



Electronic selling of Letters of Access (LoA)

*Lead Registrant Workshop
Helsinki, 2-3 February 2012*



Turning our REACH expertise into practical help for industry

Mark Meesters

Aims of this presentation

- *Explain what is a LoA*
- *Show advantages of LoA electronic sales*
- *Remove concerns in regards to LoA sales as lead registrant*



What is in a LoA?



- Name of owner of data (legal entity granting the right)
- Name of grantee(s)
- UU-ID grantee(s)
- Substance name
- Tonnage band
- Information covered

What is in



Letter of Access to the Registration Dossier of { Field 11 } ({ Field 6 }) for REACH Registration by the members of the {Field 1} Consortium

Subject: Letter of Access for the registration of the Substance under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning *inter alia* the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH")¹

Dear Sirs,

Subject to the terms set forth in the SIEF agreement between { Field 4 } and the members of the REACH { Field 1 } consortium represented by the Lead Registrant { Field 3 } and in consideration of the payment of the relevant Joint Registration compensation, by this letter, the consortium members of the { Field 1 } agree that the REACH Registration Dossier, including data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments, owned by Members of the Consortium and submitted in support of the registration under REACH of the Substance, may be referred by the Grantee { IF "{ FIELD 5}" <> "" "and its affiliates" "" }, in order to support its/their registration of the Substance under REACH.

It is agreed that:

1. The right to refer is restricted only for the registration purpose as specified above.
2. The right to refer is solely granted in favour of the Grantee and is not transferable to any other entity or person, except as explicitly stated in the SIEF agreement.
3. This Letter of Access shall in no event be construed as granting the Grantee any property rights.

GRANTEE: { Field 4 } (UU-ID: { Field 15 })
{ IF { Field 22 } <> "" "Representing:" "" } { Field 22 } { IF { Field 22 } <> "" ", { Field 23 } "" }
{ IF "{ FIELD 5}" <> "" "and its affiliates:" "" }
{ Field 5 }

SUBSTANCE: { Field 11 } ({ Field 8 })

TYPE OF DOSSIER: { Field 6 }

Sincerely,|

For: The members of { Field 1 },
represented by ReachCentrum.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

owner of data
grantee(s)
grantee(s)
name
and
covered

Determination of price



Duties Lead Registrant

Communication

- General information to SIEF members
- Answering questions
- Handling direct competitors

