

WTO SPS COMMITTEE:
Thematic Session on Approval Procedures

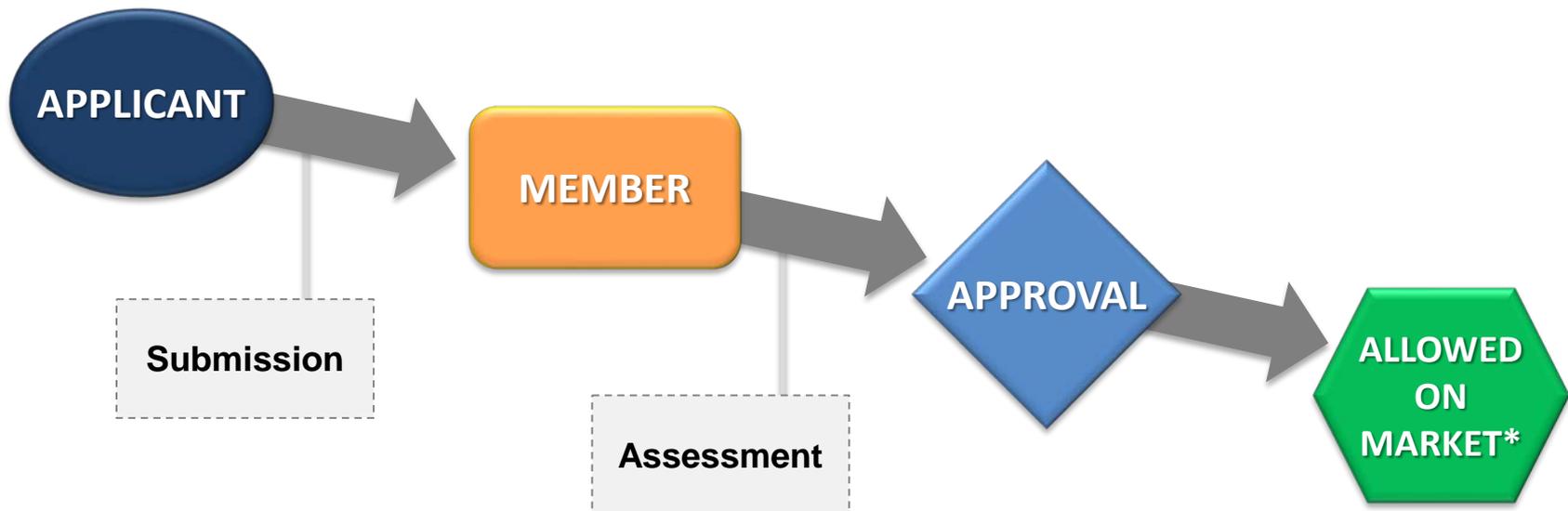
Canada's Regulatory Approach to Approval Procedures from an Import Perspective

Pre-market product approvals

November 5, 2019

Pre-market Product Approvals

- Often requires specific individual products to be assessed against appropriate level of protection before they can be placed on the market
- In many cases, product developer or manufacturer submits an application for pre-market approval – not the end user or exporting Member
 - E.g., Products of biotechnology, Food additives, Veterinary drugs, Pesticides



