Crop Protection 139 (2021) 105287

Contents lists available at ScienceDirect

Crop Protection

journal homepage: www.elsevier.com/locate/cropro

The importance of distinguishing between demonstrating the efficacy and implementation of phytosanitary systems approaches

A R T I C L E I N F O

Keywords
Fruit fly
IPPC
Market access
Pest risk assessment
Phytosanitary systems approaches
Trade
WTO

A B S T R A C T

A risk framework including four risk reduction objectives was developed to guide the selection of the most effective, least trade restrictive measures for use in phytosanitary systems approaches. Here we discuss its role in relation to control points, verification and traceability systems. Development of systems approaches is typically a two-step process, identifying and assessing measures to reduce pest risk to set a phytosanitary import requirement for a regulated article, and then agreeing on how those measures are to be implemented within a protocol or work plan. The risk framework was explicitly designed to address the first step, by classifying proposed measures according to how they reduce risk. We argue that control points, verification and traceability systems are most relevant to the implementation of protocols. Control points focus on where and when specific measures can be applied to mitigate risk, and should not be used as the basis for determining how the measures manage risk as measures applied at the one control point can manage risk in very different ways and times. Continued effort is required to develop, test and harmonise concepts that underpin phytosanitary systems approaches.

1. Introduction

Phytosanitary systems approaches, where two or more independent measures are combined to manage pest risk, are designed to meet phytosanitary import requirements for plants, plant products and other regulated articles (FAO, 2017b). In our recent paper (van Klinken et al., 2020) we outlined a risk framework to assist with the development and analysis of systems approaches. This framework classifies phytosanitary measures according to how they reduce risk (against four risk reduction objectives) across three production stages (pre-harvest, from harvest to phytosanitary certification and post-certification). A recent commentary on that paper by Quinlan et al. (2020) confirms the interest in systems approaches and the benefits in progressing the underpinning science. Although broadly supportive of our risk framework, they argued that we did not pay sufficient attention to the use of control points, traceability systems and the verification of measures. We agree that these aspects are critical, but argue that they relate to the implementation of practical and verifiable systems approaches rather than to demonstrating its efficacy in managing identified risks. Our risk framework was developed to address the latter. We argue here that this distinction between demonstrating efficacy and the implementation of protocols is important as measures applied at the same control point can manage risk in different ways and times. Here we further clarify this distinction, and also examine the role of traceability and verification within a systems approach. To assist with this we use a case study recently published by the authors where they used “production chains” and a Bayesian network to determine how measures within a systems approach reduces risk within a proposed protocol (Quinlan et al., 2016; Holt et al., 2018). This is a fairly typical protocol to what is seen in active trade (van Klinken et al., 2020).

2. Assessment of efficacy versus protocol implementation

According to ISPM 11 (FAO, 2017a), pest risk analysis includes both a risk assessment stage and a pest risk management stage, but does not specify how pest risk management actions will be implemented. At the core of pest risk management are phytosanitary measures that demonstrably reduce risk (are efficacious), and that can be monitored or controlled by the responsible National Plant Protection Organization (NPPO) (FAO, 2017b). Our risk framework (van Klinken et al., 2020) is specifically designed to help develop and assess the ability of measures to manage risk, individually and in combination. In that sense, we agree with Quinlan et al. (2020), that our risk framework serves a different purpose to their use of control points, the primary function of which we argue is to help determine how measures are to be applied and verified. Both demonstrating the efficacy of measures (individually and in combination) and ensuring proper implementation are clearly important in the development of systems approaches, but in trade negotiations they are typically treated as distinct phases (IAEA, 2011).

We did not find an agreed definition for how the control point concept applies to biosecurity, which contributes to the confusion around its application. This concept is derived from Hazard Analysis and Critical Control Points which was first proposed in 1971 and is now widely applied to food safety. The CODEX Alimentarius or “Food Code” defines a critical control point (CCP) as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (CODEX Alimentarius Commission, 1997). Here we refer to control points as being *where and when a specific risk management activity is applied.* To be a measure, such activities also have to be measurable and verifiable (FAO, 2017b), but sometimes verification is done at a different place or time to the risk mitigation activity. For example, sorting of fruit during harvest could be audited at the pack-house. Control points have also been defined by others to

https://doi.org/10.1016/j.cropro.2020.105287
Received 8 June 2020; Accepted 9 June 2020
Available online 24 June 2020

Table 1
Illustration of the relationship between our risk framework and control points when classifying measures, using fruit fly on dragon fruit in Vietnam as a case study. Measures and control points were inferred from Quinlan et al. (2016) and Holt et al. (2018). Measures were then classified against our risk framework (van Klinken et al., 2020) rather than the measure objectives identified in the production chain presented by Quinlan et al. 2016, (Fig. 8.1).

