Potential “Non-Tariff Barriers” (NTB)
New Standards in Europe
“*Crop Protection Sector*”

“Non-tariff barriers” from Europe for agri-commodity imports

- Most important are:
  - Quarantine related (pests and diseases) for commodity imports
  - Technical Barriers for Trade – TBT (residues) i.e. MRLs / Import Tolerances
  - Europe follows MRLs detection, but India follows limited detections in imports!

    Having standards but not exercising standards!

New regulations in Europe (1107 / 2009) "Crop Protection Products"

- European Pesticide Legislation has moved from "Risk Based Assessment" to "Hazard Based cut off criteria" for registration of agrochemicals.
- Import tolerance for products excluded from approval and used in commodities to have MRL < 0.01 ppm.
- Further, Europe is in process of adopting Endocrine Disruptors as criterion for excluding products from approval.

Hazard and Risk

- EU Pesticide legislation
  - The old Directive 91/414 applied Risk to the Hazard
  - The new Regulation 1107/2009 also applies Risk to Hazard BUT includes some Hazard only cut-offs.
    - These prevent the scientific Risk assessment and therefore potentially ban products that could otherwise be used safely as scientifically shown by Risk assessment.

Hazard and Risk

- For Example: Endocrine
  - Proposed COM criteria[1] are based on the WHO / IPCS definition which by itself does not provide criteria suitable for regulatory decision making.
  - With this definition alone, many substances of little or no concern will be identified as endocrine disruptors and banned without providing any demonstrable benefits to the protection of human health or the environment.

COM = European Commission, WHO = World Health Organisation, IPCS = International Programme on chemical Safety

Hazard and Risk

- Endocrine continued:
  - All elements of hazard characterisation (Risk), including potency, severity and toxicity, should be built into the criteria.
  - Hazard characterisation/Risk is an essential step in the overall hazard assessment of a substance and regulators should be provided with the necessary tools to clearly separate those substances which have the real potential to cause harm, from those that do not.

Hazard and Risk

- The Scientific Committee of EFSA reviewed ED assessment on request of the COM[2]. The conclusions were:

  - "With regard to the use of severity, (ir)reversibility and potency for the hazard characterisation of EDs, the SC considers that to inform on a level of concern for endocrine disrupting substances, these elements should be evaluated in relation to the degree, duration and timing of exposure".

(continued over)

EFSA = European Food Safety Authority, ED = Endocrine, SC = Scientific Committee

Hazard and Risk

- “EDs can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment”.

- In other words, the EFSA Scientific Committee concluded use of Hazard alone is insufficient and use of Risk should be added.

Hazard and Risk

- However the COM persists in developing endocrine assessment based only on Hazard despite
  - The conclusion of the EFSA Scientific Committee
  - General principles of WTO based on Risk (Article 5 of SPS)
  - The accepted principles of global regulators to use Risk based assessment and not just Hazard

Feedback to the notification on new regulations in Europe (USA, Canada, Argentina, Brazil, Chile…. & others)

- Measures to evaluate risk must be developed in accordance with scientific principles and based on the relevant scientific evidence.
- Science based evaluation brings transparency in the system across countries: otherwise the process is misleading.
- Ensure new regulations must comport with Europe's obligation under the WTO agreement on the application of SPS Agreement.
- Ensure such regulations are not a disguised barrier to trade, the SPS Agreement requires measures grounded in science (article 2.2 of the SPS Agreement).
- Implementation of any hazard-based "cut off" option, as outlined in the ED roadmap, that removes the requirement for conducting a full risk assessment could have severe implications for EU imports of US agricultural goods.

Impact of new non-tariff barriers & suggestions for Indian response to Europe

- Europe imports $ 166 Billion worth of agriculture commodities including from India ($ 4 Billion, which can significantly grow), which is at risk !
- Accepting new NTB means creating a significant asymmetry in the global regulatory standards.
- NTB from Europe; if a product not approved by EU as per the new criteria is used on agri-commodities.
- India to strongly oppose the potential changes in EU's new regulations via
  - Opposition from India through regular notification process
  - Bilateral agreements (both with European countries, and total Europe)
  - Option is also to take up with WTO being the Appellate Body
- India needs to exercise its rights to use already agreed standards:

India to make standards and not only Taking Standards.

Thank You