
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation
Directorate of Plant Protection, Quarantine & Storage
N.H-IV., Faridabad-121001

January 2004
Preface

This Pest Risk Analysis Process Manual is developed to set out the administrative process to be followed by National Pest Risk Analysis Unit established under Directorate of Plant Protection, Quarantine & Storage to undertake Pest Risk Analysis to international standard. This manual is guiding spirit for formalization of PRA. The user of this manual shall ensure familiarize with the international agreements/standards that influence PRA process so that the PRA’s developed to a international standard. For any further information regarding this manual you may contact either Plant Protection Adviser or Joint Director (Plant Quarantine), Directorate of Plant Protection, Quarantine & Storage, Faridabad. The information contained in this manual is reproducible with written permission from the Plant Protection Adviser.

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1.0. Purpose & scope:

This manual set out for the stake holders and other interested parties the administrative process followed by the Directorate of Plant Protection, Quarantine & Storage (Ministry of Agriculture, Government of India) for undertaking import pest risk analysis for developing and reviewing quarantine policies for importing plants and plant products into India.

The process is designed to ensure that

- risk of introduction and spread of a pests and their potential economic impacts are fully evaluated;
- importation is only permitted when such risks can be managed in a manner consistent with the phytosanitary regulations
- stake holders are fully informed and are satisfied with the process followed and understand the decisions made

2.0. Quarantine Policy

2.1. Objectives

The objective of the India’s Plant Quarantine Policy referred in this manual is to:

- prevent the introduction and spread of exotic pests that are destructive to crops by regulating/restricting the import of plants/plant products.
- support market access for India’s Agriculture products
- facilitate safe global trade in agriculture by assisting the producers and exporters by providing a technically competent and reliable phytosanitary certification system to meet the requirements of trading partners.

2.2. Risk Management and SPS measures

The plant biodiversity resources of India are maintained through the effective implementation of phytosanitary measures so as to facilitate safe import of plants and plant products and at the same time protecting from ravages of destructive pests affecting plants. The India’s approach to address the requests of import of plants/plant products, where there are phytosanitary risks, is to extend phytosanitary measures for similar products with comparable risks. However, where risk mitigating measures for comparable phytosanitary risks have not previously in place, a thorough assessment will be necessary to identify the risk involved and to determine what phytosanitary measures are needed to reduce these risks to confirm appropriate level of protection

3. National Pest Risk Analysis Unit

A National Pest Risk Analysis (NPRA) Unit would be soon established as a part of the Directorate of Plant Protection, Quarantine & Storage, dedicated to implement science-based pest risk analysis for the application of phytosanitary measures consistent with the WTO-SPS Agreement,
the IPPC and international standards on pest risk analysis. This includes transparent, fully documented PRA information systems and stakeholders consultation mechanisms to address the issues related to PRA.

The NPRA Unit is responsible for:

- develop import PRAs consistent with international standards
- develop and maintain pest database and pest categorization activities
- organize consultations with stakeholders in developing PRAs
- work in close collaboration with the scientists/experts from research organizations of the ICAR and State Agricultural Universities in undertaking the Pest Risk Analysis to international standards
- set out risk management measures and reviewing existing phytosanitary measures for allowing importation of plants/plant products consistent with quarantine policies and regulations.
- work in partnership relation with the states and union territories in addressing the issues related to regional status of pest and risk within India and consequent application of appropriate phytosanitary measures and resolving the issues connected therewith,
- conduct technical negotiations and PRA related issues with counter agencies in other countries to develop new market access and maintain and improve access for India’s agricultural exports.

The National Pest Risk Analysis Unit is independently headed by Dy Director (Plant Pathology) and assisted by one Asst Director (Plant Pathology) and one Asst. Director (Entomology) and four Senior Scientific Assistants to begin with. Further Dy Director (PP) is provided with secretarial assistance.

4. Quarantine Legislation

The plant quarantine measures are implemented by the Central Government in accordance with the provisions of The Destructive Insects & Pest Act, 1914 with the mandate of prevention of entry, establishment and spread of pests likely cause destruction to crops. The quarantine regulations for import of plants and plant products and other regulated articles such as insects, fungi, bio control agents, microbial cultures and soil etc., contained in the Plant Quarantine (Regulation of Import into India) Order, 2003 published in Gazette of India Notification No. S.O. 1322 (E) dated 18th November 2003.

As per the clause 3 and sub-clause (7) no import permits are issued for consignments other than those specified in schedule-V, VI and VII of the order unless the pest risk analysis (PRA) is carried out in accordance with the guidelines issued by the Plant Protection Adviser based on international standards and subject to such restrictions and conditions specified therein and for this purpose the importer is required to file an import PRA request form (Appendix-I) with Plant Protection Adviser, Directorate of Plant Protection, Quarantine & Storage, N.H.IV, Faridabad-121001 The process of PRA involves the categorization pests associated with commodity into quarantine pests; evaluation their introduction potential; critical assessment of economic and environmental impact of their introduction; and specification of risk mitigating measures against them. In the event of interception of a quarantine pest in an imported consignment, further imports shall be suspended until earlier PRA in respect of the consignment is reviewed and the risk mitigating measures are evaluated.

5. International Agreements & Standards
The import PRA process set out in this manual confirms to India’s international obligations in line with the WTO Agreement on Application of Sanitary and Phytosanitary Measures i.e. SPS Agreement and international standards and guidelines on pest risk analysis developed under the International Plant Protection Convention (IPPC).

