2019 FIRST CONSULTATION

1 July – 30 September 2019

Compiled comments for Draft PT: Irradiation treatment for *Carposina Sasakii* (2017-026)

Summary of comments

Name	Summary	SC Response
Cuba	Estamos de acuerdo con la propuesta de tratamiento, no hay comentarios.	**Bueno**
European Union	Comments submitted by the European Commission on behalf of the European Union and its 28 Member States.	**OK**
Malawi	Malawi supports draft on Irradiation treatment for Carposina sasakii(2017-026)	**OK**
South Africa	The National Plant Protection Organisation of South Africa (NPPOZA) has no comments and therefore accepts this standard.	**OK**

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating

FAO sequential number	Para	Text	T	Comment	SC Response
1	G	(General Comment)	C	**Mexico** I support the document as it is and I have no comments *Category : SUBSTANTIVE*	**OK**
2	G	(General Comment)	C	**Guyana** We support the document in its entirety and have no objection with it moving forward. *Category : SUBSTANTIVE*	**OK**
3	G	(General Comment)	C	**European Union** The comments by the European Union and its 28 Member States are provided without prejudice to EU food safety legislation imposing limitations on the acceptance of irradiated goods. *Category : TECHNICAL*	**OK**
4	G	(General Comment)	C	**Indonesia** Indonesia supports this draft *Category : SUBSTANTIVE*	**OK**

5	G	(General Comment)	C	**Barbados** Barbados has no changes to make to this draft. *Category : EDITORIAL*	**OK**
6	G	(General Comment)	C	**Slovenia** Slovenia would like to formally endorse the EPPO comments submitted via the IPPC Online Comment System. *Category : TECHNICAL*	**OK**
7	G	(General Comment)	C	**Bahrain** no comment *Category : TECHNICAL*	**OK**
8	G	(General Comment)	C	**Congo** i approve the draft annex to ISPM 28 and have nothing to add. *Category : SUBSTANTIVE*	**OK**
9	G	(General Comment)	C	**Australia** Extrapolating from treatment efficacy of 228 Gy on peach fruit moth in apple to 'all fruits and vegetables' without the knowledge of the most-tolerant stage (MTS) is a generalised approach which may not always work for all commodities. MTS needs to be confirmed even if it is not found frequently in the fruit. Identifying MTS provides complete safety against all of the life-stages. The MTS here, the late 5th instar may not be the MTS in another vegetable or fruit and may require higher/lower, although in the latter case it would still be within the proposed treatment schedule. *Category : TECHNICAL*	**Considered, not incorporated** The question over potential for tolerance differences depending on host is addressed in [40] of the draft PT.
10	G	(General Comment)	C	**Thailand** Thailand has no objection on the proposed draft irradiation treatment for Carposina sasakii *Category : SUBSTANTIVE*	**OK**
11	G	(General Comment)	C	**United States of America** 1. The primary research used in support of the proposed treatment is Zhan et al. 2014b. In this study the most radio-tolerant life stage was identified through linear regression of the arcsine transformed mortality data. Use of the arcsine transformation is not ideal, use of a generalized linear model is preferable (Warton and Hui, 2001). The research indicates poor model fit for most stages tested, with the exceptions of Egg and L5. For the probit analysis the 95% confidence intervals overlap for several stages, suggesting the difference in radio-tolerance between stages may not have been as significant as the linear regression of transformed data	**Comments are addressed individually** **1. Considered, not incorporated** Most tolerant stage was based on survival of of larvae of different ages in the fruit. How the developmental times for different instars were estimated was not described. Numerically the larvae determined to L5 exhibited highest survival rates to adult.

