

Meeting Report
AGPP/IPPC/1998

**EXPERT CONSULTATION ON THE STRENGTH OF MEASURES
FOR REGULATED PESTS
WHICH HAVE A MINOR BIOLOGICAL IMPACT**

Rome, Italy : 2-5 June 1998



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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1. OPENING OF MEETING

The Expert Consultation was organized by the Secretariat of the International Plant Protection Convention (IPPC) as part of the work programme for the international harmonization of phytosanitary measures. It was hosted by FAO at Rome Headquarters with financial assistance provided by the North American Plant Protection Organization.

The experts were asked to evaluate the issue of "strength of measures" for regulated pests in light of the World Trade Organization "Agreement on the Application of Sanitary and Phytosanitary Measures" (SPS Agreement), the IPPC, and existing and draft international standards for phytosanitary measures (ISPMs), particularly those relating to pest risk analysis. The meeting used Karnal bunt as a case study, with the objective of reaching conclusions having implications for all pests.

The proceedings of the meeting provide the IPPC Secretariat with reference material for further development within the work programme of the IPPC, including recommendations for possible consideration by the Interim Commission on Phytosanitary Measures.

2. WELCOME ADDRESS AND INTRODUCTION

Dr M. Duwaryi, Director, FAO Plant Production and Protection Division, welcomed the experts and outlined the need to explore more broadly the area of "strength of measures" for regulated pests. He noted that the meeting was not expected to resolve all the issues relating to these pests, but rather to begin to clarify the issues and provide some fundamental points of reference for the Secretariat to use in wider consultation.

Dr N.A. Van der Graaff, Chief, FAO Plant Protection Service, noted the experimental nature of this consultation on a very topical issue, and looked forward to the experts providing useful guidance on the subject.

Mr R. Griffin, Coordinator of the IPPC Secretariat, addressed the group of international scientists, risk analysts and regulatory specialists, encouraging their full exploration of the issues, considering their various scientific and regional views. He noted that the recommendations of the meeting could assist in the development of international standards, guidelines and recommendations for phytosanitary measures.

The Provisional Agenda (Annex I) was accepted.

3. OVERVIEW OF MAIN ISSUES AND BACKGROUND OF CASE STUDY

Three key areas were discussed as sources of important background for the meeting: the SPS Agreement; the International Plant Protection Convention, specifically the New Revised Text of the IPPC approved by the FAO Conference in November 1997; and pest risk analysis (PRA).

It was noted that the SPS Agreement requires members to ensure that their phytosanitary measures are based on a risk assessment that draws upon scientific and technical information as the basis for decision-making. Article 5 of the SPS Agreement is devoted entirely to this subject and provides specific guidance concerning the elements of risk assessment which can be considered.

In particular, Article 5 states that an assessment of the potential damage from a pest involves a range of factors, including biological and economic factors, whose sum represents the magnitude of the consequences. As a result, it was apparent that both the probability and the consequences of pest introduction, spread, or unacceptably high damage should be viewed as scaleable variables in the characterization of risk.

Among the many important points noted in the SPS Agreement is the language in Article 5, paragraph 3, describing relevant economic factors which *shall* be taken into account when assessing risk. What is not explicit is how these elements are used in determining the appropriate level of protection in relation to the acceptable level of risk. This was deemed to be an area where guidance is needed as it seemed to have significant relevance as a factor in determining the strength of measures.

Discussion of the IPPC began by emphasizing the role envisioned for it with respect to the SPS Agreement and the recent revision of the Convention. This led to elaboration of the concepts and definitions that had been developed under the Convention in such standards as: *Principles of Plant Quarantine as Related to International Trade* (ISPM Publication No. 1, FAO 1995) and *Guidelines for Pest Risk Analysis* (ISPM Publication No. 2, FAO 1996). Emphasis was placed on definitions such as 'regulated pests', including 'quarantine pests' and non-quarantine pests'; and 'phytosanitary measures'.