5.1. WTO-SPS Agreement

The sanitary and phytosanitary measures outlined under WTO-SPS Agreement are aimed at protecting animal, human or plant life or health. The SPS agreement sets out the rights and responsibilities of WTO members that wish to take action to restrict the imports in order to protect the animal, human or plant life or health. However, the restrictions so placed should be minimum necessary to achieve the above objects and at the same time cause least impediment to the trade. The SPS measures should be based on scientific principles and should not be maintained without sufficient scientific evidence. Further these measures are not to be applied as arbitrary, discriminatory, unjustified, unnecessary or disguised barriers to trade. The SPS Agreement allows members to adopt stricter measures to confirm high level of protection than achieved by measures based on international standards, however, those are required to be scientifically justified and should be based on risk assessment. The WTO members are allowed to adopt provisionally SPS measures as a precautionary approach, in case where the scientific evidence is insufficient but probable risk exists. SPS agreement allows the members to accept the sanitary and phytosanitary measures of other members as equivalent even if different, where the same provide appropriate level of protection. Also the control, inspection and approval procedures should be undertaken in no less favourable manner for imported products than for like domestic products. The Annexure- contains the text of the SPS Agreement.

5.2. International Plant Protection Convention

The International Plant Protection Convention (IPPC) was established in 1951 under aegis of Food & Agriculture Organisation to facilitate international cooperation in controlling plant pests and to prevent their international spread. The IPPC role in relation to trade particularly the establishment and recognition of international standards was strengthened in the New Revised Text of the Convention approved in 1997. The SPS Agreement recognizes the IPPC as the relevant international organization responsible for the establishment of international standards on phytosanitary measures.. The SPS Committee may invite the IPPC or its subsidiary bodies to examine specific matters with respect to phytosanitary standard, guidelines and recommendation and the Committee may recommend areas where IPPC standards are elaborated. The WTO may establish panels to review phytosanitary-based trade disputes at the request of members, which may seek advice from or consult with IPPC Secretariat in order to obtain technical information or identify technical experts in the resolution of phytosanitary based trade disputes. The IPPC also has dispute settlement provision pertaining to the implementation of the Convention, in particular where phytosanitary measures are challenged as unjustified barriers to trade. The WTO may establish panels to review phytosanitary-based trade disputes at the request of members, which may seek advice from or consult with IPPC Secretariat in order to obtain technical information or identify technical experts in the resolution of phytosanitary based trade disputes. The IPPC also has dispute settlement provision pertaining to the implementation of the Convention, in particular where phytosanitary measures are challenged as unjustified barriers to trade.
As per the Article IV (1) & (2) of the New Revised Text of the International Plant Protection Convention (IPPC), the contracting party, shall make provision to the best of its ability for an official national plant protection organisation with the main responsibilities set out in this article, which shall include the conduct of pest risk analyses;

5.3. International Standards

The process described in this manual are aligned with the following international standards on phytosanitary measures (ISPMs) developed under the IPPC viz.,


5.4. Notification obligations

Under the transparency provisions of the SPS Agreement, WTO members are required to notify other members through the WTO secretariat of proposed new sanitary and phytosanitary regulations, or changes to existing regulations, that are not substantially the same as the content of an international standard and that may have a significant impact on international trade, at a stage when any comments can be taken into account. The process set out in this manual is to notify draft PRA report and to allow 45 day period for comment and also to notify to the WTO the final outcome of PRA process.

6.0. Administrative Process for Pest Risk Analysis

6.1. What is Pest Risk Analysis?

The pest risk analysis process identifies the pests relevant to an import proposal; scientifically assess the risk posed by them; and specifies the measures should be taken to reduce the risks to an acceptable level. These analyses are conducted via administrative process described in the manual.

6.2. How the process is started?

The National PRA unit established under Directorate of Plant Protection Quarantine & Storage may initiate development of new plant quarantine policy or review existing policy in response to:

- a proposal to import plants/plant products, which presents a potential plant quarantine risk
- the identification of a changed risk profile or the receipt of new information by the N PRA Unit
- an application received by the PQS for an import permit

The proposals can be received from individuals, companies, organizations, government agencies or governments (both in India and overseas).
Where it is apparent that the quarantine risk associated an import proposal or applications similar to those addressed by existing policy an import pest risk analysis may not be considered necessary,

6.3. **When are pest risk analysis undertaken?**

Following the situations described under 6.2, the NPRA Unit may undertake import pest risk analysis, if:

- there is no relevant existing phytosanitary measure for commodity/country combination; or
- a deviation from established phytosanitary measures is considered necessary because of changed pest status or the likelihood of entry, establishment and spread of pests and economic consequences of their introduction than those previously assessed.

6.4. **Utility of this Manual:**

This manual setout the administrative process supporting the Government’s primary objectives in implementing quarantine measures, including:

- phytosanitary measures based on scientific and biological evidence of pest risks
- alignment of risk mitigating measures to confirm appropriate level of protection
- phytosanitary measures set out shall comply with India’s plant quarantine legislation and international agreements to which India is signatory.

6.5. **Variation in PRA Process**

The PRA Process set out in this manual may be significantly varied under the circumstances of development of a new relevant international standard, the PRA Team Leader in consultation with Plant Protection Adviser may determine that the conduct of an import pest risk analysis should be varied. The National PRA Unit may terminate an import pest risk analysis at any stage on its own initiative or if a proposer/applicant requests that it be terminated.. There will be occasions when variation of the administrative procedures set out in the manual is considered necessary and stakeholders are informed of such instances and actions taken as soon as possible.

