

WORKSHOP ON REACH AND RELATED CHEMICALS INITIATIVES

Only Representative

ISII 2-3 October 2008 - Helsinki

Workshop on REACH and related Chemicals Initiatives - Only Representative

Issues of concern - Questions

Change of OR

If a "non-Community manufacturer" decides to **change** his only representative after the submission of the registration dossier, the successor can submit an **update** of the earlier registration dossier **provided that the earlier only representative agrees** to this change.

- might create a problem of blockage !
- it is recommended to include clauses on the eventuality of a change into OR contracts

In the absence of an agreement, a new registration needs to be submitted

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Issues of concern - Questions

Change of OR

Reply of ECHA to question regarding the change of OR between the closing period of pre-registration and the deadline for registration:

In this case it could be considered whether the new only representative can benefit from the first-time importer rule as stated in Article 28(6) of the REACH regulation. This issue is currently under discussion in the European Commission and we advise you to monitor our website regularly for any new development on this issue

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Issues of concern - Questions

Who can appoint an OR ?

Only a natural or legal person established outside the Community who manufactures a substance can appoint an OR.

Although it is not strictly permitted by the Regulation, the fact that non-EU distributors/traders are not able to appoint an only representative could raise problem of competition issue and CBI issues (disclosure of clients/suppliers in high competitive business ...)

This brings to another question: who is the manufacturer ?

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Issues of concern - Questions

Who is the manufacturer? (1)

Art. 3.8: a manufacturing process means producing or extracting a substance in the natural state

- the ownership of the substance is irrelevant
- the responsibility falls on the entity which is actually engaged in the physical production or extraction of the substance



what about tolling?

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Issues of concern - Questions

Who is the manufacturer? (2)

Tolling is basically a **service**. In these circumstances, who is the responsible manufacturer?

- REACH addresses safety (to both the environment and the human health)
- since the ownership of the substance is irrelevant, the burden falls on the entities engaged in the production process, hence the toll smelter (the customer only places on the market)
- however, the nature of the tolling process should be considered: "new" substance because of a chemical reaction or mixing/blending operations?



case by case approach

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Issues of concern - Questions

Indirect imports

Manufacturers of substances traded outside the EU, integrated in a formulation which will then be imported can appoint an OR (CA meeting of 25.09.08).

As long as it is clear who in the supply chain of a substance is the manufacturer, formulator or producer of an article who has appointed the only representative and it is clear for which imports the OR is responsible, **it does not matter what are the steps or supply chain outside the EU** between the manufacturer, formulator or producer of an article and the importer in the EU

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Issues of concern - Questions

Pending questions

- Can an OR appoint a Third Party Representative (TPR) ?
- What are the deadlines in appointing an OR for the 1st time (art. 28.6) ?
- Is it still possible for an importer to register despite the fact that an OR has been nominated?

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Model agreement between an OR and a NEM

Provisions should address the following:

Mandate: appointed solely for company X for substance A

Tasks and obligations of OR:

- assumes all right and obligation of Art. 8
- must pre-register
- must compile the registration dossier: data sharing, participation in a
- consortium, carry out testing activities, ...
- must update the information
- shall provide the importers/customers the SDS and notify to what extend their imports are covered by OR's registration

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Model agreement between an OR and a NEM

Tasks and obligations of the NEM:

- shall provide the OR all available information for the registration dossier and the CSR
- shall provide the OR the information on importers/customers supplied by the NEM
- must update the information
- shall inform the importers/customers of the appointment of the OR
- shall supply the substance exclusively according to the specifications given to the OR

Representation

To be the formal representative of the NEM in legal matters, a power of attorney should be granted to the OR

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Model agreement between an OR and a NEM

Other provisions related to prior consent of the NEM:

- the role of OR for others NEM
- participation in a consortium
- function of lead registrant
- conclusion of contract for generating new studies

Budget/Remuneration

Confidentiality - important provisions to avoid blockage by OR in case of change of OR

- OR receives non transferable rights to use
- studies made available to OR remain in the ownership of NEM
- OR to transfer free of charge his rights to such studies to third party designated by NEM
- OR to facilitate transfer of registration duty to another OR appointed by NEM

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Only representative or Importer ?