The meeting noted that regulated pests are important because it is only this category to which phytosanitary measures can be applied in international trade. Consequently, the criteria and processes used to categorize such pests and to decide the appropriate strength of measures for these pests represent critical areas for harmonization. In particular, the issue was seen to involve the relationship between the potential economic impact of a pest and the strength of measures deemed appropriate to reduce the pest risk to an acceptable level.

Pest risk analysis was identified as the process recognized under the IPPC and corresponding with risk assessment in the SPS Agreement as the basis for regulatory decision-making. It was noted that although standard-setting for PRA under the IPPC was in various stages of development, the defining characteristics of regulated pests and the processes described by existing standards offered substantial guidance for determining the strength of measures.

Participants emphasized that the strength of measures should correspond to the level of risk that is determined as a result of PRA. The strength of measures was seen to be represented by a sliding scale where increasing risk may correspond to a comparable increase in the strength of measures applied to manage the risk to an acceptable level. The concept presumes that highly restrictive measures to address low risk are not justified, or vice versa. Needing further clarity were the criteria and processes used for comparing and aligning these elements.

The experts agreed that issues concerning the strength of measures for Karnal bunt or any pest should be considered in the context of PRA, and that the focus of discussions in the meeting should be to clarify this to the extent possible as well as to develop recommendations for further guidance and a broader dialogue.

4. REVIEW OF DISCUSSION PAPERS

Three papers prepared for discussion were presented by their authors on particular situations related to Karnal bunt. The various issues raised were then reviewed.

Mr S. Poe summarized a paper on the United States perspective on the regulatory background of the Karnal bunt disease before detection in 1996 and the current outlook:

Prior to 1981, the United States Department of Agriculture (USDA) prohibited the importation of wheat from a number of countries through the Flag Smut Quarantine; this happened to include all of the countries in South Asia and the Near East where Karnal bunt was known to be present. In 1981, the regulations were revised to specifically exclude wheat from any country where Karnal bunt was present. The reason given for this attention to Karnal bunt was the possibility that the disease might be capable in some cases of causing significant yield and quality losses, and to some extent by the concerns over the effect that the presence of the disease in the US might have on wheat exports.

When USDA became aware of the presence of Karnal bunt in Mexico in 1982, action was taken to halt all movement of wheat into the US from that country, and to add Mexico to the list of countries from which wheat was prohibited. This regulatory action was completed in 1983. At that time, there was a concern that the effect of the presence of Karnal bunt would have on wheat exports might be much more important than any yield losses that might occur. Surveys were conducted in the US to determine if the disease might have already been introduced, with all results at that time being negative. An emergency action plan was also developed that provided the information necessary to undertake an eradication programme if Karnal bunt should be detected.

Over the next several years perhaps the most significant change in the US was the development of improved methods for detection and identification of the Karnal bunt teliospores, in particular teliospores present at very low levels. This led to the current ability to detect Karnal bunt when present at levels as little as 1/100 of the levels that might usually be detected by previous methods depending on visual examination of seed or grain. One result of the current detection methods is that it is now possible to detect the disease when it is present at levels well below the point at which there is any effect on the quality of wheat products.

The paper reflects the current thinking in the US that gives considerably more emphasis to the potential or actual effect of Karnal bunt on trade than to any yield and quality losses that might be encountered. This is in part due to the fact that in the current infested area in the desert Southwest, these yield and quality reductions have not been observed. It seems to be the widely held opinion among US scientists, producers, and regulatory officials that the sort of Karnal bunt infestation present in the US would not result in yield or (at least in most cases) quality losses, and that the testing methods currently available should be adequate to eliminate any possible quality effect and ensure that any infected seed is excluded from the planting system. It is for these reasons that the US has questioned the need for the current stringent quarantine measures that many countries have established.

