any source of NAI virus.

Article 10.4.24. Recommendations for the importation of feather meal and poultry meal Regardless of the NAI status of the country of origin, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that: 1) these commodities were processed in a NAI free country, zone or compartment from poultry which were kept in a NAI free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter, or 2) these *commodities* have been processed either: with moist heat at a minimum temperature of 118°C for minimum a) of 40 minutes; or b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C; AND 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of NAI virus.