				indicated. Furthermore, the upper fiduciary limit for obtaining 99.9968% mortality of some stages (L1 and L2) are higher than the 228 Gy dose recommended. 2. There is no mention of dose mapping exercises used to determine the locations of Dmax and Dmin for the configurations used in the irradiations for the dose response and the confirmatory tests. Were the dosimeters placed in the min/max areas for these tests? If dosimeters were not placed at the area of maximum dose during the confirmatory trials, it is possible that the recommended dose should be increased above 228 to account for the fact that the maximum dose was not determined. The raw dosimetry data, including the spatial arrangement of each data point, would allow for a more thorough review of the treatment application. 3. In the methods section, the researchers report that they calculated the uncertainty of the dosimetry system, so it would have been good to include this information in the results. 4. Zhan et al. 2014 did not provide information on control mortality for the dose response testing. For the confirmatory testing control mortality was provided, and was generally less than 20% (acceptable). 5. The draft annex indicates the work of Li et al. 2016 was used in support of the proposed dose. Further clarification on how Li et al. 2016 strengthens the case for a 228 Gy dose would be useful. For 5th instar larvae Li et al. 2016 found a significant weight increase at higher radiation doses. Li et al. suggested a diapause mechanism may be at play, however they did not elaborate further, nor did they provide information on how a diapause response may affect radio-tolerance and survival to adulthood. 6. Carposina sasakii occurs over a wide geographic area. Information on the potential variation in radio tolerance between populations was not provided in the studies used to support this treatment schedule. In general APHIS prefers that studies use insects that represent the geographic range and potential genetic variation of the organism. 7. APHIS was unable to evaluate the claim that development and radio-tolerance did not differ between C. sasakii reared on hawthorn vs. apple because we didn’t have access to an English translation of the referenced article (Zhan et al. 2014a).	Estimated doses above 228 Gy for L1 and L2 are based on models from low numbers of insects. Models were used to compare tolerance, not to estimate treatment dose. Additionally, comparsions highlight these stages are likely less tolerant than the L5 stage that was used in confirmatory tests. Li et al 2106 also supports L5 as most tolerant. **2. Considered, not incorporated** Dose mapping information is not typically included in treatment submissions. In this case the measured dose rate Gy/min and dose uniformity was reported. The dose uniformity of 1.08 suggests there was good uniformity in the treatment chamber. During the confirmatory testing dosimeters were included in 1/5 of boxes treated to measure variability and boxes were rotated during treatment. The TPPT feels that additional dose mapping data from the submitter would not have an appreciable impact on the efficacy of the treatment or data supporting its adoption. **3. Considered, not incorported** Uncertainty was calculated based on ASTM E1026-13 as referenced. **4. Considered, not incorporated** While it would be nice to have control mortality data for the dose reponse portion. Control mortality in the confirmatory treatment supports the treatment schedule as proposed. **5. Considered, not incorporated** Li et al 2016 supports the 5th instar as most tolerant for PI treatment. **6. Considered, not incorporated.** Speculative comment that irradiation tolerance may vary by geographic location. We are not aware of any studies to support this with other pest species targeted by PI treatments.

