Reconciliation report for 2009-005_DraftISPM_RevisionISPM8_En_2018-05-30.docx (2009-005_DraftISPM_RevisionISPM8_En_2018-05-30.docx)

Summary

Title	2018 First Consultation: Draft Revision of ISPM 8 Determination of pest status in an area (2009-005) (Id 476)
Description	
End Date	30 9 2018 11:45 午後
Review Status	In Progress

Participants

Name	Status	Workgroup Role	Summary	Comments	Last Activity
Japan	In Progress	Reviewer		14	24 9 2018 7:01 午前

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating
S (Status) - A = Accepted, C = Closed, O = Open, W = Withdrawn, M = Merged

Para	Text	T	Comment	S	Author Comment
G	(General Comment)	C	*Category : SUBSTANTIVE* **(406) Japan (24 9 2018 6:42 午前)** If a new pest may be just introduced in an area, a period of time may be sometimes required to determine pest status based on technical evaluation (e.g. PRA, surveillance). Under such a circumstance, we should decide the status should be divided into "present" or "absent". Or we should decide the status like "transient" on the existing ISPM8 during conducting technical evaluation (i.e. the status is not decided) should be included in the requirements.	O	
1. Purpose of Pest Status Determination					
47	Determination of pest status in an area is a vital component of a number of activities covered under the IPPC and by the principles noted in ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) and the international standards for phytosanitary measures that have been developed from them. Pest status is determined by the NPPO responsible for the area. Pest status is determined for each targeted area, i.e. a country, a part of a country or all or parts of several countries.	P	*Category : SUBSTANTIVE* **(407) Japan (24 9 2018 6:44 午前)** Area can be officially defined country, part of a country or all or parts of several countries. To clarify that pest status in a part of a country does not apply to the whole country (i.e. The status which a pest is present in a part of the country does not directly mean that the pest status in the country is "presence") and pest status is determined for each targeted area, i.e. a country, a part of a country or all or parts of several countries. This proposed change is supported by APPPC as well as by Japan.	O	
3. Describing Pest Status in an Area					
73	The NPPO should decide upon the most appropriate description of the pest status	P	*Category : SUBSTANTIVE* **(408) Japan (24 9 2018 6:45 午前)**	O	

	in an area, based on information from various sources such as those described in Appendix 1. This includes results from surveillance. Pests only present under quarantine for diagnostic or research purposes do not affect the pest status in an area~~.~~ .If a pest may be just introduced in an area, a certain period of time is required to determine pest status.		If a new pest may be just introduced in an area, a period of time may be required to determine pest status based on technical evaluation (e.g. PRA, surveillance). This proposed change is supported by APPPC as well as by Japan.		
3.1 Presence					
92	Present: not expected to ~~establish~~establish (transience)	P	*Category : SUBSTANTIVE* **(409) Japan (24 9 2018 6:46 午前)** To clarify the status that "not expected to establish" is transience This proposede change is supported by APPPC as well as by Japan.	O	
93	The pest is evaluated and determined to be transient, or the pest is not expected to establish because appropriate phytosanitary measures have been applied (e.g. during outbreaks in a pest free ~~area)~~area) or natural conditions do not allow the pest to establish.	P	*Category : SUBSTANTIVE* **(410) Japan (24 9 2018 6:47 午前)** Add the concept of the status "transient: non-actionable" of current ISPM 8. This proposed change is supported by APPPC as well as by Japan.	O	
96	in enclosed ~~structures~~structures (e.g. in a green house)	P	*Category : SUBSTANTIVE* **(411) Japan (24 9 2018 6:49 午前)** Add an example according to tasks (10) of specification. This proposed change is supported by APPPC as well as by Japan.	O	
4. Responsibilities of NPPOs and Good Reporting Practices					
127	Contracting parties have obligations under the IPPC (Article VIII.1(a)) to report “the occurrence, outbreak or spread of pests”. Information pertaining to pest status in an area contributes to pest reports. Pest status is determined by the NPPO responsible for the area concerned using pest records and other information from different sources. If the status in the area is changed (e.g. the eradication can be accomplished), the NPPO should report the status immediately. It is the responsibility of an NPPO to provide pest records and supporting evidence upon request from another NPPO.	P	*Category : SUBSTANTIVE* **(412) Japan (24 9 2018 6:50 午前)** There is no description about report of the change of the pest status by the NPPO.	O	
APPENDIX 1: Guidance on reliability of information sources					
139	**Information source**	C	*Category : SUBSTANTIVE* **(413) Japan (24 9 2018 6:51 午前)** Information sources should be ranked in terms of their reliability.	O	
180	Only one or a few original research papers; any ~~found~~ finding do not describe methodology ***or*** methodology used is not widely accepted; published in low impact-factor journals	P	*Category : EDITORIAL* **(419) Japan (24 9 2018 7:08 午前)**	O	
183	~~No peer-reviewed literature available~~	P	*Category : SUBSTANTIVE* **(414) Japan (24 9 2018 6:52 午前)** "No peer-reviewed literature available" is inconsistent with "Peer-reviewed jounals". This proposed change is supported by APPPC as well as by Japan.	O	

184	**Databases and websites**	C	*Category : SUBSTANTIVE* **(415) Japan (24 9 2018 6:53 午前)** Databases and websites are one of information sources, but they are tools to store or provide information gathered from other information sources. As the nature Databases and websites on Appendix1 is different from ones of other information sources, databases and websites as infromation source should be separated from this table and placed to another table which includes reliability and examples of databases and websites.	O	
209	**Unpublished communications from ~~sources other than NPPO~~sources**	P	*Category : SUBSTANTIVE* **(416) Japan (24 9 2018 6:58 午前)** To delete " other than NPPO". This proposed change is supported by APPPC as well as by Japan.	O	
216	The above table ranks the categories of information source in descending order of relative reliability, however it must be recognized that these are not rigid and only designed to provide guidance in assessing the reliability.	P	*Category : SUBSTANTIVE* **(417) Japan (24 9 2018 7:03 午前)** Provide the rank of reliability of information source.	O	
218	This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues. - The necessity to consider time required to establish pest status i.e. transient cases - status is deemed as undetermined - not covered here. Propose for the standard to recognise this.	P	*Category : SUBSTANTIVE* **(418) Japan (24 9 2018 7:04 午前)** f a new pest may be just introduced in an area, a period of time may be required to determine pest status based on technical evaluation (e.g. PRA, surveillance).	O	