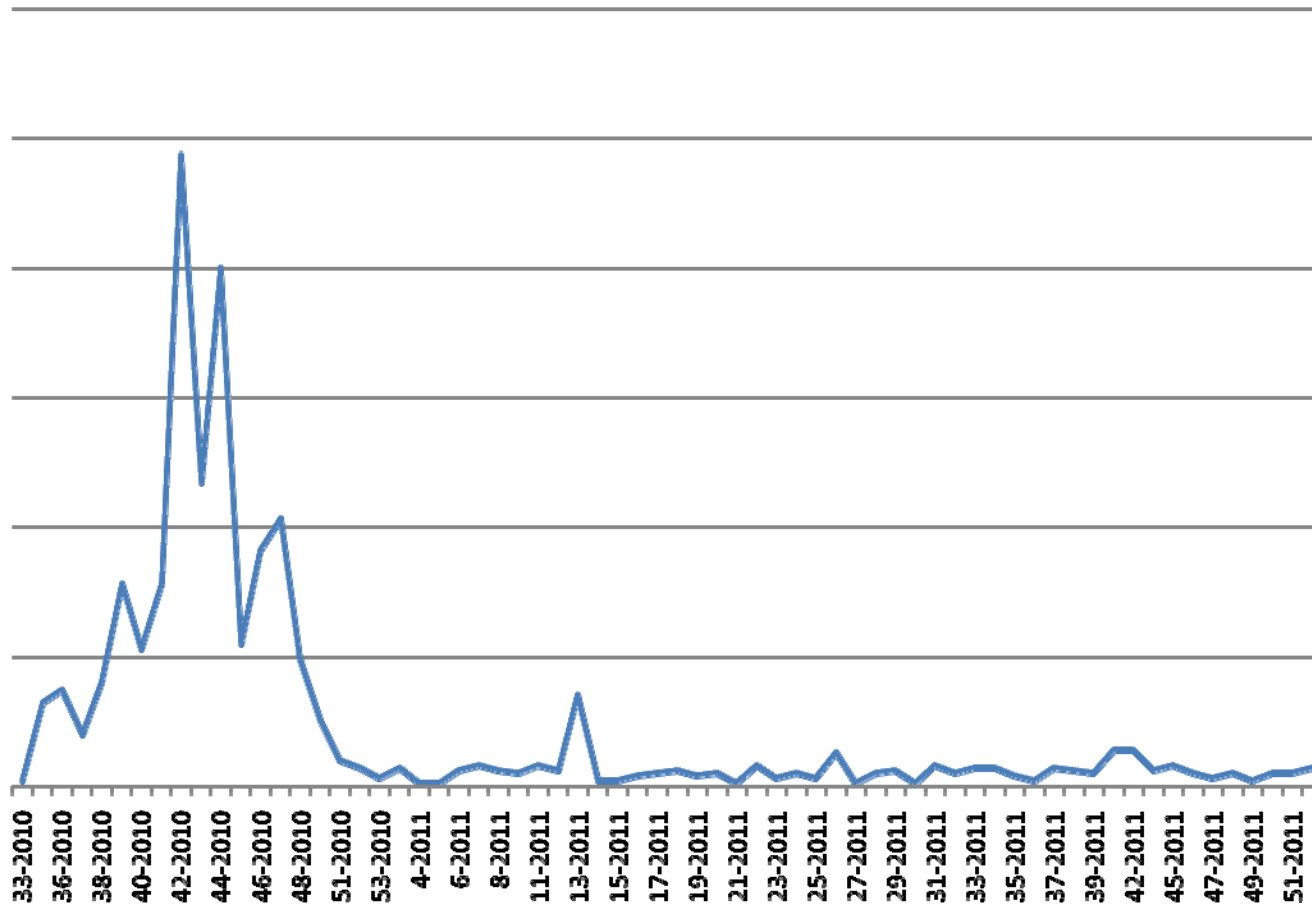
Involvement of accountancy department

- Calculate all costs and determine price Letter of Access
- Check black listed countries
- Prepare invoice
- Follow up payment
- Making credit notes and excuting reimbursements

Administration

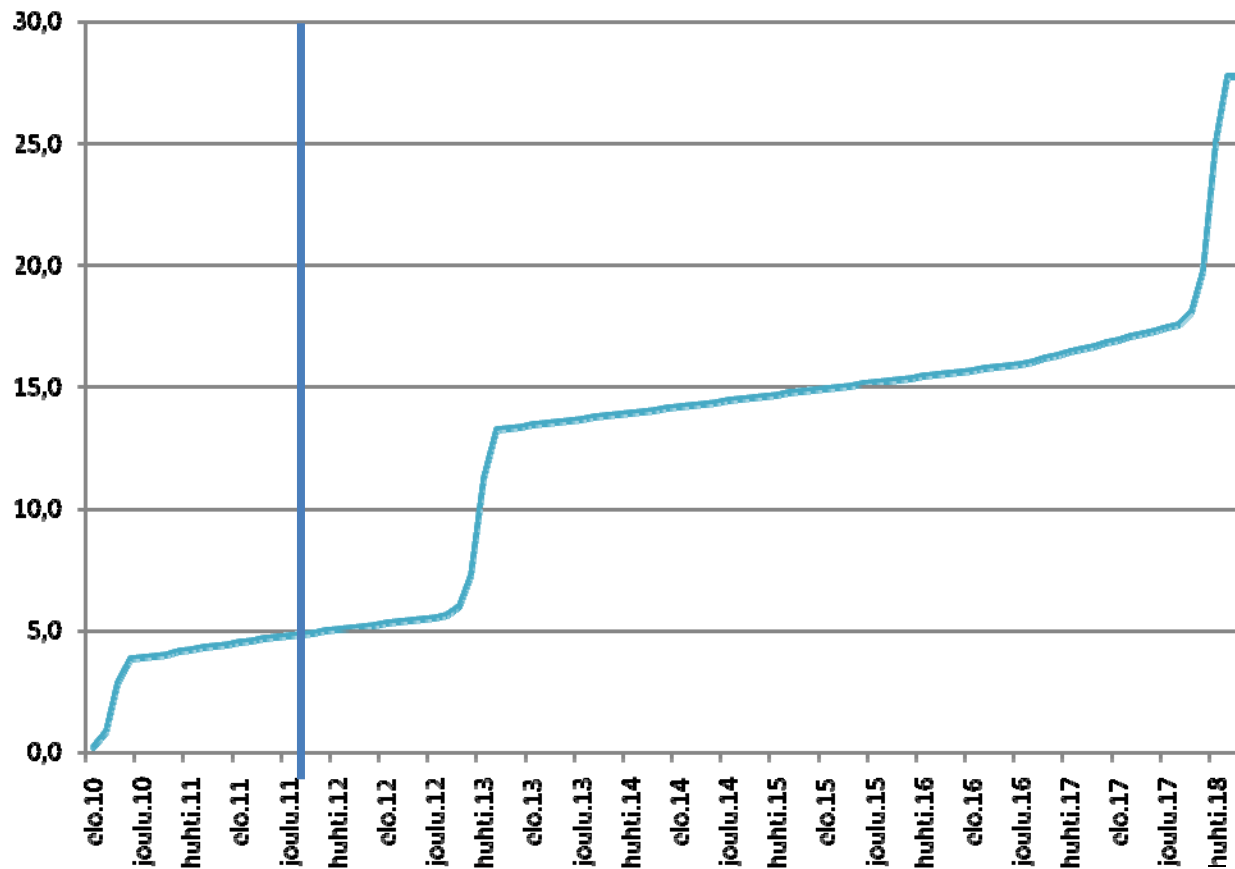
- Collect and process signed SIEF agreements
- Sending of Letter of Access and other documents
- Updating of Letter of Access
- Check used tokens in REACH IT
- Archiving all documentation