6.6. **Economic Issues**

In keeping with the mandate of the Destructive Insects & Pests Act, 1914 and the regulations issued under the Plant Quarantine (Regulation of Import into India) Order, 2003 and the international obligations as a member of the World Trade Organisation & International Plant Protection Convention, economic considerations are taken into account only in relation to matters arising from potential impact of pests that could gain entry, establishment and spread of pests in India as a result of importation of plants/plant products.

6.7. **Pest Risk Analysis-Technical Methodologies**

The Directorate of Plant Protection, Quarantine & Storage, has developed a national standard on ‘Guidelines for Pest Risk Analysis- technical methodologies’ in consistent with the existing plant quarantine legislation and the regulations issued there under. The structure of this standard is in line
with the international standards developed and established under the International Plant Protection Convention. This standard details the scientific/technical process for carrying out pest risk analysis. The standard describes various decisions making steps, clearly showing the range of technical decisions/judgments, which need to made when arriving at a set of risk management recommendations formulated to manage the identified risks presented by a quarantine pest.

6.8. Communication with Stakeholders

The NPRA Unit will maintain a register of stakeholders to assist effective consultation and communication. Stakeholders comprise Central/State Government Departments, Government Undertaking Corporations, and research organisations (public/private), industry groups, trade associations, importers, growers, consumer federations within the country and or overseas, including proposer/applicant for a specific proposal, having an interest in the subject matter of an import pest risk analysis.

The register enables stakeholders to indicate the import risk analyses in which they are interested and they way they prefer to receive information. However if a person or an organisation chooses not to be placed on the stakeholder register, they may access information on the Import risk analysis work programme and on the current status of import risk analyses through plant quarantine website:www.plantquarantineindia.org. Copies of completed import risk analyses and other relevant documents related to import risk analysis are placed in the website.

6.9. Other risk assessment processes

This manual does not cover about the risk assessment of biological control agents or genetically modified organisms. Further the procedures of weed risk assessment are dealt separately.

7.0. Steps in Pest Risk Analysis (PRA) Process

The various steps set out in administrative process of import pest risk analysis are described as under:

Initiation of PRA Process

1. Submission of PRA proposals to PPA

Requests for gaining market access may be made directly to the Ministry of Agriculture, Government of India, by relevant government authorities of the country seeking to export or the importer may require to file an import pest risk analysis request farm with Plant Protection Adviser for seeking a permit to import of plants/plant products other than those covered under Schedules V, VI and VII to PQ Order. PPA., including those commodity/country specific, shall acknowledge the receipt of the proposal and register the proposal. The PPA shall notify the proposals to all registered stakeholders with respect to a particular application specifically or generally. The applicant may require providing additional information as per the Annexure-II and also comments if any to consider proposal on priority basis for undertaking pest risk analysis. The priority assigned by PPA to the conduct of a pest risk analysis on the proposal is not subject to appeal.

2. Review of proposal by NPRA Unit
The Plant Protection Adviser (PPA) may forward such proposal or requests received by him to the NPRA Unit established under Dte of PPQS. The NPRA Unit may initiate the development or review earlier import pest risk analyses, if any, in the light of changed pest risk profiles or upon receipt of new information.
3. Determination of type of import pest risk analysis (routine/non-routine)

The NPRA Unit will evaluate such proposal to determine whether a routine or a non-routine analysis is warranted and circulate its evaluation to stakeholders to comment within 30 days. The routine analysis process will typically followed when the risk analysis is technically less complex or the proposal appears prima facie not to require assessment of significantly greater risk than those previously determined by the NPRA Unit. Further most of the routine analyses end up with pest categorization and evaluation of risk management options and specification of phytosanitary measures. Whereas non-routine analyses will be required, where there are potentially significant risks to be evaluated and that have not been previously documented and large and technically complex and may involve with detailed risk assessment of their likely hood of entry and establishment of identified quarantine pests and economic consequence and environmental impact of their introduction. The NPRA unit established under Dte of PPQS, examines proposals in the event of comments received from stakeholders on the approach to determine, which ones require a routine or non-routine risk analysis and makes a recommendation to the Plant Protection Adviser for deciding on the issue.

Scheduling and scooping

3. PRA Work Programme

Those requiring non-routine import risk analysis will be scheduled taking into account factors such as the resources available (The NPRA Unit staff as well as suitably qualified external experts); the technical complexity of import risk analysis (eg. The number and type of pests that need to be considered); the availability of information necessary to support the analysis and the quality, completeness and timing of response by the proponent country to request for information. The NPRA Unit routinely advise stakeholders about its PRA Work programme via e-mail, fax or the website. This advice describes the status of PRAs as on date and those that NPRA Unit expects to commence in the near future. Also suitable provision is made for changing priorities, research needs and resource constraints.

4. Consultation with State/Union Territories and other Central Government Agencies

Under the existing powers of the Destructive Insects & Pests Act, 1914, both States/Union Territories have to play critical role in effective implementation of domestic plant quarantine regulatory measures. Therefore consultation with States/Union territories and other relevant Central Government agencies is particularly important in the PRA process, because close cooperation at all stages of an PRA is needed to ensure that information relevant to a specific State or Union Territory is considered in the prospect of national risk analysis and regional considerations.