A paper presented by Dr R. Ikin outlined an Australian perspective on the risk associated with Karnal bunt:

Given the varied ecological regions conducive to the establishment and spread of Karnal bunt in Australia and being exotic, the pest was readily classified as quarantinable when subject to

analysis using the standard *Guidelines for Pest Risk Analysis*, even if the prospective direct economic losses due to yield were not high. A companion document prepared by Dr G. Murray identified the potential economic impact the pest would have if established in Australia with estimates of losses due to downgrading of wheat, the implementation of local quarantines and the loss of markets in the order of 203 to 490 million Australian dollars per year. The analysis did not support the establishment of any new category of plant pest. In the case of Australia, which was an exporter of almost 90% (1996/97 season) of its wheat crop, the maintenance of the advantage of freedom from Karnal bunt clearly would justify a high level of phytosanitary protection through restrictions on imports of seed as germplasm and for research purposes. Importation of wheat as feed grain had only been able to be implemented through devitalizing procedures at ports of entry.

Dr C. Sansford from the United Kingdom presented a paper noting that:

The strength of phytosanitary measures to be taken against regulated pests can only be determined by the process of pest risk analysis. By this process the probability of entry and establishment and the potential economic loss associated with a pest is determined using the widest array of information that is available at the time. The result of the PRA process is a measure of risk that is either acceptable or not acceptable to the area (importing country or trading bloc) concerned by the pest. The strength of measures to be applied will vary according to the risk. For a pest with a risk that is less than or equal to the level that is acceptable to the area, no measures need to be taken. However, if the risk is higher than the acceptable level, one or a combination of measures will be selected to reduce the risk to that which is acceptable. In order to minimize negative trade effects the measures selected should be the minimum necessary to achieve the acceptable level of risk.

It is not possible or necessary to categorize regulated pests beyond those categories that are currently available. To be a *pest* by definition, the organism must be *injurious to plants or plant products*. Therefore the concept of a category of regulated pests which have a *minor biological impact* is rejected since the PRA process when used scientifically will determine where an individual pest fits on a sliding scale of risk, and the strength of measures to be used against them will therefore vary accordingly.

The use of *Tilletia indica*, the cause of Karnal bunt of wheat, as an example of a pest with a *minor biological impact*, is both indefinable and unnecessary for phytosanitary personnel. The pathogen has a variable effect on yield, a pronounced effect on quality and the potential to affect the germination capacity of seed. The loss of export markets that may result from the presence of the pathogen is also not inconsiderable, but it is not the only factor determining its regulatory status as a quarantine pest. In conclusion, the strength of phytosanitary measures can and must be varied according to the risk as determined by the PRA process. *Minor biological impact* is a subjective and indefinable term that cannot be supported to describe any regulated pest.

5. CASE STUDY: KARNAL BUNT

After a brief review of *Tilletia indica* (cause of Karnal bunt), considerable discussion revolved around the status of Karnal bunt as a quarantine pest of wheat and triticale, and the potential losses associated with the pathogen. It was resolved that Karnal bunt did not qualify for any special status, nor that a special category need be created for this pathogen. The importance of PRA as the process for the determination of the strength of measures required for a pest was emphasised and demonstrated. Considerable discussion also revolved around economic losses and the interpretation of such losses. Opinions varied considerably on the importance and definition of economic losses.

Conclusions and Recommendations Concerning the Strength of Measures for *Tilletia indica*

The experts reached the following conclusions from their discussions:

1. It is not possible to adopt a global position on the quarantine status of *Tilletia indica* or the strength of measures to be used in regulatory programmes. This is because the pathogen does not present the same risk for all countries.
2. Karnal bunt can be associated with losses ranging from insignificant to significant, based upon a broad interpretation of losses (including losses due to reduced yield, quality and loss of markets).
3. The risk associated with Karnal bunt and the strength of measures used against *T. indica* should be considered separately for grain, commercial seed, and research material.
4. Judgements concerning the acceptable level of risk will vary depending on a number of factors which are considered in the PRA process as currently described in ISPM Publication No. 2.
5. Economic factors that are legitimately considered in risk assessment include:
(italics added to indicate additions not addressed in ISPM Pub. No. 2)
 - type of damage (*including quality losses*)
 - crop losses
 - loss of export markets (*due to quarantine or quality*)
 - *loss of domestic markets*
 - increases in control costs
 - effects on IPM programmes
 - environmental damage
 - capacity to act as a vector for other pests
 - perceived social costs such as unemployment
 - *regulatory and research costs.*
6. All impacts can be considered in economic terms, since biological and other impacts will ultimately be interpreted in economic terms in the PRA process.
7. The strength of measures for Karnal bunt should be based on the pest risk associated with the disease as determined by PRA. Stronger measures are deemed to be justified where

risk is greatest. This is visualized as a sliding scale where the strength of measures corresponds to the level of risk.