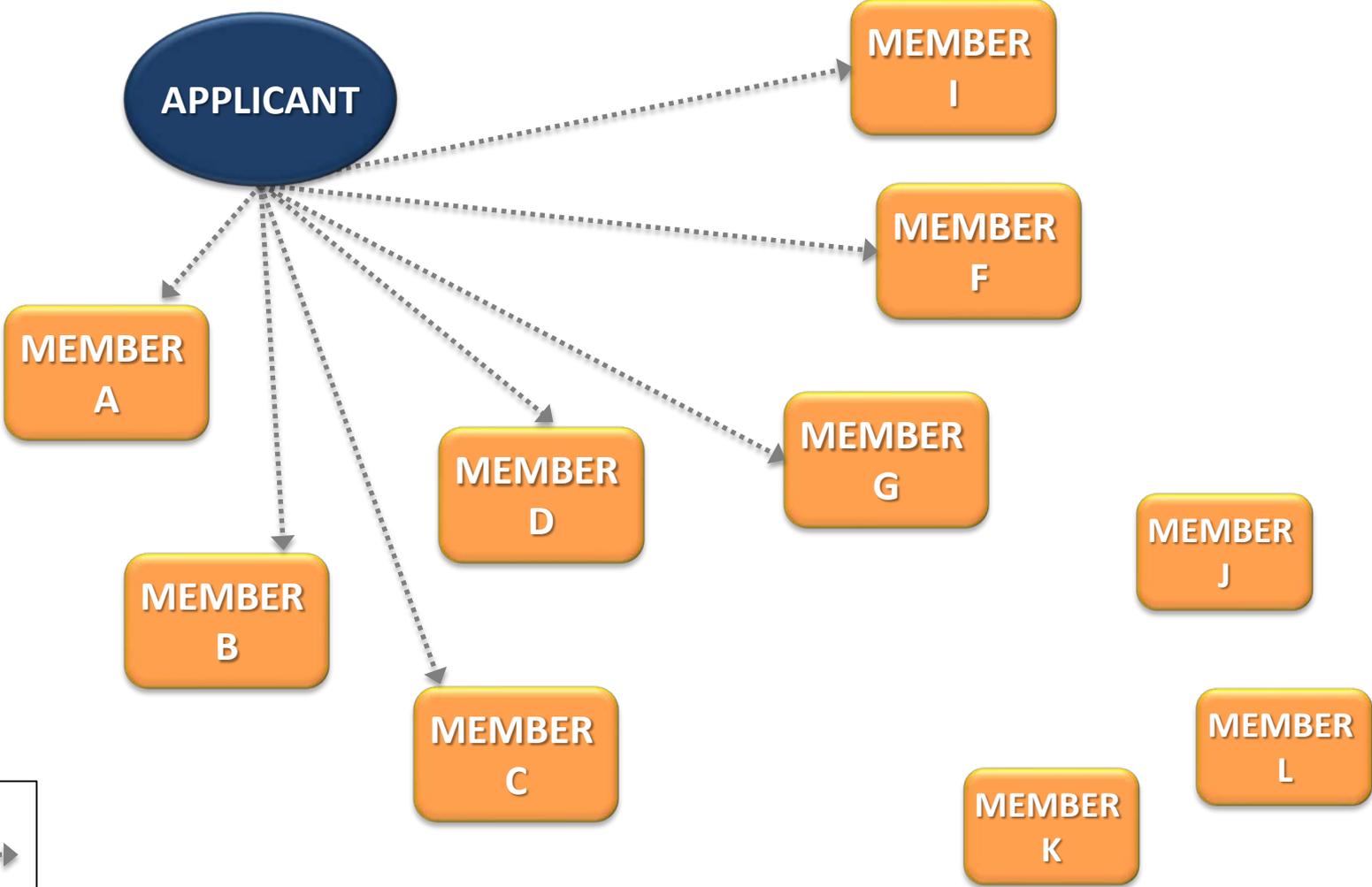
* Possibly with conditions

Pre-market Product Approvals

Slide Notes

- In Canada's view, pre-market product approval procedures have a unique potential to contribute to trade issues
- In this presentation, the term 'pre-market product approval' refers to approval procedures with the following characteristics:
 - i. Requires individual products to be assessed before they are permitted to be placed on the market as opposed to entire categories of products such as a pest risk assessment
 - ii. Often applies to tools used in agriculture or food manufacturing and the applicant is usually the developer or manufacturer of the product:
 - Not normally the grower or exporter that must meet an importing Member's requirements
 - Very rarely the exporting Member
- Examples include:
 - Pesticide and veterinary drug maximum residue limits (i.e., food safety) which are established as part of an approval procedures for the product itself
 - Products of biotechnology