Reconciliation report for 2014-002_DraftISPM_AuthorizationEntities_En_2018-06-01.docx (2014-002_DraftISPM_AuthorizationEntities_En_2018-06-01.docx)

Summary

Title	2018 First Consultation: Draft ISPM Authorization of entities to perform phytosanitary actions (2014-002) (Id 482)
Description	
End Date	30 9 2018 11:45 午後
Review Status	In Progress

Participants

Name	Status	Workgroup Role	Summary	Comments	Last Activity
Japan	In Progress	Reviewer		41	27 9 2018 4:17 午後

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating
S (Status) - A = Accepted, C = Closed, O = Open, W = Withdrawn, M = Merged

Para	Text	T	Comment	S	Author Comment
Scope					
28	This standard provides a ~~framework~~ guidance that enables national plant protection organizations ~~(NPPOs)to~~ (NPPOs) to authorize ~~privateentitiesto~~ private entities to perform specific phytosanitary actions associated with import, domestic and export ~~systemson behalf~~ systems under the responsibilities of the NPPO. Elements of this standard may also apply when authorizing public entities.	P	*Category : SUBSTANTIVE* **(706) Japan (23 9 2018 5:22 午後)** This standard should provide a guidance for NPPOs in conformity with a specification of this standard because not all NPPOs authorize entities to perform phytosanitary actions. To modify in compliance with the IPPC(Article.2). Generally, Authorization of entities is conducted by the NPPO in the country.	O	
29	This standard does not cover the issuance of phytosanitary certificates; these are issued by ~~authorized public officers~~ the NPPO only (Article V.2(a) of the IPPC).	P	*Category : SUBSTANTIVE* **(707) Japan (23 9 2018 5:24 午後)** To provide clarity that only the NPPO can provide the issuance of PCs and not other authorised public officers. This proposed change is supported by APPPC as well as by Japan.	O	
Outline of Requirements					
36	This standard outlines the key requirements for the development of an authorization programme and the eligibility criteria for entities to become authorized. The standard identifies the roles and responsibilities of the parties involved in the implementation of an authorization programme. It also describes processes for audits, types of ~~nonconformities~~non-conformities, and types of authorization status that may apply to entities.	P	*Category : EDITORIAL* **(858) Japan (27 9 2018 7:25 午前)**	O	
Background					
38	It is becoming common in various countries throughout the world for national plant	P	*Category : SUBSTANTIVE*	O	

	protection organizations to authorize entities to perform specific phytosanitary actions such as inspection, testing, surveillance and treatment. Concepts of quality management systems applied in the manufacturing sector are increasingly being applied to the delivery of a wide range of phytosanitary actions, including those undertaken by such authorized entities. However, there is a need to ensure the credibility of such authorizations and that the practice aligns with the principles of the ~~IPPC~~IPPC in that the NPPO remains accountable for phytosanitary actions.		**(708) Japan (23 9 2018 5:25 午後)** To clarify that NPPO remains accountable for phytosanitary actions. This proposed change is supported by APPPC as well as by Japan.		
Requirements					
43	Authorization is a process that may be used by ~~NPPOsto~~ NPPOs to formally recognize entities to undertake specific NPPO phytosanitary actions. An NPPO's authorization programme operates within its phytosanitary system.	P	*Category : EDITORIAL* **(720) Japan (23 9 2018 5:52 午後)**	O	
44	NPPO has responsibilities to decide which phytosanitary action can be conducted as an authorization programme and which elements need to include in the programme depend on its country's situation. An NPPO should determine whether to authorize entities to perform phytosanitary actions.Examples of phytosanitary actions that an NPPO may authorize an entity to perform on its behalf include monitoring, sampling, inspection, testing, surveillance, treatment, post-entry quarantine, destruction, ~~supervisionand~~ supervision and auditing. Under an authorization programme, entities may perform phytosanitary actions within a phytosanitary regulatory system (import, domestic or export).	P	*Category : SUBSTANTIVE* **(721) Japan (23 9 2018 5:53 午後)** It clearly specifies that NPPO has responsibilities to decide which phytosanitary action can be conducted as an authorization programme and which elements need to include in the programme depend on its country's situation.	O	
46	NPPOs should ensure that their legal framework enables them to authorize entities to perform phytosanitary actions on their ~~behalf~~behalf when authorizing entities. In such cases, The NPPO's legal framework should allow ~~itto~~ it to suspend, revoke and reinstate authorizations, and should also enable an authorized entity to withdraw from the authorization programme.	P	*Category : SUBSTANTIVE* **(709) Japan (23 9 2018 5:29 午後)** Legal framework should be considered when authorizing entities.	O	
1. Development of Authorization Programme					
56	develop criteria to determine ~~nonconformities~~non-conformities	P	*Category : EDITORIAL* **(859) Japan (27 9 2018 7:25 午前)**	O	
57	develop a process to address ~~nonconformity~~non-conformity, this including, where appropriate, suspending or revoking authorization	P	*Category : EDITORIAL* **(741) Japan (23 9 2018 6:09 午後)**	O	
2. Criteria for Eligibility of Entities					
67	it declares any possible conflict of interest and identifies how this would be managed to ensure that it acts impartially as regards the specific phytosanitary ~~actionsit~~ actions it undertakes.	P	*Category : EDITORIAL* **(722) Japan (23 9 2018 5:54 午後)**	O	
3. Roles and Responsibilities forImplementingthe Authorization Programme					
68	**3. Roles and Responsibilities ~~forImplementingthe~~ for Implementingthe Authorization Programme**	P	*Category : EDITORIAL* **(723) Japan (23 9 2018 5:54 午後)**	O	
3.1 Roles and responsibilities of the NPPO					
73	to evaluate the entity against the requirements set by the NPPO regarding its	P	*Category : EDITORIAL* **(724) Japan (23 9 2018 5:55 午後)**	O	