The pro's and con's for a non-EEA manufacturer can be very different than those for importers/traders.

From an importer's point of view, aggregating the tonnages is more interesting whereas for the non-EEA manufacturer appointing an OR offers the advantage of having only one registration for all its exports to the EEA territory.

Depending on the supply chains, appointing an OR might need the agreement of the importers since as downstream users of the future OR they are supposed to provide him with a series of data which they might considered as confidential...

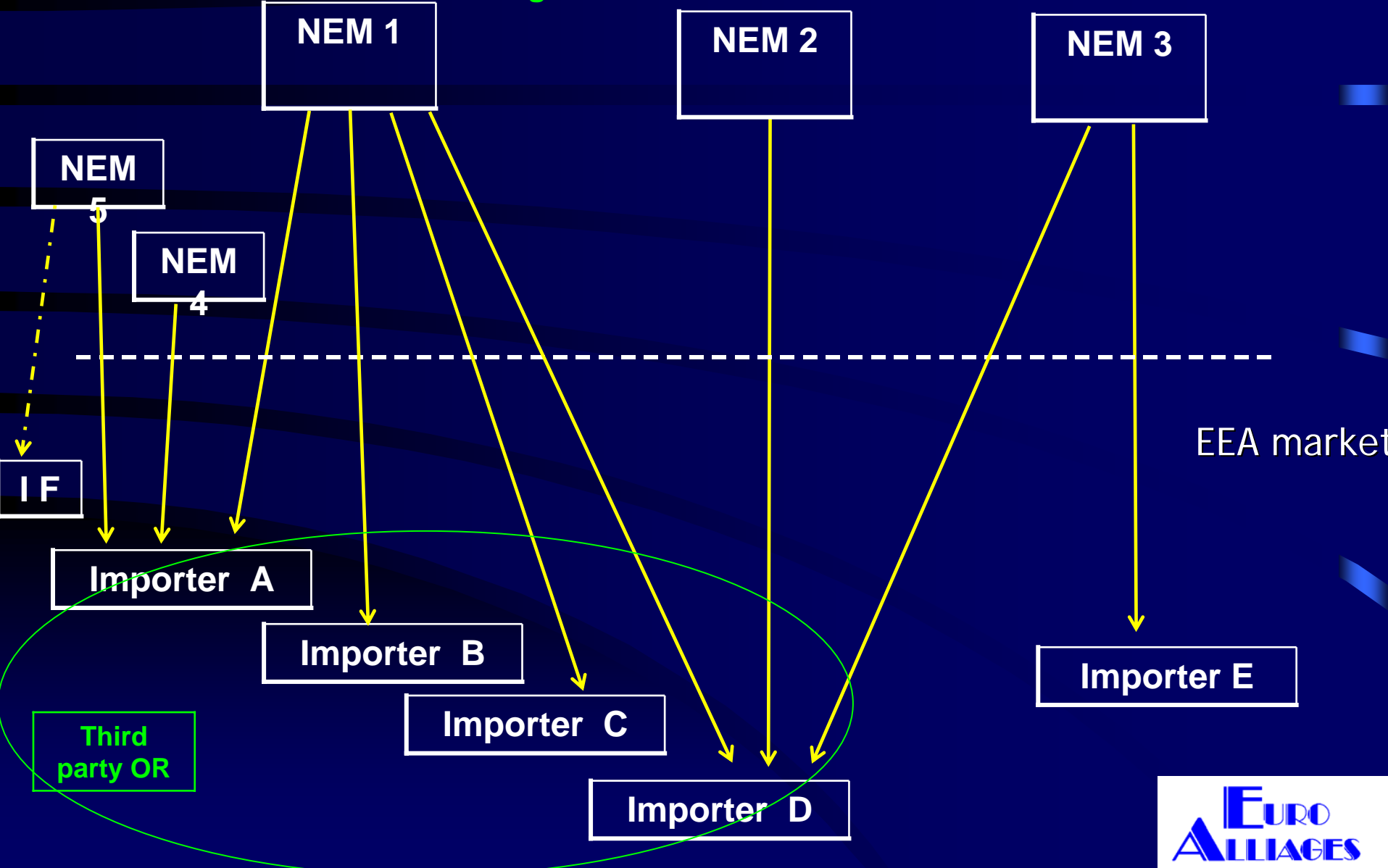
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Substance: X