A. Applicant Submits Application for Approval to Members Where Its Product is Likely to Be Sold

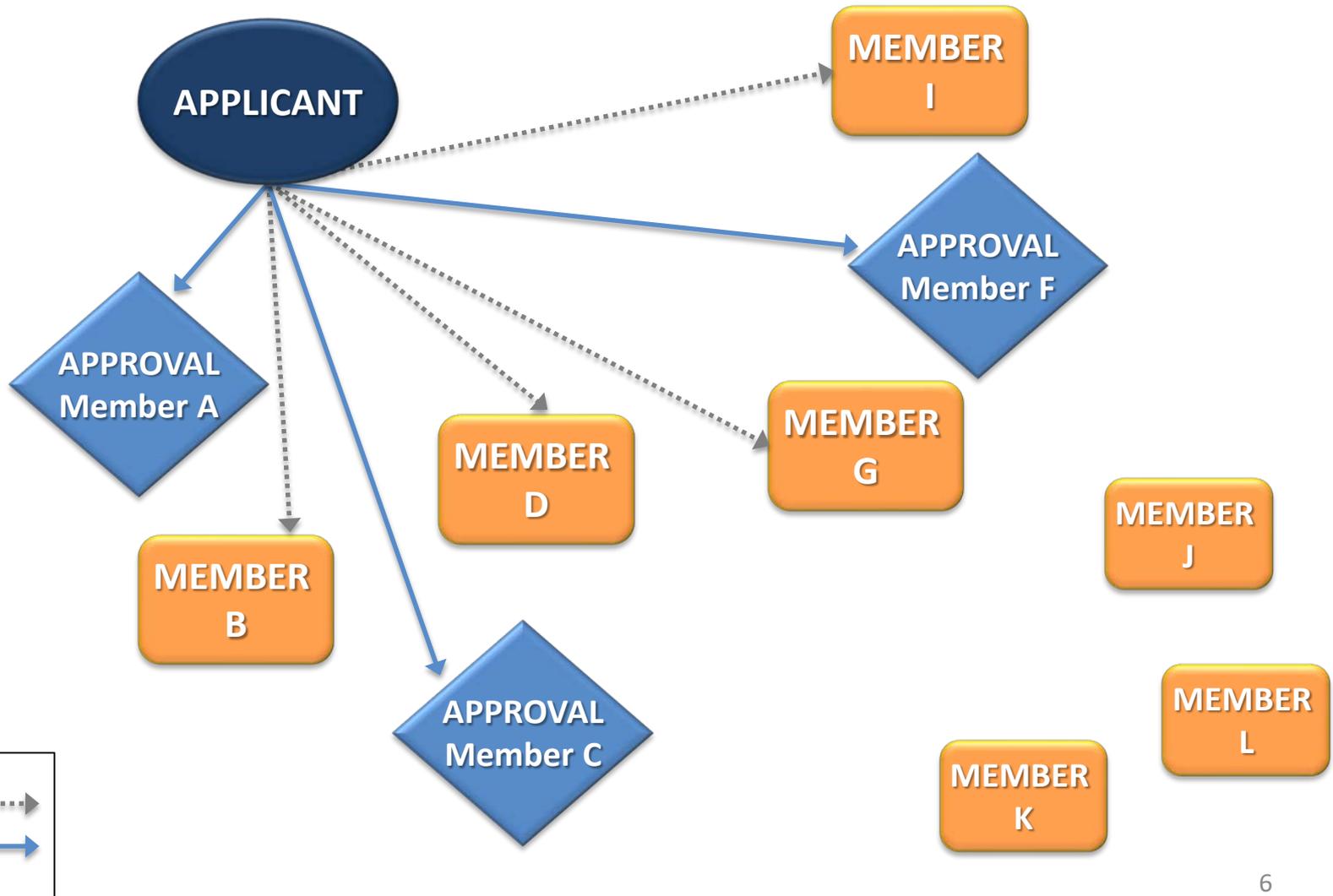


A. Applicant Submits Application for Approval to Members Where Its Product is Likely to Be Sold

Slide Notes

- The next few slides are intended to demonstrate how pre-market product approval procedures can have an impact on trade
- The applicant – normally a private entity - applies for approval in Members where it anticipates the product will be produced or used, sold and/or exported to
- For this reason, it may not submit application to all markets (i.e., J, K, L on the graphic)
- Remember the applicant tends not to be the end-user; for them, the application process makes the applicant's product eligible for commercialization – and therefore its product marketable to end-users (e.g., farmers, food manufacturers)