	documented quality manual (or documentation sufficient to address the specific phytosanitary ~~actions)and~~ actions) and implementation of standard operating procedures on-site, and propose suggestions for improvement as necessary				
78	to implement processes for addressing identified ~~nonconformities~~non-conformities, including, where appropriate, suspending or revoking authorization, which may include regulatory enforcement	P	*Category : EDITORIAL* **(860) Japan (27 9 2018 7:27 午前)**	O	
3.2 Roles and responsibilities of the authorized entity					
89	document control, which includes: - revision of documents - records, in particular of the activities undertaken in relation to the specific phytosanitary actions	P	*Category : SUBSTANTIVE* **(710) Japan (23 9 2018 5:34 午後)** "revision of documents" and "records, in particular of the activities undertaken in relation to the specific phytosanitary actions" are included "document control"	O	
90	~~revision of documents~~	P	*Category : SUBSTANTIVE* **(711) Japan (23 9 2018 5:35 午後)** "revision of documents" and "records, in particular of the activities undertaken in relation to the specific phytosanitary actions" are included "document control"	O	
91	~~records, in particular of the activities undertaken in relation to the specific phytosanitary actions~~	P	*Category : SUBSTANTIVE* **(712) Japan (23 9 2018 5:35 午後)** "revision of documents" and "records, in particular of the activities undertaken in relation to the specific phytosanitary actions" are included "document control"	O	
93	management of ~~nonconformity~~non-conformity	P	*Category : EDITORIAL* **(742) Japan (23 9 2018 6:10 午後)**	O	
95	to ensure personnel have the relevant education and experience required by the NPPO to perform the specific phytosanitary actions	P	*Category : SUBSTANTIVE* **(713) Japan (23 9 2018 5:37 午後)** The relevant education and experience for personnel should be ones required by the NPPO.	O	
3.2.1 Roles and responsibilities of entities authorized to audit or supervise					
101	develop and carry out an action plan or procedures for dealing with ~~nonconformities~~ non-conformities that compromise the integrity of and trust in the programme, including notification of ~~theseto~~ these to the authorizing NPPO	P	*Category : EDITORIAL* **(725) Japan (23 9 2018 5:56 午後)**	O	
102	~~maintain confidentiality of information gained through its phytosanitary actions~~	P	*Category : SUBSTANTIVE* **(714) Japan (23 9 2018 5:39 午後)** Maintaining confidentiality is mentioned only in this paragraph in this draft ISPM. In addition, confidentiality is not specified in other ISPMs.	O	
103	maintain impartiality and independence from the entities to be audited or supervised, and be free from any ~~conflictof~~ conflict of interest.	P	*Category : EDITORIAL* **(726) Japan (23 9 2018 5:57 午後)**	O	
4.1 Audits to authorize an entity					

107	When the quality manual (or other documentation sufficient to address the specific phytosanitary actions) is acceptable, the NPPO (or its authorized entity) should carry out an audit to evaluate the entire system and the capability of the entity ~~toimplement~~ to implement the standard operating procedures for each phytosanitary action.	P	*Category : EDITORIAL* **(727) Japan (23 9 2018 5:57 午後)**	O	
109	The NPPO should ~~normally~~ grant authorization to the entity if the system audit conducted by the NPPO (or its authorized entity) demonstrates that the NPPO's requirements for authorization of entities have been met.	P	*Category : SUBSTANTIVE* **(715) Japan (23 9 2018 5:40 午後)** The entities should be authorized if the entities meet the NPPO's requirements for authorization of entities.	O	
4.2 Audits to maintain authorization					
111	The NPPO should determine the ~~ongoing~~ frequency of the audits to maintain authorization, based on the level of ~~riskand~~ risk and complexity associated with the phytosanitary actions,the performance and the conformance of the ~~entity~~entity (e.g. once a year).	P	*Category : SUBSTANTIVE* **(716) Japan (23 9 2018 5:41 午後)** Delete the "ongoing" because it is not necessary. The frequency of the audits should be decided based on the level of risk and complexity associated with the phytosanitary actions, the performance and the conformance of the entity. The interval between the audits (i.e. frequency) can be extended on the basis of the level of risk and complexity and the results of the previous audits (e.g. once every few years).	O	
112	~~Audits to maintain authorization should be conducted at least once a year on the entity's entire system.~~ Additional audits on a specific part or parts of the entity's system may be conducted as necessary.	P	*Category : SUBSTANTIVE* **(785) Japan (26 9 2018 7:09 午前)** The frequency of the audits should be decided based on the level of risk and complexity associated with the phytosanitary actions, the performance and the conformance of the entity. The interval between the audits (i.e. frequency) can be extended on the basis of the level of risk and complexity and the results of the previous audits (e.g. once every few years).	O	
5. Types of Nonconformity					
113	**5. Types of ~~Nonconformity~~Non-conformity**	P	*Category : EDITORIAL* **(728) Japan (23 9 2018 5:58 午後)**	O	
114	When the authorized entity does not meet the requirements specified by the NPPO, this should be considered as a ~~nonconformity~~non-conformity.	P	*Category : EDITORIAL* **(729) Japan (23 9 2018 5:59 午後)**	O	
115	A nonconformity may be identified during audits, supervision, investigations, records from authorized entities or through notification of non-compliance (ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*)).	P	*Category : SUBSTANTIVE* **(718) Japan (23 9 2018 5:47 午後)** A nonconformity may be identified through records from authorized entities. This proposed change is supported by APPPC as well as by Japan.	O	
115	A ~~nonconformity~~ non-conformity may be identified during audits, supervision,	P	*Category : EDITORIAL* **(730) Japan (23 9 2018 5:59 午後)**	O	