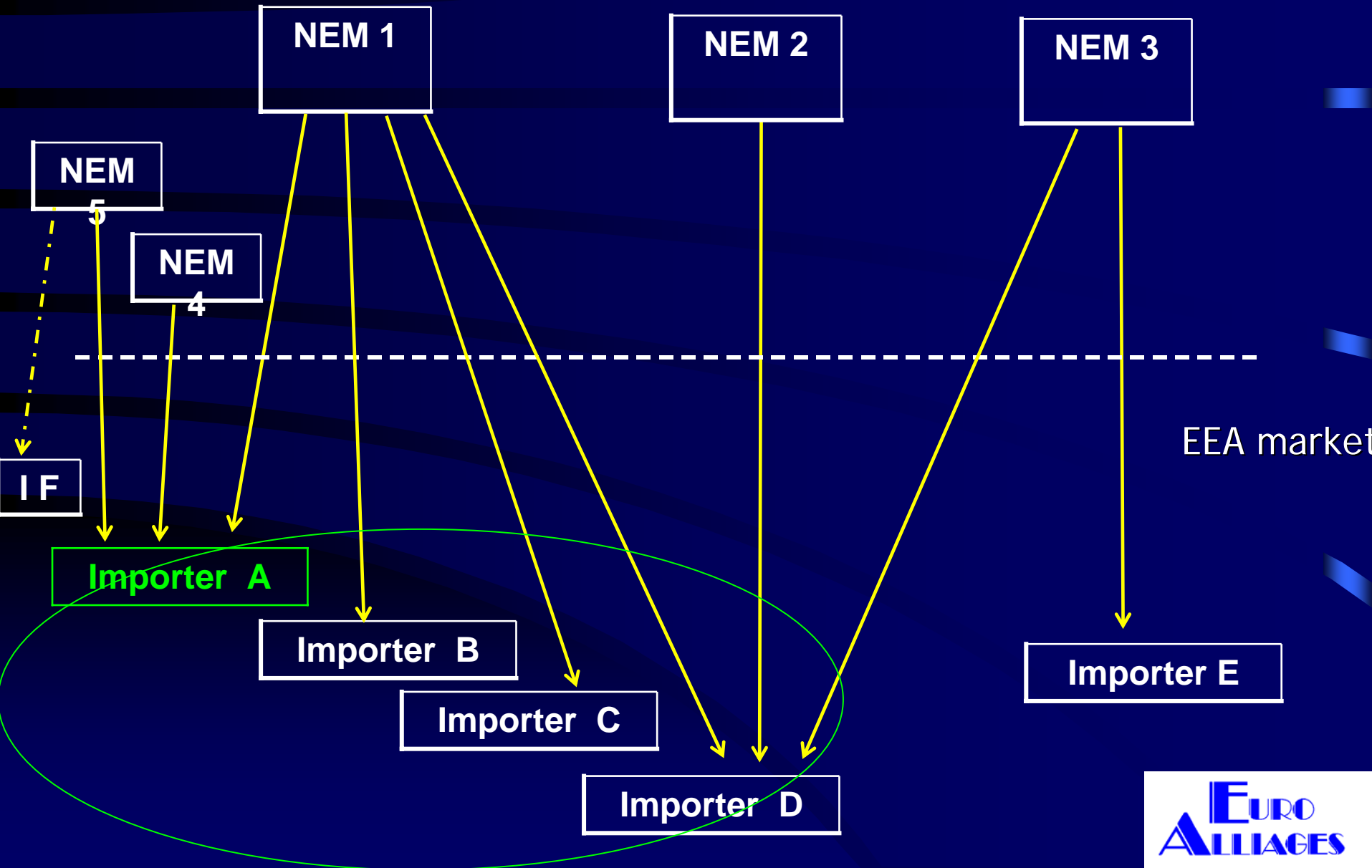
	Importer A	Importer B	Importer C	Importer D	Importer E	Importer F	Duties from NEM view if Only Repr. Option	Duties from NEM view if Importers option
NEM 1	5000	3000	2000	1000	-----	-----	5000 + 3000 + 2000 + 1000 = 11 000 T; 1 fee	4 fees , 4 dossiers/responsibilities
NEM 2	-----	-----	-----	7000	-----	-----	7000, 1 fee	Same as OR unless new client
NEM 3	-----	-----	-----	4000	6000	-----	4000 + 6000 = 10 000 T, 1 fee	2 fees , 2 dossiers/responsibilities
NEM 4	3000	-----	-----	-----	-----	-----	3000, 1 fee	Same as OR unless new client
NEM 5	2000	-----	-----	-----	-----	7000	2000 + 7000 = 9 000 T, 1 fee	2 fees , 2 dossiers/responsibilities
Duties from Importer view if Importer option	5000 + 3000 + 2000 = 10 000; 1 Fee for X	3000; 1 Fee for X	2000; 1 Fee for X	1000 + 7000 + 4000 = 12 000; 1 Fee for X	6000; 1 Fee for X	7000; 1 Fee for X		