8. Risk management options for importing or exporting countries are few, and their strength, suitability and availability may vary in relation to the presence or absence of Karnal bunt and whether the country produces and/or exports wheat (see Table, Annex III, used for illustrative purposes only).

9. Risk management requirements should not be prescriptive, but allow for the flexibility to recognize equivalent measures (including systems approaches).

10. Cost-benefit analyses are an important part of evaluating risk management options (including the option of taking no action), and determining the strength of measures.

11. Research is needed to identify more risk management options and provide further information for PRA.

Given the defining criteria for existing pest categories in the process of PRA, it is not necessary or appropriate to create new categories such as "low impact" or "minor biological significance" for *T. indica* or other pests.

6. DISCUSSION OF STRENGTH OF MEASURES FOR REGULATED PESTS

The participants agreed that a number of conclusions from the case study using Karnal bunt should have broader application to other pests. It was emphasized that Karnal bunt could not be judged universally, but instead the unique situation in each country should be assessed using PRA as the basis for determining the strength of measures. The extension of this concept to other pests should be normal PRA practice.

Conclusions and Recommendations on the Strength of Measures for Regulated Pests

1. The strength of measures for regulated pests should be based on the risk associated with the pest as determined by PRA. Stronger measures may be justified where risk is greatest.

2. Pest risk assessment necessarily precedes consideration of the strength of measures.

3. The level of pest risk and the strength of measures used to manage the pest risk are visualized as a sliding scale where the strength of measures corresponds to the level of risk. However, it must be recognized that a precise correlation may be difficult since there may only be available a limited number of options for pest risk management.

4. A regulated pest may not require measures (action) if the results of PRA indicate that the level of risk is acceptable, measures are not possible, feasible, or cost effective, or where particular circumstances do not warrant action which may be taken based on the risk posed by the pest under other conditions (e.g. consumption versus propagation).

5. It should not be assumed that increasing the strength of measures results in a directly proportional increase in protection. Analysis is required to determine the nature of the relationship (see Graph, Annex IV).

6. It should not be assumed that increasing the strength of measures involves a directly proportional increase in costs. Costs may increase significantly for incremental increases in the strength of measures that result in little or no significant increase in protection. Analysis is required to determine the nature of the relationship.

7. Measures should not be prescriptive, but allow for the consideration of equivalent measures or combination of measures which manage pest risk at an acceptable level with minimal impact on trade.

8. The feasibility of implementing measures, including the costs should be considered when selecting measures.

9. The volume, frequency, and seasonality of the trade are important considerations in PRA which affect the choice of measures.

10. Quality, as a factor in determining economic loss in the PRA process, has a bearing on the determination of strength of measures.

Measures

A non-inclusive listing of phytosanitary measures was compiled to help visualize the range of options from which measures can be selected. It was noted that the strength of measures varied between and within measures depending on the intensity of their application. In particular, systems approaches were identified as offering significant flexibility.

Examples of possible measures include:

- Prohibition
- Post-entry quarantine
- Pest free or low prevalence area
- Systems approaches
- Certification programmes
- Testing and diagnostics
- Restrictions on movement and marketing (distribution), entry points, time of entry, and end-use
- Inspection
- No restrictions.

7. GENERAL RECOMMENDATIONS

A number of general observations, conclusions, and recommendations were offered by the participants.

1. The relationship between PRA, the acceptable level of risk, the appropriate level of protection and the strength of measures, is fundamental to the concept of safe trade. It is essential that these concepts and their relationship are described as explicitly as possible, and are widely understood by scientists, industry, the general public and regulators in all countries.