The NPRA Unit therefore works closely with Directorate of Agriculture/Horticulture and State Agriculture Universities of relevant State and Union Territory on PRA Work Programme and on arrangements for PRAs about to commence. For particular PRAs, the scope, the likely risks and the expertise that may be required to address those risks will also be discussed. The State and Union Territory may identify specific technical issues that they would like to consider during an PRA, including regional differences in pest status and may nominate officers with relevant expertise, who could participate in the PRA.
The NPRA Unit work closely with other Central Government Agencies such as experts from research institutes and organizations under the Indian Council of Agricultural Research/Commodity Boards and other scientific bodies, where they have responsibilities relevant to IPRA.

5. Scope, Approach & constituting PRA Team Membership

A PRA Team conducts each PRA. Membership of the team is governed by the availability of the required expertise within NPRA Unit and if necessary, the extent to which the expertise outside NPRA Unit may be required. For all PRAs, a senior officer nominated by PPA, who is having relevant expertise in PRA, chairs the team. It is equally important that PRA team members do not have vested interests in relation to the PRA, that they are able to exercise sound scientific judgment and that the process is objective oriented.

Details of the terms of reference, operating procedures and considerations on membership for PRA Team are indicated in Annexure-3.

The NPRA Unit shall provide administrative and secretarial support for PRA teams.

The NPRA Unit determines the intended scope of the PRA with the proposer/applicant, that is the commodity pathway to be assessed and the country of origin, end use and end distribution. The commodity and source (s) need to be defined to allow the precise list of relevant pest species (e.g. insects, mites, nematodes, fungi, bacteria, viruses, molecules etc.) to be drawn up for pest categorization. The NPRA Unit may determine that for reasons of efficiency or address related proposals or applications, the scope of PRA should be varied to include or exclude other commodities and/or other sources. The NPRA Unit may decide to involve third parties to assist in conducting PRAs. In such cases the NPRA Unit assesses the documents produced by a third party, their scientific basis, and whether they confirm to the Government’s objectives stated under Plant Quarantine Policy.

6. Initial consultation with registered stakeholders

When work on an PRA is about to commence, the NPRA Unit consults with registered stakeholders through a memorandum that includes:

- the proposed scope and approach of the PRA
- the required expertise
- where appropriate, an invitation for nominations for external membership of the PRA team

The information is placed on the Plant Quarantine website. Stakeholders were given 30 days from the date of issue of memorandum to provide comments and membership nominations to NPRA Unit. Submissions received are placed in PRA Folder (Annexure-6) created for the specific PRA unless a request for confidentiality of matter solicited.

7. Decision on scope, approach & membership

The NPRA Unit considers submissions received from registered stakeholders in response to the memorandum and will hold discussions with stakeholders, if necessary. The In-charge of NPRA Unit in consultation with PPA then decides the scope for the PRA, and membership of the PRA team, identifying the issues raised by stakeholders and the manner in which they have been addressed. The
NPRA Unit advises registered stakeholders of the outcome and places the information on plant quarantine website.

8. Provision for stakeholder appeal

A stakeholder may appeal to the Joint Secretary, In-charge of Plant Protection, Dept of Agriculture and Cooperation, Ministry of Agriculture, if aggrieved against the decision taken by PPA on the scope, approach and PRA team membership within 15 days of its publication in website. In lodging an appeal, stakeholders must give grounds and reasons for their appeal. Receipt of appeals will be acknowledged.

Matters taken into account in considering an appeal are given in Annexure.3.

9. Determination of appeal

The Joint Secretary, In-charge of Plant Protection, considers the appeal, makes a decision and notifies the appellant along with reasons within 30 days from the date of closing of appeals. The Joint Secretary shall not pass any decision without consulting PPA.

If an appeal is allowed the PRA returns to step 5 as stated above in respect of those issues for which the appeal was allowed. If the appeal is disallowed, the PRA team will commence work on the PRA.

The NPRA Unit communicates the outcome of the appeal to registered stakeholders and the information placed in plant quarantine website and PRA Folder.

Risk Assessment

10. Initial work

After a PRA team is established, it liaises with the proponent/applicant about the technical information needed to enable a PRA to proceed. If there is insufficient information, the PRA may be delayed until the information is received.

The PRA team commences work by:

- determining work programme for the PRA
- establishing a risk communication strategy, including identifying relevant stakeholder groups
- preparing a technical issue paper

The technical issue paper:

- summarises background and administrative matters pertaining to the PRA
- lists the pests that the PRA team has identified as being potentially associated with importation of commodity
- categorises the pests (in some cases in a preliminary manner) according to whether they need to be considered in the subsequent detailed risk assessment
The technical issue paper may also include:

- an outline of the additional tasks identified at that stage, e.g. for technical working groups (TWGs) and consultants
- a list of potential independent peer reviewers

Pests are categorized conservatively. If there is lack of adequate information about their quarantine significance, they are included for risk assessment.

The PRA team may also commission, as appropriate, consultancies and TWGs to examine and report on specific technical or economic issues.

11. Consultation on the technical issue paper

The NPRA Unit distributes the technical issues paper to registered stakeholders and places it on the plant quarantine website. Stakeholders given 30 days to comment. This is the first formal request for detailed technical input into PRA. Submissions will be sought on:

- the completeness of the list of pests and their categorization
- the list of potential independent peer reviewers
- any additional work identified

The PRA team may conduct meeting of stakeholders to discuss matters raised in submissions, if necessary. The submissions received from the stakeholders (unless otherwise requested) are placed in PRA folder along with PRA team’s response to the issues raised. The team may conduct field visits to relevant regions in India and/or potential source areas (country of origin) to investigate trading patterns, industry practices and procedures relevant to assessment of pest risk.