				8. Zhan et al. (2014a) states in the English abstract that the mean ED99.9968 for mature larva ranges from 195. 2 to 208. 7 Gy. The upper 95% confidence intervals associated with these ED99.9968 values are as high as 276.4. Thus the upper 95% confidence interval generated in this work falls above the proposed 228 Gy dose. References: Li, B., Gao, M., Liu, B., Li, T., Wang, Y., & Zhan, G. (2016). Effects of irradiation of each of the five peach fruit moth (Lepidoptera: Carposinidae) instars on 5th instar weight, larval mortality and cumulative developmental time: A preliminary investigation. Florida Entomologist, 99(6), 62-66. Warton, D. I., & Hui, F. K. (2011). The arcsine is asinine: the analysis of proportions in ecology. Ecology, 92(1), 3-10. Zhan et al., 2014a. (no English translation provided). Journal of Nuclear Agricultural Sciences, 2014, 28 (3): 0453-0458. Zhan, G., Li, B., Gao, M., Liu, B., Wang, Y., Liu, T., & Ren, L. (2014b). Phytosanitary irradiation of peach fruit moth (Lepidoptera: Carposinidae) in apple fruits. Radiation Physics and Chemistry, 103, 153-157. *Category : TECHNICAL*	**7. Considered, not incorporated.** Comparisons of probit model estimates from Zhan et al 2014a suggest there is no differnece in tolerance between larvae reared on the two plant species. **8. Considered, not incorported.** Probit models often produce large confidence intervals that are not reflective of actual effective doses. In this case confirmatory tests were performed to determine the effective dose for the treatment and establish treatment efficacy.
12	G	(General Comment)	C	**Uruguay** We have no comments on this draft. We agree with the proposal as it is. *Category : TECHNICAL*	**OK**
13	G	(General Comment)	C	**Malawi** Malawi supports draft Irradiation treatment for Carposina sasakii(2017-026) *Category : SUBSTANTIVE*	**OK**
14	G	(General Comment)	C	**Botswana** In agreement with the annex. *Category : TECHNICAL*	**OK**
15	G	(General Comment)	C	**New Zealand** New Zealand supports the standard. Given the efficacy information was extrapolated to cover all hosts we encourage the panel to review the standard should evidence become available to show that the extrapolation of the treatment to cover all hosts of this pest is incorrect. *Category : SUBSTANTIVE*	**Considered, not incorporated** The question over potential for tolerance differences depending on host is addressed in [40]

16	G	(General Comment)	C	**Congo** j'approuve le projet d'annexe à la NIMP 28 *Category : SUBSTANTIVE*	**OK**
17	G	(General Comment)	C	**Cuba** Estamos de acuerdo con la propuesta de tratamiento. *Category : TECHNICAL*	**OK**
18	23	This treatment describes the irradiation of fruits and vegetables at 228 Gy minimum absorbed dose to prevent the emergence of viable adults of *Carposina sasakii* at the stated ~~efficacy.~~ efficacy [1].	P	**European Union** Typo. *Category : EDITORIAL*	**Incorporated**
19	23	This treatment describes the irradiation of fruits and vegetables at 228 Gy minimum absorbed dose to prevent the emergence of viable adults of *Carposina sasakii* at the stated efficacy~~.~~[1].	P	**EPPO** Typo. *Category : EDITORIAL*	**Incorporated**
Treatment schedule					
20	32	Minimum absorbed dose of 228 Gy to prevent the emergence of viable adults of *Carposina sasakii*.when irradiated as eggs and larvae.	P	**China** This standard mainly covers the irradiation of eggs and larvae to prevent them from developing into normal adults. The text here should be consistent with other standards to avoid misunderstanding. *Category : SUBSTANTIVE*	**Considered, not incorported** The treatment schedule is consistent with other irradation treatments in ISPM 28 which do not state which life stage is treated.
21	33	There is 95% confidence that the treatment according to this schedule prevents development of viable adults from not less than 99. ~~9893%~~ 9968% of eggs and larvae of *Carposina sasakii*.	P	**Australia** The dose of 228 Gy is suggested based on the data from testing 30,850 late 5th instars of peach fruit moth in apples preventing an estimated 99.9968% adult emergence at 95% confidence level. as per Zhan et al., 2014 *Category : TECHNICAL*	**Consideration, not incorporated** The stated efficacy of 99.9893% and 95% confidence level are based on testing of 30 580 late 5th instar larvae with no viable adult emergence with consideration of emergence in the control group which was 91.4%. The calculation is included in Appendix 9 of the 2018 TPPT Meeting Report.
Other relevant information					
22	39	The efficacy of this schedule was calculated based on a total of 30 580 late fifth-instar larvae treated with no viable adult emergence; the control emergence was 91.~~4%~~4% when tested in apple fruit.	P	**Australia** Mention in which fruit (and cultivar) it was tested to maintain consistency with other ISPMs that mention the commodity tested. *Category : EDITORIAL*	**Considered, not incorported** It is noted in [38] that the treatment research was done using apple, *Malus pumila*