Third party acting as Only Representative of NEM 1
Importers A to D = Downstream users of third party
OR

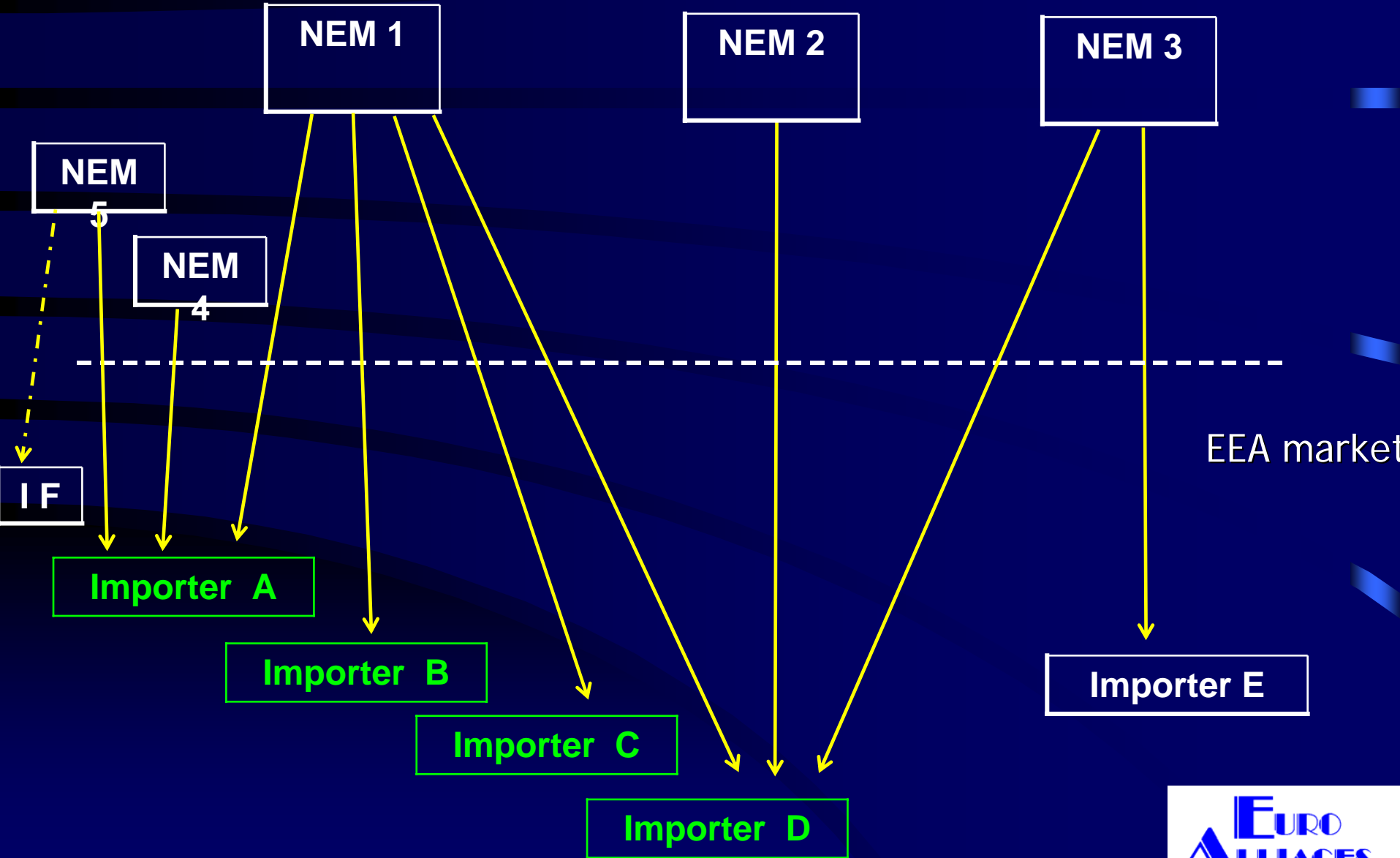
1 registration for NEM 1



Importer A acting as Only Representative of NEM 1
Importers B to D = Downstream users of Importer A
1 registration for NEM 1



**Importer A to D acting as Importer registrants
4 registrations for NEM 1**



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Only representative or Importer ?

'Only representative' (OR)	Importer
<p data-bbox="140 522 316 554"><u>Advantages</u></p> <ul data-bbox="140 601 858 972" style="list-style-type: none">+ more control over the registration process+ avoids disclosure of potentially sensitive information to the importer+ importer regarded as downstream user: relieved of burden of registration+ 1 representative of multiple entrance points of same NEM = 1 fee <p data-bbox="140 1058 357 1089"><u>Disadvantages</u></p> <ul data-bbox="140 1136 906 1393" style="list-style-type: none">- commercially bonded to the OR: restriction of "freedom". Can only represent NEM and not non-EEA traders-sensitive commercial data in one hand- competition concerns likely	<p data-bbox="1003 522 1182 554"><u>Advantages</u></p> <ul data-bbox="1003 601 1810 1051" style="list-style-type: none">+ importer able to import identical substances from other source under same registration+ no disclosure to third parties if same company+ can aggregate tonnages form multiple sources (NEM and traders)+ independent+ competition concerns unlikely <p data-bbox="1003 1136 1220 1168"><u>Disadvantages</u></p> <ul data-bbox="1003 1215 1715 1279" style="list-style-type: none">- 1 registration per importer = multiple fees per NEM

Pre-registration in case of special preparations

Who is the importer ?

Art 3.10: import means the physical introduction of the material into the EU (EEA)

HOWEVER: the criteria of "responsible for physical introduction" depends on many factors and on the contractual situation

- the customs clearance might not be either the decisive factor
- ownership is not relevant either



case by case approach