12. Preparation of draft PRA Report

The PRA team, on the basis of its analysis and using input from technical working groups and consultants as necessary, prepares a draft PRA report, taking into account submissions received on the technical issues paper and other input derived through the consultation of stakeholders. The team also incorporates input received through consultations of States/Union territories on regional pest status and pest risk issues.

The draft PRA report:

- Confirms the pest status being assessed
- Describes major pathways by which these could gain entry, establish and spread within India
- Identifies for each pest on individual pathways, the likely hood of its entry, establishment or spread and economic consequences and environmental impact that would result of their introduction
- Specifies whether the resulting risk require mitigation (i.e. to bring risk within appropriate level of protection defined by India
- Incase where the risks are rated as un acceptable, presents an evaluation of technically feasible risk management measures to determine whether the risk can be successfully mitigated to achieve the appropriate level of protection as defined by India.
• Includes a preliminary view of the appropriate risk management options

13. Consultation with stakeholders on Draft PRA Report

The NPRA Unit distributes the Draft PRA Report to stakeholders and places it on the plant quarantine website. Stakeholders given 30 days to submit comments. The PRA team may organize meeting of the stakeholders to discuss on the Draft Report. The submissions made by the stakeholders are placed in the PRA folder unless a request for confidentiality is made.

14. Notification to WTO

The NPRA Unit will notify Draft PRA Report to the WTO as per established procedures. The notification includes advice on the time by which comments should reach the PRA Unit.

15. Independent Peer Review

Before finalizing either the Draft or Final PRA Report, the PRA team may seek advice from independent peer reviewers.

Final Reporting

16. Preparation of Final PRA Report by PRA team

The PRA team prepares final PRA Report with the input from technical working groups and consultants as necessary. While finalizing the report the PRA team consider submissions on the draft report received from stakeholders and comments of peer reviewers and consult them as appropriate.

If new information comes to light that may significantly affect the analysis, or if the PRA team identifies the need to make significant changes to the analysis in finalizing the PRA Report, the PRA team in consultation with the In-charge of NPRA Unit may recommend for consideration of PPA to prepare a revised Draft PRA Report for consultation with stakeholders. In this case the NPRA Unit distributes revised Draft PRA Report to stakeholders and places it on PQ website. The stakeholders given 45 days to comment on the revised Draft Report.

The final PRA Report draws all issues together and includes:

• The PRA team’s response to the issue raised
• An inventory of significant changes to the Draft PRA Report, with reasons to those changes
• Information on the issues raised by independent peer reviewers and the PRA team responses
• Recommendations on appropriate risk management options

17. Consideration of Final PRA Report by PPA

The PRA team presents the Final PRA Report to the In-charge of NPRA Unit and who in turn forward to PPA for necessary consideration.

In considering the recommendations in the Final PRA Report, In-charge of NPRA Unit must be satisfied that the PRA has been conducted in accordance with the process described in this manual and the recommendations made in the report.
• are reasonable in the light of scientific and biological evidence of pest risk
• meet the Government’s primary objectives of plant quarantine policy
• are consistent with plant quarantine legislation and regulations
• accord with India’s international rights and obligations

The In-charge of NPRA Unit may refer the report to the PRA team for further consideration, if this deemed necessary. If satisfied the final report shall be forwarded to PPA.

18. Consultation with States and Union Territories

The NPRA Unit consults the Director of Agriculture/Horticulture of States/Union Territories on the proposed outcomes of the PRA, including regional pest status and risk issues and aspects of joint responsibility arising from the PRA team’s recommendations.

The In-charge of NPRA Unit may refer the report to the PRA team for further consideration of the outcomes of consultation as appropriate.


In releasing the Final PRA Report and specification of phytosanitary measures, which will set the parameters for import, the Plant Protection Adviser takes into account:

• the recommendations of the PRA team
• outcomes of consultation with the Director of Agriculture/Horticulture of relevant States/Union Territories
• plant quarantine legislation requirements
• international obligations
• any other relevant information or consideration

The NPRA Unit distributes the Final PRA Report and the recommendation of policy determination to the proponent/applicant and registered stakeholders and places in plant quarantine website and in the PRA folder.

20. Provision for appeals on Final PRA Report

The stakeholders given 30 days time from the publication of the recommendation for a policy determination to lodge an appeal in writing with Pest Risk Analysis Appeals Panel (PRAAP)-a body independent from NPRA Unit- on one or both of the following grounds:

• there was a significant deviation from the process set out in the Pest Risk Analysis-Administrative Process Manual that adversely affected the interests of a stakeholder
• a significant body of scientific information relevant to the outcome of the PRA was not considered

In lodging appeals, stakeholders give reasons for their appeal.

The terms of reference for and composition of PRAAP are given in Annexure-
If there are no appeals within 30 days, the process is complete and the recommended policy will be submitted to the Plant Protection Adviser for finalization.

21. Appeal determination

The PRAAP will consider any appeal and report its findings to the appellant(s) and the Plant Protection Adviser within 30 days of the closing date for appeals.

If the appeal is disallowed, the process is complete.

If appeal is allowed, the PRAAP may advise the In-charge of NPRA Unit how to overcome identified deficiencies. This may involve minor amendments to the final PRA Report, significant revision or further stakeholder consultation. The In-charge of NPRA Unit considers any advice from the PRAAP in deciding how to proceed further. He advises the appellant(s) and apprises the PRAAP of the outcomes of further work undertaken to address deficiencies. The information placed in PQ website and PRA folder.