23	39	The efficacy of this schedule was calculated based on a total of ~~30 580~~ 30,850 late fifth-instar larvae treated with no viable adult emergence; the control emergence was 91.4%.	P	**Australia** Numbers are from Zhan et al., 2014 *Category : EDITORIAL*	**Considered, not incorporated** See the response in 21.
24	40	Extrapolation of treatment efficacy to all fruits and vegetables was based on knowledge and experience that radiation dosimetry systems measure the actual radiation dose absorbed by the target pest independent of host commodity, and evidence from research studies on a variety of pests and commodities. These include studies on the following pests and hosts: *Anastrepha fraterculus* (*Eugenia uvalha*, *Malus* ~~*pumila*,~~ *pumila* and *Mangifera indica*); *A. ludens* (*Citrus paradisi*, *Citrus sinensis*, ~~and~~ *M. indica* and artificial diet), *A. obliqua* (*Averrhoa carambola*, *C. sinensis*~~,~~ ~~and~~ and *Psidium guajaba*); *A. suspensa* (*A. carambola*, *C. paradisi* and *M. indica*), *Bactrocera tryoni* (*C. sinensis*, *Solanum lycopersicum*, *Malus domestica*, *M. indica*, *Persea americana* and *Prunus avium*), *Pseudococcus jackbeardsleyi* (*Cucurbita* sp. and *Solanum tuberosum*), *Tribolium confusum* (*Triticum aestivum*, *Hordium vulgare* and *Zea mays*), *Cydia pomonella* (*M. pumila* and artificial diet) and *Grapholita molesta* (*M. pumila* and artificial diet) (Bustos *et al.*, 2004; Gould and von Windeguth, 1991; Hallman, 2004a, ~~2004b~~2004b and~~,~~ 2013; Hallman and Martinez, 2001; Hallman *et al.*, 2010; Jessup *et al.*, 1992; Mansour, 2003; Tuncbilek and	P	**European Union** Typos. *Category : EDITORIAL*	**Noted** The issue will be addressed by the IPPC editor in alignment with the FAO and IPPC Style Guide.

		Kansu, 1966; von Windeguth, 1986; von Windeguth and Ismail, 1987; Zhan *et al*., 2016). It is recognized, however, that treatment efficacy has not been tested for all potential fruit and vegetable hosts of the target pest. If evidence becomes available to show that the extrapolation of the treatment to cover all hosts of this pest is incorrect, the treatment will be reviewed.			
25	40	Extrapolation of treatment efficacy to all fruits and vegetables was based on knowledge and experience that radiation dosimetry systems measure the actual radiation dose absorbed by the target pest independent of host commodity, and evidence from research studies on a variety of pests and commodities. These include studies on the following pests and hosts: *Anastrepha fraterculus* (*Eugenia uvalha*, *Malus* ~~*pumila*,~~ *pumila* and *Mangifera indica*); *A. ludens* (*Citrus paradisi*, *Citrus sinensis*, ~~and~~ *M. indica* and artificial diet), *A. obliqua* (*Averrhoa carambola*, *C. sinensis*~~,~~ ~~and~~ and *Psidium guajaba*); *A. suspensa* (*A. carambola*, *C. paradisi* and *M. indica*), *Bactrocera tryoni* (*C. sinensis*, *Solanum lycopersicum*, *Malus domestica*, *M. indica*, *Persea americana* and *Prunus avium*), *Pseudococcus jackbeardsleyi* (*Cucurbita* sp. and *Solanum tuberosum*), *Tribolium confusum* (*Triticum aestivum*, *Hordium vulgare* and *Zea mays*), *Cydia pomonella* (*M. pumila* and artificial diet) and *Grapholita molesta* (*M. pumila* and artificial diet) (Bustos *et al*., 2004; Gould and von	P	**EPPO** Typos. *Category : EDITORIAL*	**Noted** The issue will be addressed by the IPPC editor in alignment with the FAO and IPPC Style Guide.