	investigations, or through notification of non-compliance (ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*)).				
116	The type and number of ~~nonconformities~~ non-conformities identified should be used by the NPPO to determine the ongoing status of the entity (authorized, suspended or revoked) and the subsequent audit frequency.	P	*Category : EDITORIAL* **(731) Japan (23 9 2018 5:59 午後)**	O	
117	Any ~~nonconformity~~ non-conformity identified should result in a corrective action to be agreed between the NPPO (or the entity authorized to audit or supervise) and the authorized entity being audited.	P	*Category : EDITORIAL* **(732) Japan (23 9 2018 6:00 午後)**	O	
118	~~Nonconformities~~ Non-conformities may be considered as critical ~~nonconformities~~ non-conformities (section 5.1) or other ~~nonconformities~~ non-conformities (section 5.2).	P	*Category : EDITORIAL* **(733) Japan (23 9 2018 6:00 午後)**	O	
5.1 Critical nonconformity					
119	**5.1 Critical ~~nonconformity~~non-conformity**	P	*Category : EDITORIAL* **(734) Japan (23 9 2018 6:01 午後)**	O	
120	Critical ~~nonconformity~~ non-conformity is nonconformity that immediately impacts the integrity ~~ofand trustin~~ of and trust in the NPPO's phytosanitary system and that requires an immediate corrective ~~actionto~~ action to be identified and implemented.	P	*Category : EDITORIAL* **(735) Japan (23 9 2018 6:02 午後)**	O	
121	If the authorized entity does ~~notimmediately~~ not immediately implement the mutually agreed corrective action or the corrective ~~actionis~~ action is not implemented to the satisfaction of the NPPO (or the entity authorized to audit or supervise), the authorization of the entity should be ~~suspendedor~~ suspended or revoked by the NPPO.	P	*Category : EDITORIAL* **(736) Japan (23 9 2018 6:03 午後)**	O	
5.2 Other nonconformity					
122	**5.2 Other ~~nonconformity~~non-conformity**	P	*Category : EDITORIAL* **(737) Japan (23 9 2018 6:03 午後)**	O	
123	Other ~~nonconformity~~ non-conformity is ~~nonconformity~~ non-conformity that does not directly or immediately impact the integrity of and trust in the NPPO's phytosanitary system but that will need corrective actions to be taken within a timeframe specified by the NPPO (or the entity authorized to audit or supervise).	P	*Category : EDITORIAL* **(738) Japan (23 9 2018 6:04 午後)**	O	
6. Suspension,Revocation andReinstatement of Authorization					
124	**6. Suspension~~,~~ Revocation ~~andReinstatement~~and Reinstatement of Authorization** In the context of this standard, three types of authorization status change are as follows.	P	*Category : SUBSTANTIVE* **(719) Japan (23 9 2018 5:48 午後)** Add an explanation of authorization status.	O	
125	**Suspension~~.~~** An entity whose authorization is suspended may continue to operate only under the direct supervision of the NPPO (or the entity authorized to audit or supervise).	P	*Category : EDITORIAL* **(739) Japan (23 9 2018 6:05 午後)**	O	
127	**Reinstatement.** An entity whose authorization has been suspended	P	*Category : EDITORIAL*	O	

	or ~~revokedand~~ revoked and that wishes to have its authorization status reinstated should apply to the NPPO for reinstatement.		**(740) Japan (23 9 2018 6:06 午後)**		
128	An entity that has voluntarily withdrawn from an authorization programme and that wishes to have its authorization status ~~reinstatedshould~~ reinstated should also apply to the NPPO for reinstatement.	P	*Category : EDITORIAL* **(861) Japan (27 9 2018 7:29 午前)**	O	

Reconciliation report for 2014-006_DraftISPM_ModifiedAtmosphere_En_2018-05-30.docx (2014-006_DraftISPM_ModifiedAtmosphere_En_2018-05-30.docx)

Summary

Title	2018 First Consultation: Draft ISPM Requirements for the use of modified atmosphere treatments as phytosanitary measures (2014-0 (Id 483)
Description	
End Date	30 9 2018 11:45 午後
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Participants

Name	Status	Workgroup Role	Summary	Comments	Last Activity
Japan	In Progress	Reviewer		19	26 9 2018 8:29 午前

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating
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Para	Text	T	Comment	S	Author Comment
Outline of Requirements					
43	The roles and responsibilities of ~~parties~~ entities (person or organization) involved in the modified atmosphere treatments are described. Guidance is provided to NPPOs on authorizing, monitoring and auditing entities involved in modified atmosphere treatments.	P	*Category : SUBSTANTIVE* **(360) Japan (23 9 2018 8:30 午後)** To ensure consistency with the requirement of "ISPM 42 Requirements for the use of temperature treatments as phytosanitary measures". This proposed change is supported by APPPC as well as by Japan.	O	
2. Treatment Application					
60	In a modified atmosphere treatment, the lethal level of the atmosphere should be maintained for an adequate length of time, typically for more than a day. An enclosure is therefore required to achieve and maintain the lethal atmospheric conditions over the duration of the treatment. Enclosures can be designed as a continuous gas flow system or a static system.	P	*Category : EDITORIAL* **(374) Japan (23 9 2018 9:09 午後)**	O	
60	In a modified atmosphere treatment, the lethal atmosphere should be maintained for an adequate length of time~~, typically for more than a day~~. An enclosure is therefore required to achieve and maintain the lethal atmospheric conditions over the duration of the treatment. Enclosures can be designed as a continuous gas flow system or a static system.	P	*Category : SUBSTANTIVE* **(361) Japan (23 9 2018 8:33 午後)** As the adequate treatment time of MA treatment varies depend on gas concentration and kind of pests, "typically for more than a day" is not appropriate. This proposed change is supported by APPPC as well as by Japan.	O	
61	Maintenance of the atmosphere at the required gas composition levels depends on being able to compensate for the gas loss from the enclosure. This is influenced by the permeability of the structural fabric of enclosures and the effectiveness of seals at structural connections or joins and entry ~~points~~points of enclosures, where	P	*Category : SUBSTANTIVE* **(362) Japan (23 9 2018 8:36 午後)** To clarify what for the structural fabric is. The term "entry points" is not appropriate in this context. Add "of enclosures" to clarify the term.	O	