Production stage where risk is managed Control points	Measure	Risk reduction objective		Notes
		Minimise pest exposure	Reduce infestation rate	
PRIMARY INFESTATION				
Production stage: Pre-harvest				
Plant and preparing	Field sanitation at start of season	Pest management (field hygiene)		
Field/orchard/farm	Pheromone traps/MAT	Pest management (trapping)		
Field/orchard/farm	Protein bait	Pest management (baiting)		
Field/orchard/farm	Insecticide cover sprays	Pest management (spraying)	Kill pest in fruit (if systemic)	The type of spray was not specified, but systemic insecticides can address two risk reduction objectives.
Field/orchard/farm	Fruit bagging	Pest exclusion		
Field/orchard/farm	(Pest surveillance)[a]	Pest monitoring		Surveillance would become a measure if combined with a consequence (e.g. corrective action above a threshold)
Harvesting	Reject and fallen fruit collected and destroyed at each harvest time during fruiting season	Pest management (field hygiene)		Although control point is at harvest time, it reduces pre-harvest risk for remaining fruit and subsequent harvests
Production stage: From harvest to certification				
Harvesting	Sorted at harvest to remove all damaged and infested fruit[a]		Remove infested fruit and damaged fruit at increased risk of being infested	
Treatment, packing	Sorting in packhouse to remove damaged and infested fruit		Remove infested fruit	
Treatment, packing	Vapour heat treated		Kill pest in fruit (heat)	Also addresses post-harvest infestation risk (see below)
Treatment, packing	Quarantine inspected (post-packed) prior to PC signing, rejection of substandard lots[a]		Inspect and reject “consignment” during certification	Classified as “measure of implementation”, but also meets requirements for being a measure in own right (van Klinken et al., 2020)
PREVENT POST-HARVEST INFESTATION				
Production stage: From harvest to certification				
Harvesting	Harvested fruit kept in shade, in plastic boxes with insect netting for prompt transportation to processing facility	Segregation and safeguarding		
Harvesting	Harvested fruit held in pest-proof containers while awaiting packing	Segregation and safeguarding		
Treatment, packing	Vapour heat treated		Kill pest in fruit (heat)	This treatment would also kill any post-harvest infestation up until this point
Treatment, packing	Packing boxes manufactured to high standard with ventilation holes covered in mesh to prevent insect entry, with rejection of substandard boxes	Segregation and safeguarding		
Production stage: Post certification				
Export from country	Consignments transported only in sealed refrigerated vehicles	Segregation and safeguarding		

[a] These times where level of pest challenge could be estimated were also referred to as control points in Holt et al. (2018).

include both the management activity and its measurement and verification (Quinlan et al., 2016, p. 66), to only include where and when verification of either the individual measure or the overall systems approach takes place (IAEA, 2011); or be where it is possible to obtain an estimate of pest infestation (Quinlan et al., 2016, p. 110; Holt et al., 2018). As we use the term here, control points can vary from being very specific (e.g. sorting of fruit conducted at harvest) to diffuse (e.g. some pre-harvest pest management treatments) (Table 1). Control points have also been defined more loosely as being where risk management measures *could be* applied (Quinlan and Ikin, 2009; FAO, 2017b; Allen et al., 2017). This can result in quite broad categorisations, such as pre-harvest, harvest, post-harvest, processing, pre-shipping storage, transport and post-shipping in the case of forest products (Allen et al., 2017), which is akin to production stages (IAEA, 2011; FAO, 2017b; van Klinken et al., 2020). Although diverse, one thing that these definitions for control points have in common is that they do not explicitly consider how a measure manages risk, or how measures combine to do so.

Our risk framework focusses on how measures reduce risk. It thereby provides a harmonised list of objectives for measures as advocated by Quinlan et al. (2020). It identifies four ways in which risk can be reduced, namely: i) minimising exposure to pests when the commodity is vulnerable; ii) minimising host vulnerability; iii) reducing infestation rate; and iv) reducing establishment likelihood (van Klinken et al., 2020). The risk framework is intended to assist with the development of measures that reduce risk to acceptable levels as determined by pest risk assessment. In so doing, it effectively collates measures that manage risk in similar ways, irrespective of the exact point along the production chain they occur and who applies them. This works to cut complexity by focusing on the effect and outcome of certain types of activities. How these are subsequently applied within a protocol thereby remains flexible.