		Windeguth, 1991; Hallman, 2004a, 2004b~~,~~ <u>and</u> 2013; Hallman and Martinez, 2001; Hallman *et al*., 2010; Jessup *et al.*, 1992; Mansour, 2003; Tuncbilek and Kansu, 1966; von Windeguth, 1986; von Windeguth and Ismail, 1987; Zhan *et al*., 2016). It is recognized, however, that treatment efficacy has not been tested for all potential fruit and vegetable hosts of the target pest. If evidence becomes available to show that the extrapolation of the treatment to cover all hosts of this pest is incorrect, the treatment will be reviewed.			
26	40	Extrapolation of treatment efficacy to all fruits and vegetables was based on knowledge and experience that radiation dosimetry systems measure the actual radiation dose absorbed by the target pest independent of host commodity, and evidence from research studies on a variety of pests and commodities. These include studies on the following pests and hosts: *Anastrepha fraterculus* (*Eugenia uvalha*, *Malus pumila*, and *Mangifera indica*); *A. ludens* (*Citrus paradisi*, *Citrus sinensis*, and *M. indica* and artificial diet), *A. obliqua* (*Averrhoa carambola*, *C. sinensis*, and *Psidium guajaba*); *A. suspensa* (*A. carambola*, *C. paradisi* and *M. indica*), <u>*Bactrocera dorsalis (Psidium guajava), B. tau (Cucurbita maxima),*</u> *Bactrocera tryoni* (*C. sinensis*, *Solanum lycopersicum*, *Malus domestica*, *M. indica*, *Persea americana* and *Prunus avium*), *Pseudococcus jackbeardsleyi* (*Cucurbita* sp. and *Solanum tuberosum*),	P	**China** These researches are suggested adding to this paragraph and relevant references are added. These researches have been published and adopted for developing the draft Annexes to ISPM 28. *Category : SUBSTANTIVE*	**Considered, not incorporated** The additional publications suggested do not support extrapolation of efficacy for a single treatment across multiple hosts as each only evaluated PI treatment in single host.

		Tribolium confusum (*Triticum aestivum*, *Hordium vulgare* and *Zea mays*), *Cydia pomonella* (*M. pumila* and artificial diet) and *Grapholita molesta* (*M. pumila* and artificial diet) (Bustos *et al.*, 2004; Gould and von Windeguth, 1991; Hallman, 2004a, 2004b, 2013; Hallman and Martinez, 2001; Hallman *et al*., 2010; Jessup *et al.*, 1992; Mansour, 2003; Tuncbilek and Kansu, 1966; von Windeguth, 1986; von Windeguth and Ismail, 1987; Zhan *et al*., 2016). It is recognized, however, that treatment efficacy has not been tested for all potential fruit and vegetable hosts of the target pest. If evidence becomes available to show that the extrapolation of the treatment to cover all hosts of this pest is incorrect, the treatment will be reviewed.			
References					
27	48	**Hallman, G.J., Levang-Brilz, N.M., Zettler, J.L. & Winborne, I.C.** 2010. Factors affecting ionizing radiation phytosanitary treatments, and implications for research and generic treatments. *Journal of Economic Entomology*, 103:~~1950-1963~~1950–1963.	P	**European Union** Typo. *Category : EDITORIAL*	**Incorporated**
28	48	**Hallman, G.J., Levang-Brilz, N.M., Zettler, J.L. & Winborne, I.C.** 2010. Factors affecting ionizing radiation phytosanitary treatments, and implications for research and generic treatments. *Journal of Economic Entomology*, 103:~~1950-1963~~1950–1963.	P	**EPPO** Typo. *Category : EDITORIAL*	**Incorporated**