	surface to volume ratio has a major influence.		This proposed change is supported by APPPC as well as by Japan.		
63	Temperature is a factor in achieving the required efficacy of modified atmosphere treatments, in particular because it affects the respiration rate of the target ~~organism~~pest. In general, the lower the temperature, the lower the respiration rate of the ~~organism~~ pest and the greater the duration of exposure needed to achieve the required efficacy.	P	*Category : SUBSTANTIVE* **(363) Japan (23 9 2018 8:38 午後)** The term “organism” is not used in both ISPMs, ISPM42 "Requirements for the use of temperature treatments as phytosanitary measures" and draft ISPM_Fumigation. To ensure consistency with the requirement of both ISPMs. This proposed change is supported by APPPC as well as by Japan.	O	
2.1 Methods for modifying atmospheres					
66	changing the proportion of ~~O~~oxygen (O_2-) and ~~CO~~carbon dioxide (CO_2-) in the atmosphere by adding CO_2 or an inert gas (such as nitrogen) and maintaining this atmosphere	P	*Category : EDITORIAL* **(380) Japan (24 9 2018 1:52 午後)** Chemical symbol and elemental name are mixed in whole text of this ISPM	O	
68	hermetic or semi-hermetic storage in which the respiration of the commodity and ~~organisms~~ pests infesting it deplete the level of O_2 and increase the level of CO_2	P	*Category : SUBSTANTIVE* **(364) Japan (23 9 2018 8:40 午後)** The term “organism” is not used in both ISPMs, ISPM42 "Requirements for the use of temperature treatments as phytosanitary measures" and draft ISPM_Fumigation. To ensure consistency with the requirement of both ISPMs. This proposed change is supported by APPPC as well as by Japan.	O	
3. Enclosures Used for Modified Atmosphere Treatments					
71	The enclosure used for modified atmosphere treatments may consist of ~~modified atmosphere~~ a packaging, or a portable or fixed structure. An enclosure used as a modified atmosphere packaging is a protective atmosphere packaging, which involves either actively or passively controlling or modifying the atmosphere surrounding the commodity within a package made of various types and/or combinations of films.	P	*Category : SUBSTANTIVE* **(381) Japan (24 9 2018 1:55 午後)** Add new sentence to explain "packaging" used as enclosure for modified atmosphere.	O	
80	Modified atmosphere treatments that rely on positive pressure of inert gases to achieve anoxic conditions may use non-gas-tight chambers or use enclosures that ~~were~~ are not specifically designed for modified atmosphere treatments. Particular attention to pressure should be made when using enclosures that ~~were~~ are not specifically designed for modified atmosphere treatment use.	P	*Category : EDITORIAL* **(382) Japan (24 9 2018 1:58 午後)**	O	
4.1 Measuring gas concentration					
84	Atmospheric gas concentrations should be measured at regular intervals during modified atmosphere treatments. Treatment providers (e.g. companies or individuals) should verify, before each treatment, that sensors and data recording equipment used to measure gases are calibrated according to the manufacturer’s instructions.	P	*Category : SUBSTANTIVE* **(365) Japan (23 9 2018 8:45 午後)** In addition to sensors, data recording equipment should be calibrated.	O	

4.2 Measuring and mapping temperature					
86	Treatment providers should verify that ~~sensors used to measure~~ temperature ~~are~~ monitoring equipment is calibrated according to the manufacturer's instructions.	P	*Category : SUBSTANTIVE* **(366) Japan (23 9 2018 8:48 午後)** Temperature monitoring equipment is calibrated to measure adequate temperature.	O	
88	Temperature mapping should be conducted according to appropriate procedures using loads and packaging equivalent to that used in commercial application. Temperature variation in the enclosure can be used to determine the best locations for placing the temperature ~~sensors~~sensors (analogue or digital).	P	*Category : TECHNICAL* **(367) Japan (23 9 2018 8:50 午後)** Temperature sensors include analogue sensors and digital sensors.	O	
5.1 Authorization of entities					
94	In this standard, "entities" include both treatment providers and treatment facilities. Modified atmosphere treatments are applied by treatment providers in treatment ~~facilities~~facilities (including facilities for packaging used as modified atmosphere treatment).	P	*Category : TECHNICAL* **(368) Japan (23 9 2018 8:53 午後)** The enclosure used for modified atmosphere treatments includes "packaging" as well as fixed structures (e.g. vacuum chambers, freight containers, warehouses, cargo ship holds). So treatment facilities also include facilities for packaging used as modified atmosphere treatment.	O	
5.6 Monitoring and auditing					
105	**5.~~6~~4 Monitoring and auditing**	P	*Category : EDITORIAL* **(383) Japan (24 9 2018 1:59 午後)**	O	
107	Parameters to consider when verifying treatment programmes include meeting requirements for treatment atmospheric conditions, treatment time, temperature, ~~humidity~~ humidity, pressure and ventilation. A modified atmosphere treatment protocol should include the following to ensure that the treatment schedule is met:	P	*Category : TECHNICAL* **(369) Japan (23 9 2018 8:56 午後)** "Pressure" is also one of parameters to affect treatment programmes.	O	
6. Documentation					
113	The NPPO of the country in which the facility is located is responsible for ensuring that treatment providers maintain documents of procedures and keep appropriate records, such as raw data on treatment parameters recorded during treatments. Accurate record keeping is essential to allow for trace-back capability. The NPPO is also responsible for documentation related to NPPO procedures.	P	*Category : SUBSTANTIVE* **(370) Japan (23 9 2018 8:58 午後)** In conformity with section 6.1, 6.2 and 6.3. This proposed change is supported by APPPC as well as by Japan.	O	
6.2 Record keeping					
131	lot ~~size, volume~~ size and ~~identification~~volume, including number of articles or packages	P	*Category : SUBSTANTIVE* **(371) Japan (23 9 2018 8:59 午後)** The meaning of "identification" is not clear, so it should be deleted.	O	
134	any observed deviation from the treatment specification. - temperature, gas concentration, other treatment parameters (if required) and time recorded - calibration data	P	*Category : TECHNICAL* **(372) Japan (23 9 2018 9:01 午後)** Records of treatment parameters and calibration data should be retained. ISPM42 (Requirements for the use of temperature treatments as phytosanitary measures) also	O	

			states that similar treatment parameters should be retained.		
8. Responsibilities					
141	The NPPO of the country in which the treatment is initiated or conducted is responsible for the evaluation, approval and auditing of modified atmosphere treatments as phytosanitary measures, including those performed by other authorized entities. However, when treatments are conducted or completed during transport, the NPPO of the exporting country is usually responsible for authorizing the entity applying the treatment during transport, and the NPPO of the importing country is responsible for verifying if the treatment requirements have been met. To the extent necessary, it is the NPPO's responsibility to cooperate with other national and international regulatory agencies concerned with the development, approval and safety of the modified atmosphere treatment, including the training and certification of personnel conducting the treatment, the authorization of ~~operators~~entities, and the approval of modified atmosphere facilities. Their respective responsibilities should be identified to avoid requirements that are overlapping, conflicting, inconsistent or not technically justified.	P	*Category : SUBSTANTIVE* **(373) Japan (23 9 2018 9:03 午後)** In conformity with section 5.1. "Operators" include "entities". This proposed change is supported by APPPC as well as by Japan	O	