Final policy determination

22. Notification of final specification of phytosanitary measure

When the above processes are complete, the Plant Protection Adviser finalizes specification of phytosanitary measure. The NPRA Unit submits the final specification of phytosanitary measures to Joint Secretary, In-charge of Plant Protection, Department of Agriculture & Cooperation for notification in Gazette of India and also informs the proponent or applicant and registered stakeholders and notify the WTO of final policy determination.

The final PRA Report, the policy determination, the outcomes of any appeals and responses of NPRA Unit to issues raised, are provided to the proponent/applicant, registered stakeholders and places on the PQ website and PRA folder.

PPA will forward the published notifications for implementation by PQS.
Annexure-1: Contact for information

1. The Plant Protection Adviser

   Address:  Directorate of Plant Protection, Quarantine & Storage
            N.H-IV, Faridabad-121001 (Haryana)

   Telephone: 91-129-2413985
   Fax          : 91-129-2412125
   E-mail: ppa@hub.nic.in

2. Secretariat of Plant Protection Adviser

   Address:  409, B Wing, Shastribhavan,
             New Delhi-110001

   Telephone: 91-11-23385026
   Fax:        91-11-23384182

3. Joint Director (Plant Quarantine)

   Address:  Directorate of Plant Protection, Quarantine & Storage
             N.H-IV, Faridabad-121001

   Telephone: 91-129-2418506
   Fax:        Nil
   E-mail: jdpq@hub.nic.in
Annexure-2: Stakeholders’ Register & Registration Form

A stakeholder is a government agency, individual, company or industry group, association, research organisation, whether in India or overseas, that has interest in the subject matter of pest risk analysis, including the proponent/applicant for a specific proposal. The National Pest Risk Analysis Unit maintains a register of stakeholders to facilitate consultation and communication.

Interested parties or individuals wishing to be included in communications and consultation on a particular proposal or application, or generally should complete and return a stakeholder registration form to the National Pest Risk Analysis Unit for registration. When PRA issue is being actively considered, stakeholders listed on the register with an interest in that issue will be consulted.

The registration form (in MS Word and pdf format) may be downloaded from plant quarantine website: http://www.plantquarantineindia.org. Completed registration form should be mailed to:

Joint Director (PQ) & In-charge
National Pest Risk Analysis Unit
Plant Quarantine Division
Directorate of Plant Protection, Quarantine & Storage
N.H-IV, Faridabad-121001 (Haryana).

In case of any difficulty in downloading of the format, a copy of the same can be had from the above address.
Annexure-3: PRA Request Form

India National Standard for PRA
DPPQ&S, Ministry of Agriculture, Government of India

<table>
<thead>
<tr>
<th>Client Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name/Organisation: …………………………………………………………………………..</td>
</tr>
<tr>
<td>Address: ……………………………………………………………………………………….</td>
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<tr>
<td>………………………………………………………………………………………………………</td>
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<tr>
<td>Phone: …………… Fax: ………………… E-mail: …………………………………………</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PRA General Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity (circle one): Import Export</td>
</tr>
<tr>
<td>Common/Product name:………………………………………………………………………..</td>
</tr>
<tr>
<td>Scientific/botanical name (genus &amp; species):……………………………………………</td>
</tr>
<tr>
<td>Scientific/botanical name (Strain/variety/cultivar):……………………………………</td>
</tr>
<tr>
<td>Country/countries of origin:…………………………………………………………………</td>
</tr>
<tr>
<td>Quantity/Volume:………………………………………………………………………………</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Type (circle one or more)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processed/Non-processed Living/non-living</td>
</tr>
<tr>
<td>Plant/Animal Genetically modified/non-genetically modified</td>
</tr>
<tr>
<td>Seed/plant/soil Culture/non-culture</td>
</tr>
<tr>
<td>Other……………………………………………………………………………………………..</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Processing (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If seed: ground/kibbled/whole/preserved</td>
</tr>
<tr>
<td>If plant: fresh/dried/freeze dried/preserved</td>
</tr>
<tr>
<td>Processing refinement: cooked/frozen/pulped/steamed</td>
</tr>
<tr>
<td>Specify treatment details……………………………………………………………………..</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Origins (please state if question not relevant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source location(by country, origin &amp; locality)………………………………………………………</td>
</tr>
<tr>
<td>Production method, Certification scheme and/or accreditation type?………………………</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Received:</th>
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<tbody>
<tr>
<td>Signed:</td>
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</table>


### Attachment 3: PEST RISK ANALYSIS REQUEST FORM (cont.)

India National Standard for PRA  
DPPQ&S, Ministry of Agriculture, Government of India

<table>
<thead>
<tr>
<th>End Use (circle one or more)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Human consumption/Processing/Stock feed/Pet food/Fish food/Seeds for sowing/Nursery stock/Multiplication/Post-entry Quarantine/Therapeutic/Fertilisers/In-vivo/In-vitro</td>
<td></td>
</tr>
<tr>
<td>Other……………………………………………………………………………………………………………</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>End Destination (circle &amp;/or specify)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Rural/urban Multiple locations/single</td>
<td></td>
</tr>
<tr>
<td>Specify Country, State &amp;/or region (PRA defined area)…………………………………………</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Entry (circle one or more)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Ship/Air/Ground transport/Rail</td>
<td></td>
</tr>
<tr>
<td>Other………………………………………………………………………………………………………………</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>General Comment</th>
<th></th>
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<tbody>
<tr>
<td>(any further general comment or notes that need to be made, please make here)</td>
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</tbody>
</table>

Date Received:
Signed:
Annexure-4: Terms of Reference & composition of PRA team

A team of experts constituted for undertaking pest risk analyses. The team is responsible for generating PRA report, which contain host pest lists, pest categorization in to quarantine pests, risk assessment of those identified pests and risk mitigating measures. The team reports to the Plant Protection Adviser the outcome of PRA.