29	51	**Li, B., Gao, M., Liu, B., Li, T., Wang, Y. & Zhan, G.** 2016. Effects of irradiation of each of the five peach fruit moth (Lepidoptera: Carposinidae) instars on 5th instar weight, larval mortality and cumulative developmental time: A preliminary investigation. *Florida Entomologist*, 99 (Special issue 2): ~~62 –66~~62–66.	P	**European Union** Typo. *Category : EDITORIAL*	**Incorporated**
30	51	**Li, B., Gao, M., Liu, B., Li, T., Wang, Y. & Zhan, G.** 2016. Effects of irradiation of each of the five peach fruit moth (Lepidoptera: Carposinidae) instars on 5th instar weight, larval mortality and cumulative developmental time: A preliminary investigation. *Florida Entomologist*, 99 (Special issue 2): ~~62 –66~~62–66.	P	**EPPO** Typo. *Category : EDITORIAL*	**Incorporated**
31	51	**Li, B., Gao, M., Liu, B., Li, T., Wang, Y. & Zhan, G.** 2016. Effects of irradiation of each of the five peach fruit moth (Lepidoptera: Carposinidae) instars on 5th instar weight, larval mortality and cumulative developmental time: A preliminary investigation. *Florida Entomologist*, 99 (Special issue 2): 62–-66.	C	**China** Same Journal, same author, but different name format. The format of 2 references from the same journal should be uniform. *Category : EDITORIAL*	**Incorporated**
32	53	**Tuncbilek, A.S. & Kansu, I.A.** 1966. The influence of rearing medium on the irradiation sensitivity of eggs and larvae of the flour beetle, *Tribolium confusum* J. du Val. *Journal of Stored Products Research* 32: ~~1-6~~1–6.	P	**European Union** Typo. *Category : EDITORIAL*	**Incorporated**
33	53	**Tuncbilek, A.S. & Kansu, I.A.** 1966. The influence of rearing medium on the irradiation sensitivity of eggs and larvae of the flour beetle, *Tribolium confusum* J. du	P	**EPPO** Typo. *Category : EDITORIAL*	**Incorporated**

		Val. *Journal of Stored Products Research* 32: ~~1-6~~1–6.			
34	56	**Zhao, J.P., Ma, J., Wu, M.T, Jiao, X.G., Wang, Z.G, Liang, F. & Zhan, G.P.** 2017. Gamma radiation as a phytosanitary treatment against larvae and pupae of Bactrocera dorsalis (Diptera: Tephritidae)**Zhan, G., Li, B., Gao, M., Liu, B., Wang, Y., Liu, T. & Ren, L.** 2014. Phytosanitary irradiation of peach fruit moth (Lepidoptera: Carposinidae) in apple fruits. *Radiation Physics and Chemistry*, 103: 153–157.**Zhan, G.P., Ren, L.L., Shao, Y., Wang, Q.L., Yu, D.J., Wang, Y.J. & Li, T.X.** 2015. Gamma irradiation as a phytosanitary treatment of Bactrocera tau (Diptera: Tephritidae) in pumpkin fruits. Journal of Economic .Entomology, 108(1): 88–94	P	**China** These researches have been published and adopted for developing the draft Annexes to ISPM 28. *Category : SUBSTANTIVE*	**Considered, not incorporated** The additional publications suggested do not support extrapolation of efficacy for a single treatment across multiple hosts as each only evaluated PI treatment in single host.
35	57	**Zhan, G.P., Shao, Y., Yu, Q., Xu, L., Liu, B., Wang, Y.J. & Wang, Q.L.** 2016.	P	**European Union** Typo. *Category : EDITORIAL*	**Incorporated**
36	57	**Zhan, G.P., Shao, Y., Yu, Q., Xu, L., Liu, B., Wang, Y.J. & Wang, Q.L.** 2016.	P	**EPPO** Typo. *Category : EDITORIAL*	**Incorporated**
37	57	**Zhan, G.P., Shao, Y., Yu, Q., Xu, L., Liu, B., Wang, Y.J. & Wang, Q.L.** 2016.	C	**China** Same Journal, same author, but different name format. The format of 2 references from the same journal should be uniform. *Category : EDITORIAL*	**Incorporated**