Reconciliation report for 2014-004_DraftISPM_Fumigation _En_2018-06-28.docx (2014-004_DraftISPM_Fumigation _En_2018-06-28.docx)

Summary

Title	2018 Second Consultation: Draft ISPM Requirements for the use of Fumigation (2014-004) (Id 475)
Description	
End Date	30 9 2018 11:45 午後
Review Status	In Progress

Participants

Name	Status	Workgroup Role	Summary	Comments	Last Activity
Japan	In Progress	Reviewer		54	27 9 2018 8:43 午前

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating
S (Status) - A = Accepted, C = Closed, O = Open, W = Withdrawn, M = Merged

Para	Text	T	Comment	S	Author Comment
G	(General Comment)	C	*Category : SUBSTANTIVE* **(338) Japan (24 9 2018 7:12 午前)** Although safety and health issue is important, the relevant part was removed from the draft ISPM as countries commented that it should not be part of an ISPM. Instead, a general description was added in section 10 (Responsibilities). However, safety and health issue is important for NPPOs and entities who conduct fumigation activities, so it is better to include in this ISPM. For a specific comment, the relevant information like the 1st sentence of Section 7.3 "Environment, health and safety" in the 1st round draft ISPM may be added in BACKGROUND as a new paragraph after paragraph No 49.	O	
Outline of Requirements					
45	The roles and responsibilities of ~~parties~~ entities (person or organization) involved in fumigation are described. Guidance is provided to NPPOs on authorizing, monitoring and auditing treatment entities.	P	*Category : SUBSTANTIVE* **(339) Japan (24 9 2018 7:13 午前)** To ensure consistency with the requirement of "ISPM 42 Requirements for the use of temperature treatments as phytosanitary measures".	O	
BACKGROUND					
49	Fumigation is considered to be effective when the specific concentration of fumigant at the minimum temperature and duration required for the stated efficacy is achieved. Prior to any application of a fumigant, a review of the health and safety risks should be completed to ensure that all the requirements of domestic regulations are met and the safety of applicators and those living or working in	P	*Category : SUBSTANTIVE* **(340) Japan (24 9 2018 7:14 午前)** Please see the general commnent on safety and health issue . For a specific comment, the relevant information like the 1st sentence of Section 7.3 "Environment,	O	

	proximity to the fumigation site are ensured.		health and safety" in the 1st round draft ISPM may be added in BACKGROUND as a new paragraph after paragraph No 49.		
IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT					
51	Historically, fumigation has been widely applied to prevent the introduction and spread of regulated pests and has, therefore, been beneficial to biodiversity. However, fumigant gases, such as methyl bromide, sulphuryl fluoride, phosphine and ethyl formate, may have negative impacts on the environment. For example, the emission of methyl bromide into the atmosphere is known to deplete the ozone layer and sulphuryl fluoride is ~~a~~ recognized as a greenhouse gas. The IPPC Recommendation on the replacement or reduction of the use of methyl bromide as a phytosanitary measure (CPM R-03, 2017) has been adopted in relation to this issue. It encourages contracting parties to choose other fumigants, where possible. Environmental impacts of fumigants can be mitigated through the use of destruction (chemical breakdown) or recapture technology to reduce gas emissions.	P	*Category : EDITORIAL* **(352) Japan (24 9 2018 1:22 午後)**	O	
2. Fumigation Application					
58	as an integral part of production or packaging ~~operations~~operations (e.g. during storage before packaging, during packaging)	P	*Category : SUBSTANTIVE* **(341) Japan (24 9 2018 7:16 午前)** Add an example to clarify the differnece between this indent and the other (i.e. "during storage" after packaging in paragraph No60) because packaging operations in paragraph No59 include different types of operations, "during storage before packaging" and "during packaging".	O	
65	Fumigation efficacy may be affected by factors such as the moisture content of the commodity and, within the enclosure used for the fumigation, the humidity, pressure, and changes in the atmospheric gas composition created by the packaging or by the commodity. Other factors to consider during fumigation are the penetration of the fumigant, sorption of the fumigant by the packaging or the commodity, and circulation of the fumigant. For circulation of fumigants, ~~NPPOs should take into account~~ the differences in the loading configuration between the commodity loaded in boxes with spacing and the commodity loaded in ~~bulk~~bulk should be taken into account.	P	*Category : SUBSTANTIVE* **(342) Japan (24 9 2018 7:18 午前)** It is not only NPPO's responsibility.	O	
4. Ways of Applying Fumigation					
68	**43. Ways of Applying Fumigation**	P	*Category : EDITORIAL* **(353) Japan (24 9 2018 1:24 午後)**	O	
4.1	Single fumigant treatments				
70	**43.1 Single fumigant treatments**	P	*Category : EDITORIAL* **(354) Japan (24 9 2018 1:24 午後)**	O	
4.2	Combination treatments				