B. Members Grant Approval on Different Timelines

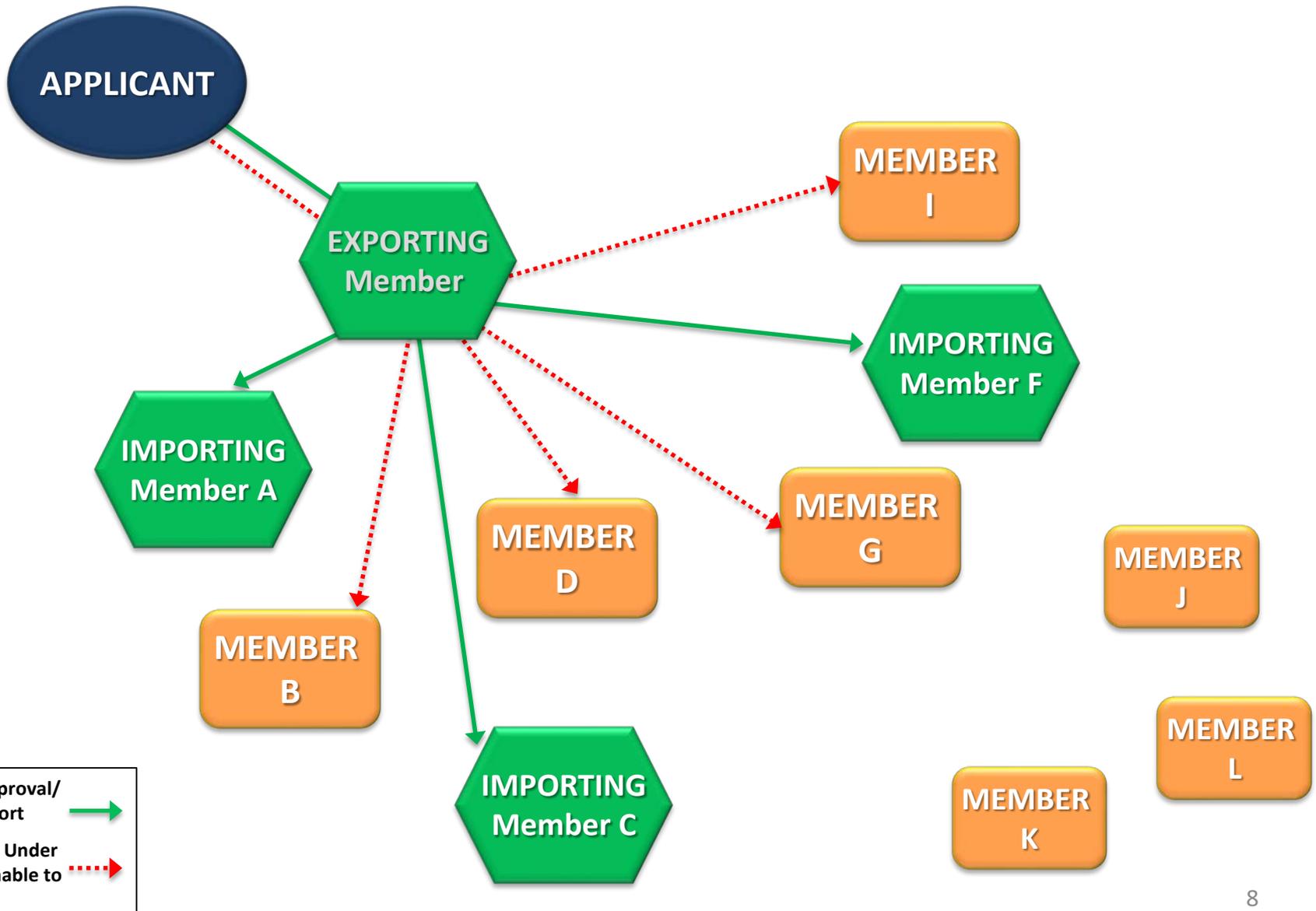


B. Members Grant Approval on Different Timelines

Slide Notes

- As Members complete their risk assessments and conclude the product to be safe, approvals are granted. (These are Members A, C, and F, denoted by the blue triangles)
- These first approvals open the door for commercialization
 - The applicant is still waiting for approval in all the Members in which it applied but industry in Members that have approved can now begin producing or using that product
- However, those industry exporters must be very careful to ensure the product does not get exported to Members where it is not approved