Terms of Reference:

- Develop the work programme for PRA
- Establish a risk communication strategy
- Determine whether technical working groups (TWGs) and/ or consultants will be required to collate information, conduct research, undertake assessments (technical, economic and environmental) or otherwise, or to assist the PRA team on specific issues; and if so, determine their terms of reference and oversee their work
- Consult as appropriate to obtain a full and accurate understanding of relevant issue
- Use internal and independent peer review if appropriate in preparing papers and reports
- Take appropriate account of India’s appropriate level of protection and quarantine legislation and regulations and India’s rights and obligations
- Consider stakeholder submissions in preparing papers and reports
- Produce technical issue paper for consultation
- Produce a Draft PRA Report for consultation
- Produce other papers and reports as appropriate for efficient conduct of PRA
- Produce a Final PRA Report for consideration by the Plant Protection Adviser
- Provide additional advice and information as requested by the Plant Protection Adviser

Composition & Membership:

The PRA team varies in numbers, depending on expertise required. Usual number restricted to five. Team members collectively provide an appropriate combination of experience and expertise in:

- Risk analysis in relation to plant quarantine
- Science and regulations
- Categorization of pests
- Industry and/or commercial practices
- Other disciplines (environment/economics/ecology) relevant to the proposal or application under consideration

Membership depends on whether the required technical expertise is available in National Pest Risk Analysis Unit. The National PRA Unit sources outside expertise as required. Such expertise may be drawn from other government agencies (Central/State & UT), industry, scientific organisation, grower’s association, academician, private consultants etc.

A senior officer from the National PRA Unit chairs the PRA team. The chair has experience in quarantine policy and sound knowledge of India’s plant quarantine legislation and regulations, the
Government objectives of implementing plant quarantine policy and international agreements. The National Pest Risk Analysis Unit provide administrative support and secretarial assistance.

In finalizing PRA team membership, the National PRA Unit under the chair of Joint Director (PQ) Assesses the prospective team members against the following criteria:

- Experience and expertise relevant to the import proposal under consideration
- Proven capacity in a relevant scientific field or crop specialization
- Knowledge of government processes and procedures and the national policies and international agreements and standards related to pest risk analysis
- Willingness to cooperate and collaborate and work together
- Provide impartial and independent advice
- Technically competent in the relevant pest risk analysis

If in the course of a PRA, any external member of the PRA team ceases to operate or if any other reason ceases to be member of PRA team, the Plant Protection Adviser or Joint Director (Plant Quarantine) may co-opt the member in consultation with key stakeholders as appropriate to ensure that the work of the PRA can be satisfactorily completed and the stakeholders may be informed accordingly.

Working Procedure:

The team conducts PRA with support from the National PRA Unit as needed

National PRA Unit produces the papers and reports and circulates these reports to stakeholders

The PRA team operates within the operational and financial constraints of the National PRA Unit and budgetary allocation of Plant Quarantine service, in consultation with PRA team agrees on a budget and the resources needed to conduct the work programme efficiently. The agreed budget covers such items as internal meetings of the PRA team, analysis work, travel cost of members to attend face-to-face meeting with stakeholders and preparation of reports and publications. The National Pest Risk Analysis Unit contracts external members for the duration of PRA in accordance with Central Government Financial Rules and Guidelines.

The PRA team determine whether additional will be required and the most effective method of carrying out that work, for example by TWGs and/or consultants. In deciding to use TWGs or in commissioning consultancies, the PRA team takes into account resource and time constraints and relative cost effectiveness.
Annexure-5: PRA Appeal to Joint Secretary (PP)

Stakeholders may appeal to Joint Secretary, In-charge of Plant Protection, Department of Agriculture & Cooperation against the decision of the Plant Protection Adviser on the proposed scope and approach of the PRA and the required expertise, including the membership of the PRA team. The appeal must be made within 15 days of the publication of the decision. In lodging an appeal, stakeholders must give reasons for their appeal.

If the Joint Secretary, In-charge of Plant Protection considers the appeal, makes determination, he has to notifies the appellant(s) within 30 days of closing date for appeals:

Contact details:

Joint Secretary (PP)
Department of Agriculture & Cooperation
Ministry of Agriculture
Room No. 151, Krishibhavan,
New Delhi-110012.

Matters the Joint Secretary (PP) will take into account in making a decision on the appeal include:

- Whether the scope of the PRA is reasonable (with regard to the proposal or application and any current related work) and is an efficient use of public resources
- Whether the nominated PRA team membership will provide appropriate expertise
- Indian plant quarantine legislation, regulations and Government policies
- India’s rights and obligations as a member of the WTO
- Any other matter Joint Secretary may consider relevant
Annexure-6: PRA Appeal Panel

The chair of the Pest Risk Analysis Appeal Panel convenes the panel when appeal is received that provides prima facie evidence that there has been a material deficiency or failure falling within the PRAAP’s terms of reference. Stakeholders have 30 days from the date of publication of the recommendations for a policy determination to lodge an appeal in writing.

The chair advises the appellant(s) and the Plant Protection Adviser through the PRAAP Secretariat of the chair’s decision on whether the appeal warrants consideration by the PRAAP. If consideration is warranted, the proponent of the import proposal is also advised.