The protocols and work schedules we revised for our risk framework paper (van Klinken et al., 2020) rarely included information on the efficacy of measures as this was not their purpose. Rather, they are focussed on operational aspects (IAEA, 2011). Production chains and control points are useful concepts here for designing and implementing protocols. They help show exactly what measures must be applied when, who is responsible, who will ensure it is done and what the consequence will be for responsible parties if it isn't done.

In Table 1 we summarise the proposed measures and control points for the Vietnam dragon fruit case study (Quinlan et al., 2016; Holt et al., 2018), and then assign them against the three production stages and four risk reduction objectives in our risk framework.

The proposed measures addressed two of the four risk reduction objectives: minimising exposure to pests and reducing infestation rates. No measures addressed the remaining two risk reduction objectives, minimising host vulnerability or reducing establishment risk. This is typical of existing protocols, at least based on publicly available material (van Klinken et al., 2020), suggesting that measures addressing these latter risk reduction objectives are underutilised.

Measures were classified similarly by Quinlan et al. (2016) and us, but the few differences are instructive.

2.1. Pre-harvest measures

We classified seven proposed measures as reducing pre-harvest risks, namely five pest management measures, one pest exclusion measure and a surveillance measure (Table 1). Although the control point for the measure requiring reject and fallen fruit to be destroyed is at harvest, it reduces the risk of unharvested fruit being exposed to the pest (either in the current or following season). Thus, measures can be classified differently depending on whether a risk management (risk framework) or implementation (control point) perspective is taken.

All pre-harvest measures in the dragon fruit protocol reduces the risk of vulnerable fruit being exposed to pests. The type of insecticide in the proposed cover spray measure was not stated, but one with systemic effects would also simultaneously address a second risk reduction objective by killing eggs and larvae in fruit prior to harvest (Table 1) (Rahman and Broughton, 2016). Individual measures can therefore simultaneously reduce risk in multiple ways.

Measures to reduce exposure of fruit to pests mostly relied on pest management. This included hygiene practices conducted at the start of the season and at harvest, and IPM and surveillance measures applied variously throughout the growing season (Table 1). From a risk perspective the critical question is not when the measure was applied but how they combine to reduce exposure to pests when fruit are vulnerable. For fruit flies that is typically the weeks leading up to harvest though this varies according to fruit type and fruit fly species (Clarke, 2019). In the proposed dragon fruit protocol evidence would be needed to demonstrate that pre-season and at-harvest hygiene practices contributed significantly to late-season pest pressure, for example. In contrast to the pest management measures, fruit bagging acts through excluding flies from the fruit. If effectively applied it can reduce exposure to pests to near-zero, irrespective of pest pressure and the efficacy of pest management measures.

Surveillance (through in-field trapping) needs to be coupled with an action threshold and associated action if it is to reduce risk (IAEA, 2011; van Klinken et al., 2020). Where reported, publicly available protocols either use a threshold-triggered corrective action (such as cover sprays) or exclusion of the block or area from the protocol (van Klinken et al., 2020). A properly defined threshold-triggered corrective action enables the systems approach to be dynamic, as advocated by Quinlan et al. (2020), whilst remaining within tight parameters built into the control measure's effective application. From a risk perspective a simplified systems approach can rely on surveillance and response as the "independent measure" (IAEA, 2011), provided the surveillance technology and thresholds are well supported. Integrated pest management then becomes either a way of keeping populations under that threshold, or provides additional confidence where surveillance with a threshold-triggered corrective action is not considered to be sufficient on its own.

2.2. Post-harvest measures to reduce infestation rates

Four measures were suggested to reduce fruit infestation rates from point of harvest: sorting measures at two different control points, vapour heat treatment and inspection of post-packed fruit (Table 1). These reduce risk in quite different ways. Fruit sorting seeks to identify and remove infested fruit (symptom grading) or fruit that are at higher risk of being infested (quality grading) and is sensitive to detection efficacy (Ekramid et al., 2016). Vapour heat treatment is a kill step that will kill all or a proportion of pests in all fruit. Inspection of post-packed fruit is common to most protocols, although most often as a general verification that conditions have been met and to identify gross contamination (IAEA, 2011; van Klinken et al., 2020) and typically results in the whole consignment being rejected if a pest is found. Fruit inspection, with rejection of the consignment, property or area, can also be conducted pre-harvest, and at any time from point of harvest to receival by the importing jurisdiction (van Klinken et al., 2020).