C. Ability to Trade Relies on Approval

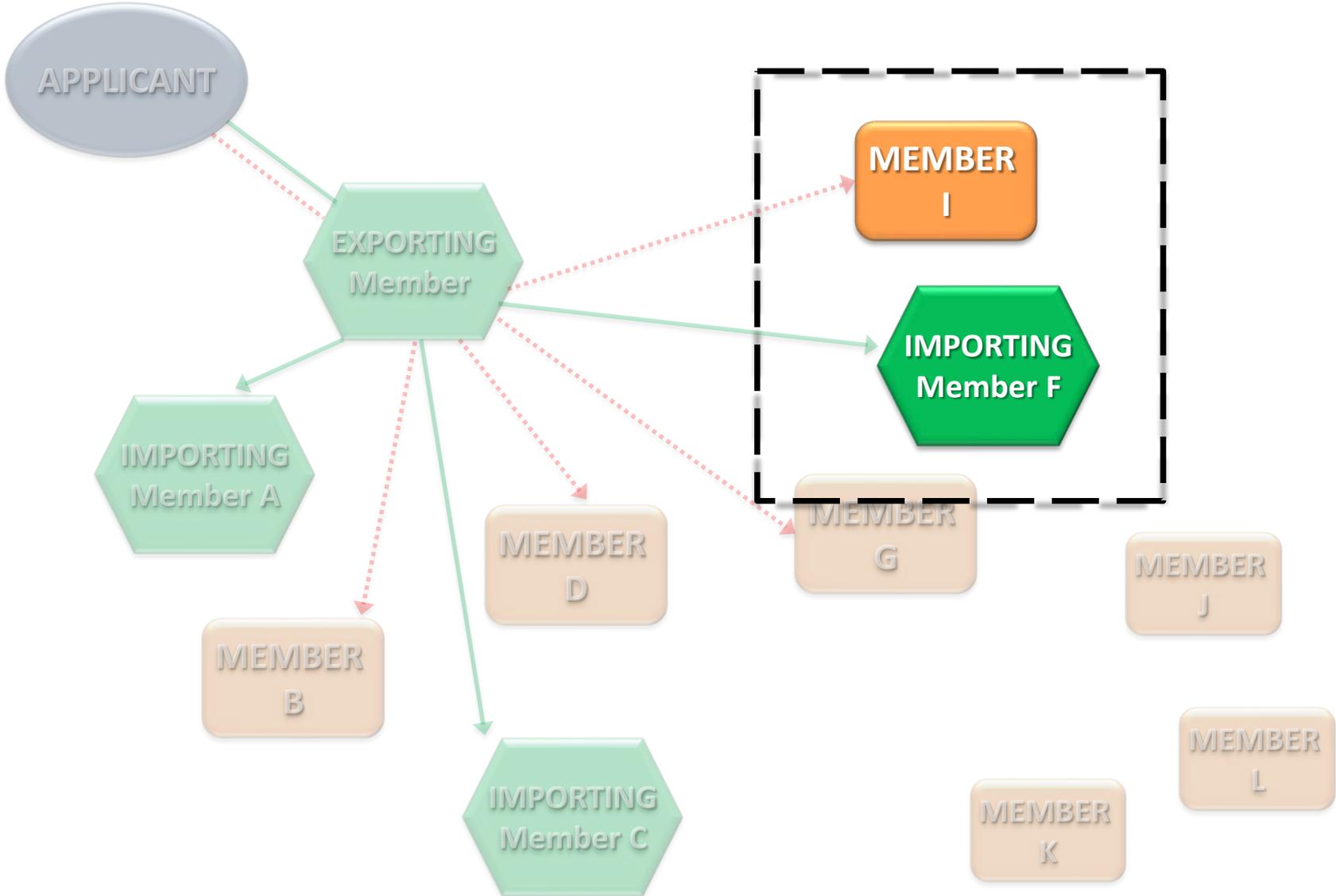


C. Ability to Trade Relies on Approval

Slide Notes

- This slide emphasizes that the ability to trade relies on the approval procedures where an application has been submitted
- For Members that take longer to complete their approval procedures, exporting Members must either:
 1. Delay commercialization of a new product domestically; or
 2. Bear the increased cost of:
 - i. Ensuring compliance in those markets until approval is granted and
 - ii. Shouldering the risk associated with non-compliance
- Making matters more complex, ability to trade relies on an approval procedure between a private entity and an importing Member – the exporting Member and exporter have no role
- And even more challenging, the applicant may not be a national of the exporting Member
- I hope this has helped to illustrate that these types of pre-market product approval procedures can give rise to trade issues when a product has approval in one Member but not another

How Can an Importing Member's Approval Procedures Minimize Trade Issues?



