



# ISF Conference on AP and LLP: Risk Management Proposal

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# Understanding the Problem:

## LLP Definition:

Event meets Biosafety “Risk Assessment” requirements and is fully approved as “safe” by at least one country but not in the country of import



## Understanding the Problem:

Preferred First Option:

Synchronized assessment and full approval in importing countries.

BUT:

- Some countries do not have capacity to operate a functional approval process
- Countries may not receive applications for species that will not be cultivated



## Understanding the Problem:

Thresholds may be required for:

1. Biosafety requirements (0% to 100%) Depends on Risk
2. Quality Standards (0.1 to 3%)
3. Marketing or Labeling Standard (0.9 to 5.0%)



## Understanding the Problem:

1. A “Biosafety threshold” of zero for crops widely grown makes trade impossible
2. A “Marketing or Labeling Standard” which is more stringent than existing international seed quality standards can not be met using existing seed production and handling procedures.



# LLP Biosafety Requirements

Criteria are:

1. Internationally recognized risk assessment process (FAO Codex or OECD)
  - Concludes there is little or no risk to humans, animals or environment
2. Import is eligible to be “in compliance” if it meets the next level of standards (Quality)
3. Importation at levels higher than Quality standards requires full approval in the importing country



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ALINORM 08/31/34, Appendix IV

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## Appendix IV

**PROPOSED DRAFT ANNEX: FOOD SAFETY ASSESSMENT IN SITUATIONS OF  
LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD**

**(At Step 5/8 of the Procedure)**



# Quality Standards

Criteria are:

Use existing international quality standards for international movement of seed

## PART 1. Variety Purity

- OECD or AOSCA Seed Schemes for varietal purity (99.5 %) based on “Post Control” testing.
- The impurities (0.5%) include other varieties (with or without GM events) and off types that are not of the variety. Not individually identified

Currently: OECD in 57 countries and 200 species



# Quality Standards

Criteria are:

Use Existing international Quality standards for international movement of seed

## PART 2. Mechanical or Analytical Purity

- “Equivalency”  
Exporting country approved by the importer for testing seed lots containing seeds of other crop species, weeds and inert matter.
- Sampling, testing and reporting using ISTA or AOSA procedures.
- Seeds of other crop kinds that contain an LLP event are acceptable.



## Other Import Requirements

Import must meet additional Regulations including:

1. Phytosanitary requirements
2. Labeling (Origin, GM)
3. Other



## Risk Management Proposal

1. Other country assessments finding little or no risk are taken into consideration as importing country assesses risk of the LLP
2. Import is “In Compliance” if it meets existing international variety purity standards and “Post Control” procedures (99.5%)
3. Not necessary to test every shipment for numerous varietal or other species impurities (0.5%) because any one impurity found, is present below “*de minimis*” levels



## Benefits are:

1. Quality standards are acceptable for biosafety compliance because there is no risk at “*de minimis*” levels
2. Trade is predictable using existing production and handling procedures for seed
3. Testing for events, including events in seeds of other species, is not necessary except for “Post Control” purposes
4. Varieties with “discontinued” events that have not been renewed can remain in compliance at LLP.



## Closing Comments

Quality Standards for the International trade of seed remain too stringent for the grain trade because the commodity grain trade does not segregate by variety.

More work needs to be done with the grain industry to find a compliance level for LLP in grain products for used for food, feed or further processing.



# ISF Conference on AP and LLP: Impact on the International Seed Trade

Thank You