72	**43.2 Combination treatments**	P	*Category : EDITORIAL* **(355) Japan (24 9 2018 1:24 午後)**	O	
73	Where a single fumigant may not achieve the required efficacy without rendering the commodity unmarketable, or for reasons of economy or logistics, combination treatments, refer to the inclusion of another fumigant or the sequential application of another treatment may be ~~included in~~ necessary for the ~~treatment schedule~~treatment.	P	*Category : SUBSTANTIVE* **(343) Japan (24 9 2018 7:23 午前)** Add some words into the explanation about "combination treatments" for clear understanding.	O	
4.3 Fumigation under special conditions					
76	**43.3 Fumigation under special conditions**	P	*Category : EDITORIAL* **(356) Japan (24 9 2018 1:24 午後)**	O	
4.3.1 Fumigation under modified atmosphere					
78	**43.3.1 Fumigation under modified atmosphere**	P	*Category : EDITORIAL* **(357) Japan (24 9 2018 1:25 午後)**	O	
4.3.2 Fumigation under vacuum					
80	**43.3.2 Fumigation under vacuum**	P	*Category : EDITORIAL* **(358) Japan (24 9 2018 1:25 午後)**	O	
5. Enclosures and Equipment used for Fumigation					
82	**~~5~~4. Enclosures and Equipment used for Fumigation**	P	*Category : EDITORIAL* **(359) Japan (24 9 2018 1:25 午後)**	O	
5.1 Enclosures					
84	**~~5~~4.1 Enclosures**	P	*Category : EDITORIAL* **(360) Japan (24 9 2018 1:25 午後)**	O	
85	The enclosure should be a space that can be enclosed in a manner that ensures that appropriate fumigation conditions are maintained throughout the duration of the fumigation. Examples of enclosures include purpose-built fumigation chambers, silos, freight containers, warehouses, ship's holds or tarpaulin "tents". The enclosure should be constructed from materials that maintain adequate fumigant concentrations over the fumigation period and prevent fumigant escape (e.g. materials that are not porous or absorbent to the fumigant). Openings should be sealed effectively. ~~Surfaces~~ Pervious or porous surfaces consisted of such as ~~soil,~~ sand, base rock, wood and paving (stones or blocks) are not a suitable floor for a tent enclosure.	P	*Category : SUBSTANTIVE* **(344) Japan (24 9 2018 7:25 午前)** Not all materials of the surface for fumigation are improper to floor for a tent enclosure. The controversial point is pervious or porous surfaces which may not keep a certain level of concentration. Even if the surface is consisted of soil, the leveled and solidified surface can maintain the effective level of concentration for a tent enclosure. This proposed change is supported by APPPC as well as by Japan.	O	
5.2 Fumigation equipment					
87	**~~5~~4.2 Fumigation equipment**	P	*Category : EDITORIAL* **(361) Japan (24 9 2018 1:26 午後)**	O	
5.2.1 Dosing equipment					
89	**~~5~~4.2.1 Dosing equipment**	P	*Category : EDITORIAL* **(362) Japan (24 9 2018 1:26 午後)**	O	

5.2.2 Gas vaporizer					
91	~~5~~4.2.2 **Gas vaporizer**	P	*Category : EDITORIAL* **(363) Japan (24 9 2018 1:26 午後)**	O	
5.2.3 Heating equipment					
93	~~5~~4.2.3 **Heating equipment**	P	*Category : EDITORIAL* **(364) Japan (24 9 2018 1:27 午後)**	O	
94	Heating equipment should be used to ensure adequate fumigant activity. When it is necessary to raise the temperature of the commodity and the air within the enclosure, exposed heating sources should not be used with flammable fumigants or fumigants that decompose at high temperatures (see Appendix 1 for fumigant chemical properties).	P	*Category : SUBSTANTIVE* **(345) Japan (24 9 2018 7:25 午前)** Move sentences from paragraph 116 to this section because it discribes heating equipment.	O	
5.2.4 Gas circulation equipment					
95	~~5~~4.2.4 **Gas circulation equipment**	P	*Category : EDITORIAL* **(365) Japan (24 9 2018 1:27 午後)**	O	
5.2.5 Instruments to measure moisture content					
97	~~5~~4.2.5 **Instruments to measure moisture content**	P	*Category : EDITORIAL* **(366) Japan (24 9 2018 1:28 午後)**	O	
5.2.6 Instruments to measure vacuum					
100	~~5~~4.2.6 **Instruments to measure vacuum**	P	*Category : EDITORIAL* **(367) Japan (24 9 2018 1:28 午後)**	O	
5.2.7 Instruments to measure temperatures					
102	~~5~~4.2.7 **Instruments to measure temperatures**	P	*Category : EDITORIAL* **(368) Japan (24 9 2018 1:28 午後)**	O	
5.2.8 Instruments to measure gas concentration					
104	~~5~~4.2.8 **Instruments to measure gas concentration**	P	*Category : EDITORIAL* **(369) Japan (24 9 2018 1:29 午後)**	O	
6. Fumigation Procedures					
106	~~6~~5. **Fumigation Procedures**	P	*Category : EDITORIAL* **(370) Japan (24 9 2018 1:29 午後)**	O	
6.1 Commodity loading					
108	~~6~~5.1 **Commodity loading**	P	*Category : EDITORIAL* **(371) Japan (24 9 2018 1:29 午後)**	O	
6.2 Packaging					
110	~~6~~5.2 **Packaging**	P	*Category : EDITORIAL* **(372) Japan (24 9 2018 1:30 午後)**	O	

6.3 Sorption					
112	~~6~~5.3 **Sorption**	P	*Category : EDITORIAL* **(373) Japan (24 9 2018 1:30 午後)**	O	
6.4 Determination of fumigation temperature					
114	~~6~~5.4 **Determination of fumigation temperature**	P	*Category : EDITORIAL* **(374) Japan (24 9 2018 1:30 午後)**	O	
116	The temperatures of the commodity and the atmosphere within the enclosure should be measured and recorded. The lowest temperature recorded in the enclosure or the commodity should be taken as the temperature at which the fumigation is undertaken~~. Fumigation should not proceed if, before or during fumigation, the temperature within the enclosure or the commodity falls to within 3–5 °C of the fumigant boiling point at the atmospheric pressure used. Under such conditions, heating equipment should be used to ensure adequate fumigant activity.. Appendix 1 provides boiling point temperatures for some common fumigants.~~	P	*Category : TECHNICAL* **(346) Japan (24 9 2018 7:27 午前)** The sicentific evidence relared to "within 3–5 °C of the fumigant boiling point at the atmospheric pressure" is unkonwn and the figures vary with fumigants. The information on fumigant boilling point should be considered when treatment schedule is developed, which is not necessary to operate fumigation. The 4th sentence should be modified as " Heating equipment should be used to ensure adequate fumigant activity." and be moved to before the 1st sentence in Section "5.2.3 Heating equipment"	O	
6.5 Gas tightness test					
117	~~6~~5.5 **Gas tightness test**	P	*Category : EDITORIAL* **(375) Japan (24 9 2018 1:31 午後)**	O	
6.6 Introduction of the fumigant					
120	~~6~~5.6 **Introduction of the fumigant**	P	*Category : EDITORIAL* **(376) Japan (24 9 2018 1:31 午後)**	O	
6.7 Measuring and recording					
126	~~6~~5.7 **Measuring and recording**	P	*Category : EDITORIAL* **(377) Japan (24 9 2018 1:31 午後)**	O	
127	When fumigant concentration is measured and recorded, the measurements should be used to verify whether the concentration of fumigant in the enclosure is correct and that there has been no excessive leakage or sorption of the fumigant~~. The fumigation time begins once all the gas has been introduced and has distributed throughout the enclosure. Concentration readings should be taken according to the treatment schedule to ensure that the fumigant is evenly distributed in the enclosure over the duration of the treatment~~. Fumigant concentration should be continuously measured and recorded in sufficient frequency to provide confidence that the required dose has been achieved and maintained and to allow adequate calculations of the concentration–time product (CT) to be made (if required). Concentration readings should also be taken according to the treatment schedule to ensure that the fumigant is evenly distributed in the enclosure over the duration of the treatment.	P	*Category : TECHNICAL* **(347) Japan (24 9 2018 12:40 午後)** The second sentence does not cover all types of fumigation. For example, regarding phosphine fumigation, tablets as well as liquefied gas are often used. Tablets are directly introduced into grains stored in facilities and transport media. Because it takes days to vaporize tablets into gas, this case is not applied to “The fumigation time begins once all the gas has been introduced” The third sentence should be moved to the last sentence and add "also" in the sentence. The most important object of	O	