How Can an Importing Member's Approval Procedures Minimize Trade Issues?

Slide Notes

- It is important to acknowledge that the ultimate responsibility lies with:
 1. The applicant in securing approval in Members where the product will be used and/or exported to
 2. The exporter in ensuring export shipments meet the importing country requirements
- However, there are characteristics that Members can consider building into their domestic pre-market product approval procedures that meet their appropriate level of protection while also facilitating trade.
- The next few slides focus on the experience of an importing Member and use Canada's domestic approach for the pre-market approval of products of biotechnology as a case study to explore some of these characteristics

Case Study:

Canada's Pre-Market Approval Procedure for Products of Biotechnology

- Canada's pre-market approval procedure for products of biotechnology has characteristics that allow it to achieve domestic objectives of protecting human, animal and plant health in a way that reduces the potential for trade issues

Case Study:

Canada's Pre-Market Approval Procedure for Products of Biotechnology

Slide Notes

- Canada wants to share its experiences and how we believe aspects of our approval procedure reduce asynchronous approvals between Canada and other countries – that is where something is approved in an exporting Member but not yet in Canada – while still allowing us to meet our appropriate level of protection

Case Study:

Canada's Pre-Market Approval Procedure for Products of Biotechnology

OBJECTIVES

Food safety

Feed safety

Environmental
safety (includes
elements of plant & animal
health)

REGULATORS

Health Canada

Canadian Food
Inspection Agency

Environment &
Climate Change
Canada

MAIN LEGISLATION

Food & Drugs Act

Feeds Act

Seeds Act

*Canadian
Environmental
Protection Act*

Once approved, product is subject to the same domestic and import regulatory requirements as its conventional counterpart

Case Study:

Canada's Pre-Market Approval Procedure for Products of Biotechnology

Slide Notes

- This is a very general overview of Canada's framework for regulating products of biotechnology
- Canada's pre-market approval procedure for products of biotechnology involves 3 regulators that assess products to ensure they meet Canada's appropriate levels of sanitary and phytosanitary protection.
- Technically, 3 separate approvals are normally required. However:
 - The regulators take the same general approach and work closely together; and
 - Required approvals are issued at the same time to prevent any products from being prematurely commercialized
- Rather than go into the specifics of our approach, we'd like to share some characteristics of this approval procedure that could be considered by other Members in order to help facilitate trade

1. Risk-based

- A pre-market safety assessment is required
- Approvals do not have automatic expiries
 - Approvals can be revoked or conditions can be imposed if an identified risk needs to be managed (e.g., insect tolerance, efficacy)

1. Risk-based

Slide Notes

- Any product that meets Canada's regulatory trigger must be assessed for safety before it can be placed on the market in Canada. Canada's regulatory trigger is any novel product.
 - Upon approval, a novel product is considered to be as safe and nutritious as its conventional counterparts
- Canada's biotechnology approvals are based solely on the conclusions of our risk or safety assessment (as we call them in Canada);
 - Producers are free to choose amongst products deemed to be safe and to implement the production methods and marketing strategies of their choice

Expiries

- Once a product has been assessed as being as safe and nutritious as its counterparts in Canada, it is regulated in the same way as its counterparts
 - Unless new information comes to light, Canada does not view an automatic re-assessment necessitated by an expiry as necessary for the protection of human, animal or plant health or life.