2.3. Measures to reduce post-harvest infestation risks

We separated measures that address primary infestation risk from those that address risk of post-harvest infestation as they represent distinct risks that are normally addressed within a systems approach through unique measures. This differs to Holt et al. (2018) where all measures were combined in a single Bayesian network. Measures to reduce post-harvest infestation risks are not unique to systems approach protocols (van Klinken et al., 2020), but they may differ in degree. With the dragon fruit example most measures related to safeguarding and segregating the fruit, with tighter measures recommended from point of harvest than might be required if a post-harvest disinfestation treatment was being applied (Table 1). Vapour heat treatment addresses both primary infestation risk and the risk of post-harvest infestation up until the point of treatment.

2.4. Implications for analysing risk

A key challenge for the development of systems approaches is to demonstrate how measures combine to manage risk to an appropriate level (IAEA, 2011; van Klinken et al., 2020). A range of qualitative and quantitative approaches have been suggested and applied (Jamieson et al., 2016; Holt et al., 2018), although most focus primarily on a single risk reduction objective such as reducing pest infestation rates (Moore et al., 2016). Control points, with their focus on when and where measures are applied rather than how they reduce risk, can be misleading when used as a basis for the pest risk management phase of risk analysis. For example, in the dragon fruit case study, it would require combining at-harvest measures that contribute to reducing fruit infestation rates (sorting) and reducing in-field pest pressure (hygiene), rather than modelling the combined effect of sorting at-harvest and in the pack-house, and of hygiene on pest management.

3. Other components of systems approaches: verification and traceability

A second concern with our risk framework (van Klinken et al., 2020) expressed by Quinlan et al. (2020) was that it did not adequately consider elements such as verification and traceability. Although not unique to systems approaches, we agree that these elements are critical components of phytosanitary measures and protocols. However, the distinction between designing a risk management measure and implementing them is again important here.

Verification steps (such as thermal treatment readings or inspection of exclusion structures) are typically agreed upon between trading parties once the systems approach (or other conditions) has been designed and is being documented as a Work Plan or Protocol for Export (IAEA, 2011). The need for verification can put constraints on what measures are possible to implement (e.g. the application of some pest management measures will be more verifiable than others), but not how efficacious a measure is. We therefore did not include it as part of our risk framework.

Good traceability systems are a requirement for all protocols, irrespective of whether they are based on systems approaches. This is consistent with ISPM 7 (FAO, 2011) on export certification systems which states that consignments need to be traceable "*through all stages of production, handling and transport prior to export*". We therefore consider traceability primarily as an auditable requirement rather than a measure as it does not clearly contribute to risk reduction on its own. However, traceability systems can contribute to a wide range of measures within a systems approach. In the dragon fruit case study traceability systems were not explicitly included as a measure (Holt et al., 2018), but are likely to contribute to implementation and verification of segregation and safeguarding measures (Table 1). It can also be important for enacting corrective actions, such as the rejection of consignments following quarantine inspections.

The need for effective verification and traceability systems is arguably more acute for systems approaches where more diverse measures may need to be applied throughout the supply chain. The associated cost and complexity of more detailed verification and traceability systems may present a barrier to the adoption of systems approaches. There is therefore considerable scope for innovation in automated compliance and digital traceability systems to support the implementation and uptake of systems approaches (Groefsema et al., 2020).

4. Conclusions

We support the conclusion made in Quinlan et al. (2020) that if systems approaches are to realise their potential in supporting global trade, there are real opportunities and need to strengthen and harmonise the underpinning science. We welcome continued development, testing and debate towards this common goal. Maintaining a clear distinction between how measures manage risk and how they are implemented will be key to this. As illustrated in the worked example here, our risk framework provides a mechanism for understanding how measures contribute to risk reduction, singly and in combination. However, many challenges remain to be worked through, including development of harmonised methodologies to determine the efficacy of systems approaches (IAEA, 2011), and the refinement of key concepts such as control points as they apply to phytosanitary systems approaches.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We thank Matthew Hill, Ryan McAllister, Craig Hull, Matthew Smyth and Touhidur Rahman for comments on a draft. The project, Developing a national systems approach for meeting biosecurity requirements to access key Asian Markets, was funded by the Hort Frontiers Asian Markets Fund, and is part of the Hort Frontiers strategic partnership initiative developed by Hort Innovation, with co-investment from CSIRO, WA DPIRD, NSW DPI, Agriculture Victoria, and contributions from the Australian Government.