			concentration reading is to check if the required dose is achieved. To ensure that the fumigant is evenly distributed is the subsequent object.		
6.7.1 Measuring and recording the fumigant concentration					
128	**~~6~~5.7.1 Measuring and recording the fumigant concentration**	P	*Category : EDITORIAL* **(378) Japan (24 9 2018 1:31 午後)**	O	
6.7.2 CT calculation					
131	**~~6~~5.7.2 CT calculation**	P	*Category : EDITORIAL* **(379) Japan (24 9 2018 1:32 午後)**	O	
6.8 Completion of the fumigation					
134	**~~6~~5.8 Completion of the fumigation**	P	*Category : EDITORIAL* **(380) Japan (24 9 2018 1:39 午後)**	O	
135	Once the treatment time has been completed and ~~the required CT,~~ temperature and the required CT or minimum concentration have been achieved, the fumigation should be considered as completed. In circumstances where a minimum CT ~~product~~ or concentration is not initially achieved, a small extension to the fumigation period may be permitted for some fumigant types and fumigation conditions.	P	*Category : TECHNICAL* **(348) Japan (24 9 2018 12:52 午後)** Not all parameters are needed to confirm the completion of fumigation. But the temperature and the required CT or the temperature and minimum concentration is needed to be checked. Concentration at completion time of fumigation, decided by considering sorption, can be used for confirming the completion of fumigation as well as minimum CT.	O	
7. Adequate Systems for Treatment Facilities					
137	**~~7~~6. Adequate Systems for Treatment Facilities**	P	*Category : EDITORIAL* **(381) Japan (24 9 2018 1:40 午後)**	O	
7.1 Authorization of entities					
140	**~~7~~6.1 Authorization of entities**	P	*Category : EDITORIAL* **(382) Japan (24 9 2018 1:41 午後)**	O	
7.2 Monitoring and auditing					
144	**~~7~~6.2 Monitoring and auditing**	P	*Category : EDITORIAL* **(383) Japan (24 9 2018 1:41 午後)**	O	
145	The NPPO of the country in which the fumigation is conducted or initiated is responsible for the monitoring and auditing of treatment entities. Continuous supervision of fumigations should not be necessary, provided treatment ~~programmes~~ protocol are properly designed and can be verified to ensure a high degree of system integrity for the entity, process and commodity in question. The monitoring and auditing should be sufficient to detect and correct deficiencies promptly.	P	*Category : SUBSTANTIVE* **(349) Japan (24 9 2018 12:58 午後)** In conformity with other section in this draft ISPM. According to the report of SC-7 (2018), They recommended not using "treatment programme" because this may cause confusion.	O	
7.3 Prevention of infestation after fumigation					

150	~~7~~6.3 **Prevention of infestation after fumigation**	P	*Category : EDITORIAL* **(384) Japan (24 9 2018 1:41 午後)**	O	
7.4 Labelling					
156	~~7~~6.4 **Labelling**	P	*Category : EDITORIAL* **(385) Japan (24 9 2018 1:42 午後)**	O	
8. Documentation					
158	~~8~~7. **Documentation**	P	*Category : EDITORIAL* **(386) Japan (24 9 2018 1:42 午後)**	O	
159	The NPPO of the country in which the fumigation is conducted or initiated is responsible for ensuring that treatment providers maintain documents of procedures and keep appropriate records, such as raw data on ~~fumigant concentration and temperature~~ treatment parameters recorded during treatment. Accurate record keeping is essential to allow for trace-back capability. The NPPO is also responsible for documentation related to NPPO procedures.	P	*Category : SUBSTANTIVE* **(350) Japan (24 9 2018 1:06 午後)** To include not only "record keeping" but also "documentation of procedures" in this section. Add desctiption of "documentation by the NPPO".	O	
8.1 Documentation of procedures					
160	~~8~~7.1 **Documentation of procedures**	P	*Category : EDITORIAL* **(387) Japan (24 9 2018 1:42 午後)**	O	
161	Procedures should be documented to ensure that commodities are fumigated consistently in accordance with the treatment schedule. Process controls and operational parameters should be established to provide the operational details necessary for a specific authorization of a treatment entity. Calibration and quality control procedures should be documented by the treatment provider. Where appropriate, a written document on procedures should include the following:	P	*Category : SUBSTANTIVE* **(351) Japan (24 9 2018 1:08 午後)** To clarify the requirements on documentation procedures. In conformity with draft ISPM "Requirements for the use of modified atmosphere treatments as phytosanitary measures" and "ISPM 42 Requirements for the use of temperature treatments as phytosanitary measures".	O	
8.2 Record keeping					
170	~~8~~7.2 **Record keeping**	P	*Category : EDITORIAL* **(388) Japan (24 9 2018 1:43 午後)**	O	
=8.3 Documentation by the NPPO					
188	=~~8~~7.3 **Documentation by the NPPO**	P	*Category : EDITORIAL* **(389) Japan (24 9 2018 1:44 午後)**	O	
9. Inspection					
190	~~9~~8.~~.~~ **Inspection**	P	*Category : EDITORIAL* **(390) Japan (24 9 2018 1:44 午後)**	O	
10. Responsibilities					
192	~~10~~9. **Responsibilities**	P	*Category : EDITORIAL* **(391) Japan (24 9 2018 1:45 午後)**	O	