2. It is critical that phytosanitary measures are based on PRA, regardless of the level of resources or degree of complexity involved. Countries need to recognize that PRA can range from the simple to the complex.
3. PRA should be developed to become more quantitative (less subjective), identifying areas of investigation for the research community and drawing data from research wherever possible to maximize the quantitative inputs.
4. Research on risk management is needed to increase the number of options available and thereby offer greater precision in matching the strength of measures to the pest risk.
5. Guidance is required for defining and evaluating the economic factors to be considered in PRA.
6. PRA is not only the basis for deciding the strength of measures, but also for reevaluating the strength of measures when conditions change, or new information becomes available, and can be used for challenging measures.

8. SUMMARY

The Consultation found it unnecessary and inappropriate to categorize pests according to their impact. It further found that distinguishing biological from economic or other impacts was difficult and/or not useful since the PRA process accounts for all these effects together, in terms that ultimately relate to economics. PRA was recognized as the basis for the determination of the strength of measures in relation to the level of risk identified and it was applicable to a wide range of circumstances. Likewise, it was noted that guidelines for PRA need to be more explicit and the process should move towards developing quantitative methods.

A draft of the report of the meeting was prepared by the Secretariat with the participants and finalized during the meeting. The meeting was concluded with a note of appreciation to the experts for their contributions.

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PROVISIONAL AGENDA

1. Opening of the Session
2. Welcome Address and Introduction
3. Overview of Issue and Background
 - WTO SPS Considerations
 - IPPC Considerations
 - Risk Analysis and the Strength of Measures
4. Review of Submitted Papers
5. Background for Case Study: Karnal bunt
 - biology, epidemiology
 - historical perspective
 - quarantine considerations
6. Discussion of Case Study
7. Discussion of Implications for Other Regulated Pests
8. Formulation of Conclusions and Recommendations
9. Development and Adoption of the Report
10. Closure of the Session

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ANNEX III

Table. Illustration of the possible range of phytosanitary responses for countries considering the import of wheat depending upon the status of Karnal bunt and host crops in the importing country (re-exports not included in discussion).

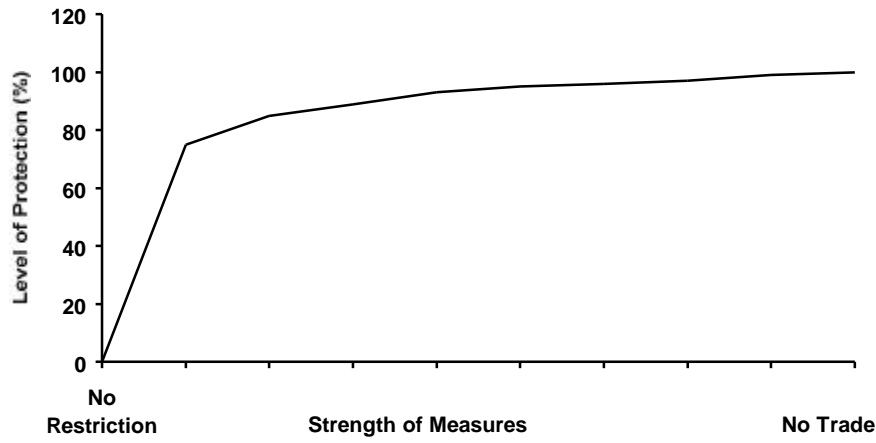
Status of Importing Country	Grain	Seed
No wheat grown	OK	0
Wheat grown and Karnal bunt / No internal regulations	OK	OK
Wheat grown and Karnal bunt / Internal regulations	B	?
Wheat grown and no Karnal bunt / No export	B?	A?
Wheat grown and no Karnal bunt / Export	A	A?

0 non-issue

OK acceptable for movement with phytosanitary certificate

B moderate concern / risk

A high concern / risk



Graph. Illustration of the relationship between the strength of measures and the level of protection.