Contact Details

The PRAAP Secretariat is provided by the Department of Agriculture & Cooperation coordinates all PRAAP activities and handles all correspondence under the chair of Joint Secretary, In-charge of Plant Protection

All appeals to be made to:

Joint Secretary (PP)
In-charge of PRAAP Secretariat
Department of Agriculture & Cooperation
Krishibhavan, New Delhi

Tel/Fax:
E-mail:

Grounds for Appeal

The PRAAP considers appeals, supported by a statement of reasons, based on one or both of the following grounds:

- There was a significant deviation from the process set out in the Pest Risk Analysis-Administrative Process Manual that adversely affected
- A significant body of scientific information relevant to the outcome of PRA was not considered

The PRAAP does not consider matters relating to:

- Issues falling within the ambit of the appeal in Step 8 of administrative process of PRA listed in this manual
- The scientific merits of the PRA, other than in relation to a claim that a significant body of scientific information was not considered
- The merits of risk management recommendation made by a PRA team or of the risk management conclusions reached by the Plant Protection Adviser.

If new information relevant to the PRA is produced during the appeal process, the PRAAP may refer the information to the Plant Protection Adviser.

Membership of PRA Appeal Panel:
Joint Secretary, In-charge of Plant Protection (Chair)
Asst. Director General (Plant Protection), ICAR
Director, National Bureau of Plant Genetic Resources or his representative
Plant Protection Adviser, Dte of PPQS
Dy Secretary, In-charge of Plant Protection
Joint Director (Plant Quarantine), Dte of PPQS

The chair of the PRAAP has right to nominate any other alternative ember, if he believes there may be a conflict of interest or perception of bias because they have been directly or indirectly involved in PRA under appeal.

Every effort is made to have the full representation of panel meet in person to consider an appeal to ensure a balanced discussion.

Working Arrangement:

When the chair of PRAAP decides that evidence presented by the appellant(s) warrants consideration by PRAAP, the chair consults with the Plant Protection Adviser on:

- Scope and time table of appeal
- PRAAP membership regarding issues of conflict of interest
- The likely need for access to particular expertise for appeals concerning whether a significant body of scientific or technical information relevant to the outcome of the PRA has not been considered

The PRAAP considers the appeal in the context of either or both of the criteria for the appeal, and reports its findings to the appellant(s) and the Plant Protection Adviser, within 30 days of closing date for appeals or else the appellant(s) is advised if the PRAAP is unable to finalize the appeal within 30 days.

The PRAAP does not consider verbal dispositions from any appellant unless they are followed by written submissions.

Upholding of appeal requires majority support. The chair does not exercise casting vote.

If the appeal is allowed the PRAAP may offer advice to the In-charge of National PRA Unit on ways of overcoming deficiencies. This may involve minor amendments to the final PRA Report or significant revision warranting further stakeholder consultation.
Annexure-7: PRA Folder

A PRA Folder non-confidential submissions and other technical documentation is established at the commencement of each PRA. The National PRA Unit maintains each PRA Folder and documents can be accessed from the folder with prior permission for perusal and copying. Submissions and other documentation in electronic form may be available to stakeholders on specific request. The stakeholders are further encouraged to make submissions electronically. Where appropriate documentation on the PRA folder, which is in electronic form is made available on PQ Website.

The PRA Folder for a PRA contains the following non-confidential information:

- a table of contents
- the background to the import proposal
- determinations and decisions on procedural matters made by the Joint Secretary (PP) and the In-charge of National PRA Unit during the conduct of PRA
- documents publically circulated by the National PRA Unit during PRA, including those providing advice and/or seeking input on:
  - commencement of PRA
  - cope and approach for the PRA and composition of PRA team
  - appeals
  - the technical issue paper and Draft and Final PRA Reports
  - the recommendation for a policy determination and the final policy determination
  - the relevant technical submissions and other correspondence including a submission except a part of a submission, that a stakeholder indicates is confidential and is capable of being classified as secretive/sensitive, which the NPRA considers confidential shall be dealt in confidential file. However the information about receipt of confidential matter will be placed in the PRA folder
  - correspondence raising relevant technical issues
  - technical material used in the PRA but subject to copy right (title of reference)
  - technical material used in the PRA, not available in the public domain and not subject to copy right
  - department of Agriculture & Cooperation responses to submissions including statements of reasons
  - where appropriate formal reports provided by a technical working group (TWG), consultant or peer reviewer.
Annexure-8: Flow chart of Pest Risk Analysis Process

1. PRA proposal received by PPA
2. NPRA unit initiates Policy & review
3. Notification of PRA Work program
4. Consultation with states/Uts
5. Scoping, approach and team membership
6. Consultation with registered stakeholders
7. NPRAU decides & advises registered stakeholders
8. Appeal
   - 8.1 JS (PP) determines appeal
     - Appeal Allowed
     - Appeal Disallowed
9. Substantive Appeal
10. PRA Team prepares technical issue paper
11. PRA team consults with registered stakeholders
12. PRA team prepares draft PRA report
13. PRA team consults with registered stakeholders
14. Notify WTO
15. PRA team consults with independent scientific peer viewers
16. PRA team finalizes PRA report
17. NPRAU considers final PRA report
18. NPRAU consults with State / Territory CEOs on PRA report
19. PPA release final PRA report and policy recommendation
20. PPA makes policy determination
21. PRAAP determines appeal
22. Notification by JS (PP) MOA