2. Timely

- Year round submission windows
 - Applicants can submit dossiers at any time
- No requirement for approval in another jurisdiction before application is accepted/assessment begins
- Result of assessment communicated to applicant soon after completion

2. Timely

Slide Notes

- Applications are accepted by regulators at any time and assessments are started based on when they are received
- Canada does not see value in requiring approval in another Member before assessment of the product can begin – or be completed
 - Canada's approval procedure is independent of other Members
- These contribute to avoiding unnecessary time gaps between countries' approvals
- Finally, when a pre-market assessment is completed, the applicant is informed in a very timely manner of the conclusion of the assessment

3. Non- Discriminatory

- Approval procedure applies in the same way to imported and domestic products:
 - Whether applicant is in Canada or abroad
 - Whether product is intended for import or domestic production

3. Non- Discriminatory

Slide Notes

- Canada's approval procedure applies equally to any product intended to be placed on the Canadian market, no matter who wishes to put it there or how it will get there

4. Stakeholder Engagement

- Voluntary pre-submission consultation with regulators
 - Mechanism to allow applicants to clarify requirements in order to provide a quality regulatory submission
- Regulators encourage open and ongoing communication with applicants, both before and after an application is submitted
- Applicants are urged to apply to all markets of interest concurrently

4. Stakeholder Engagement

Slide Notes

- Canada feels this characteristic is particularly important to the functioning of our system
- The completeness and quality of an application has a significant impact on the ability and time required of a regulator to perform an assessment
 - Canada invests in efforts to enable applicants to prepare high quality submissions
 - That way, when the dossier is finally submitted, the assessment can be undertaken in a timely manner
 - This has also helped the prospective applicants more comprehensively understand our system and how its requirements can be met
- Specifically to avoid trade issues for products that are approved in Canada, the Canadian government strongly encourages applicants to submit timely and concurrent applications to all markets of interest

5. Transparency

- Provide summaries of approval decisions and lists of approved products online
- Provide guidance documents related to the assessment process and meeting its requirements (e.g., submission requirements)
- Provide regular status updates to applicants on product approval

5. Transparency

Slide Notes

- Canada also invests in transparency and publicly provides a lot of information about our approval procedure and its outcomes
- We believe issues can be avoided by ensuring it is clear:
 - What products require assessment in Canada,
 - Canada's application submission requirements, and
 - What is already approved and can be sold in or being imported into to Canada
- As part of the approval procedure, Canadian regulators provide assessment status updates to applicants
 - Proactively or upon request, depending on the regulatory group involved

Challenge for All Pre-Market Product Approvals: *Asynchrony/misalignment is not always avoidable*

- Member approval procedures cannot always be aligned, despite best practices
- Where an approval has not yet been granted by an importing Member, that Member may consider various measures to facilitate trade, including:
 - Use of international standards
 - Regulatory cooperation
 - Expedited approvals
 - Setting of import tolerances/thresholds
 - Consideration of other countries' approvals

Challenge for All Pre-Market Product Approvals: *Asynchrony/misalignment is not always avoidable*

Slide Notes

- Unfortunately, it is not possible to completely avoid time gaps or misalignment between Member approval procedures
- There are lots of reasons for this; for example:
 - A importer may wish to import a product to meet domestic needs but an applicant has not sought in approval in that Member
 - Some Members may have aspects of their approval procedure that make it longer than other Members
- However, that does not mean trade cannot occur at all while appropriate levels of protection are still met

Examples of trade facilitative measures include:

- Use of International Standards: Basing a sanitary or phytosanitary measure on international standards, guidelines or recommendations until an approval has been established domestically
- Setting of import tolerances/ thresholds: Establishing import-specific tolerance to assure food safety while facilitating trade when the product is not used domestically or establishing an appropriate threshold that provides for food safety or animal health or plant health protection
- Consideration of other countries' approvals: Taking into account the results of another country's approval process to determine how to respond to a non-compliance

Conclusion

- Characteristics of approval procedures that can facilitate trade while protecting human, animal, plant life or health:
 - 1. Risk-based**
 - 2. Timely**
 - 3. Non-discriminatory**
 - 4. Stakeholder engagement**
 - 5. Transparent**
- If an approval procedure may lead to trade issues, Members can consider approaches to meeting their appropriate level of protection that could also facilitate trade

Conclusion

Slide Notes

In conclusion, Canada sees value in considering:

1. How Members can avoid contributing to trade issues related to pre-market product approval procedures, and
2. How Members can manage trade issues resulting from pre-market product approval procedures, if they do occur

And still ensure an appropriate level of protection.

Thank you

Questions?