References

Allen, E., Noseworthy, M., Ormsby, M., 2017. Phytosanitary measures to reduce the movement of forest pests with the international trade of wood products. Biol. Invasions 19, 3365–3376.

Clarke, A.R., 2019. Biology and Management of Bactrocera and Related Fruit Flies. CABI.

Codex Alimentarius Commission, 1997. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. Annex to CAC/RCP 1-1969. Rev. 3. Joint FAO/WHO Food Standards Programme. Viewed 30 June 2020. http://www.fao.org/3/y1579e/y1579e03.htm.

Ekramid, N., Adedeji, A.A., Alimardani, R., 2016. A review of non-destructive methods for detection of insect infestation in fruits and vegetables. Innovations in Food Research 2, 6–12.

FAO, 2011. Phytosanitary Certification System. International Standard for Phytosanitary Measures No.7. IPPC, Rome, p. 10. Published by FAO on Behalf of the Secretariat of the International Plant Protection Convention.

FAO, 2017a. ISPM 11. Pest Risk Analysis of Quarantine Pests. International Standard for Phytosanitary Measures No.14. IPPC, Rome, p. 37. Published by FAO on Behalf of the Secretariat of the International Plant Protection Convention.

FAO, 2017b. The Use of Integrated Measures in a Systems Approach for Pest Risk Management. International Standard for Phytosanitary Measures No.14. IPPC, Rome, p. 16. Published by FAO on Behalf of the Secretariat of the International Plant Protection Convention.

Groefsema, H., van Beest, N., Armas-Cervantes, A., 2020. Efficient conditional compliance checking of business process models. Comput. Ind. 115, 103181.

Holt, J., Leach, A.W., Johnson, S., Tu, D.M., Nhu, D.T., Anh, N.T., Quinlan, M.M., Whittle, P.J.L., Mengersen, K., Mumford, J.D., 2018. Bayesian networks to compare pest control interventions on commodities along agricultural production chains. Risk Anal. 38, 297–310.

IAEA, 2011. FAO/IAEA Guidelines for Implementing Systems Approaches for Pest Risk Management of Fruit Flies - Working Material. FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, Vienna, Austria, 7 - 11 June 2010.

Jamieson, L., Woodberry, O., McDonald, C., Ormsby, M., 2016. Developing a generic biosecurity risk assessment model for imports. N. Z. Plant Protect 69, 186–199.

Moore, S.D., Kirkman, W., Hattingh, V., 2016. Verification of inspection standards and efficacy of a systems approach for *Thaumatotibia leucotreta* (Lepidoptera: tortricidae) for export citrus from South Africa. J. Econ. Entomol. 109, 1564–1570.

Quinlan, M.M., Ikin, R., 2009. PRATIQUE PD. No. 4.2. A review of the Application of Systems Approach to Risk Management in Plant Health, 69. https://secure.fera.defra.gov.uk/pratique/publications.cfm?deliverables=1#fldr_D4. (Accessed 20 May 2019).

Quinlan, M.M., Mengersen, K., Mumford, J., Leach, A., Holt, J., Murphy, R., 2016. Beyond Compliance: A Production Chain Framework for Plant Health Risk Management in Trade. Chartridge Books, Oxford.

Quinlan, M.M., Leach, A., Mumford, J., 2020. Classification of objectives in Systems Approaches to manage horticultural biosecurity risks for market access. Crop Protect. (in press).
Rahman, T., Broughton, S., 2016. Evaluation of thiacloprid and clothianidin (neonicotinoids) as alternative to fenthion (organophosphate) for control of Mediterranean fruit fly (Diptera: tephritidae) in deciduous fruit orchards. Crop Protect. 90, 170–176.
van Klinken, R.D., Fiedler, K., Kingham, L., Collins, K., Barbour, D., 2020. A risk framework for using systems approaches to manage horticultural biosecurity risks for market access. Crop Protect. 129, 1–12. https://doi.org/10.1016/j.cropro.2019.104994, 104994.

Rieks D. van Klinken*
CSIRO, GPO Box 2583, Brisbane, QLD, 4001, Australia

Kathryn Fiedler
CSIRO, GPO Box 2583, Brisbane, QLD, 4001, Australia

Lloyd Kingham
Wagga Wagga Agricultural Institute, New South Wales Department of Primary Industries, PMB Pine Gully Road, Wagga Wagga, NSW, 2800, Australia

Darryl Barbour
Plant Health Australia, Level 1 Phipps Close, Canberra, ACT, Australia

* Corresponding author.
E-mail address: rieks.vanklinken@csiro.au (R.D. van Klinken).