Sales before and after 2010 deadline



Based on actual sales by ReachCentrum for 2010 dossiers

Expected number of LoA's per SIEF

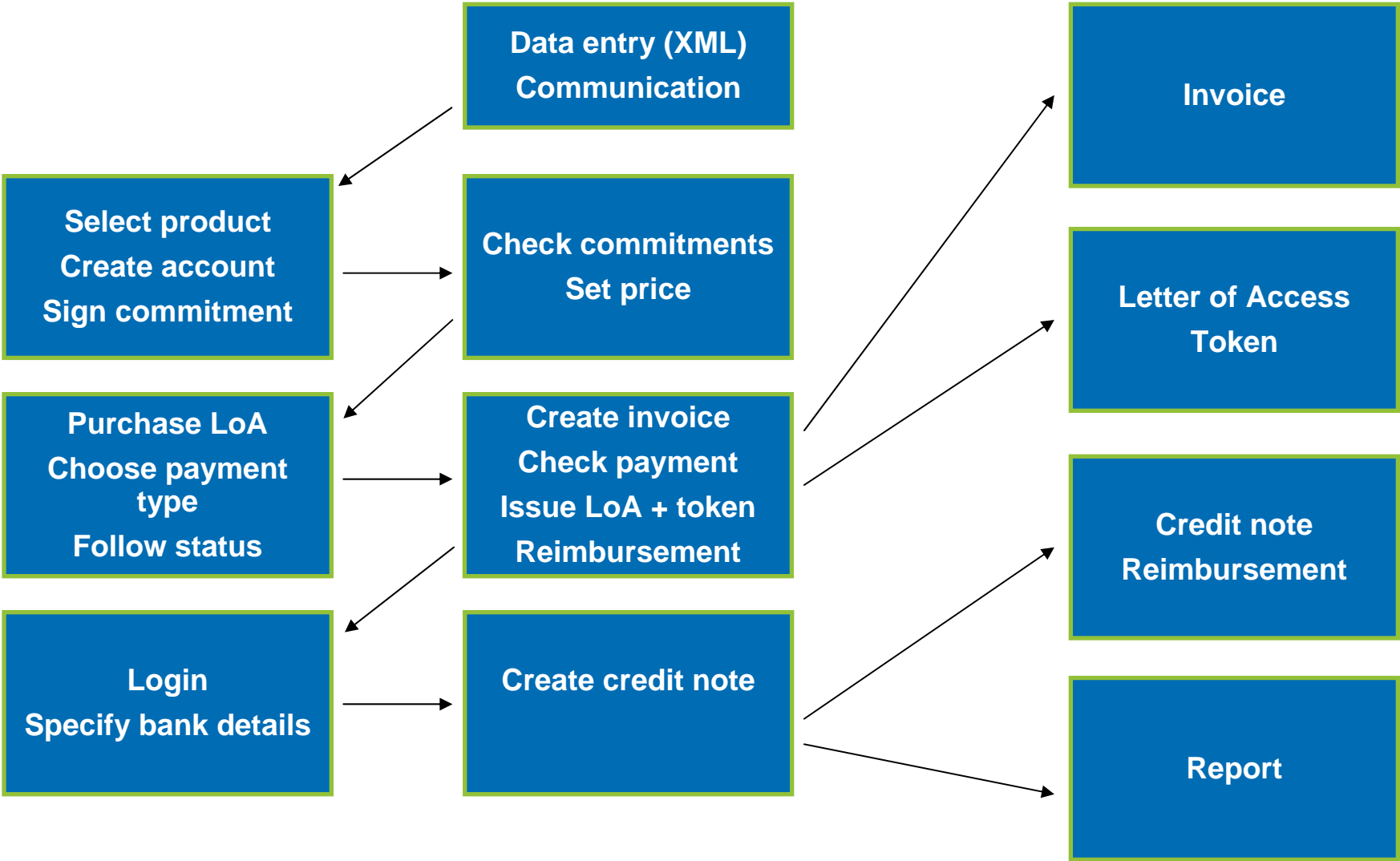


Estimation, based on average number of sales in 2010 and expected registrants in 2013 and 2018

Selection of an electronic system

- **Easy process for dealing with Letters of Access by Lead Registrant**
- **Easy to access the system (via internet)**
- **Easy process to obtain Letters of Access by REACH registrants and follow status**
- **Easy process to (partially) retrieve investments in REACH dossier by Lead Registrant**
- **Easy process to reimburse early registrants in later tiers**

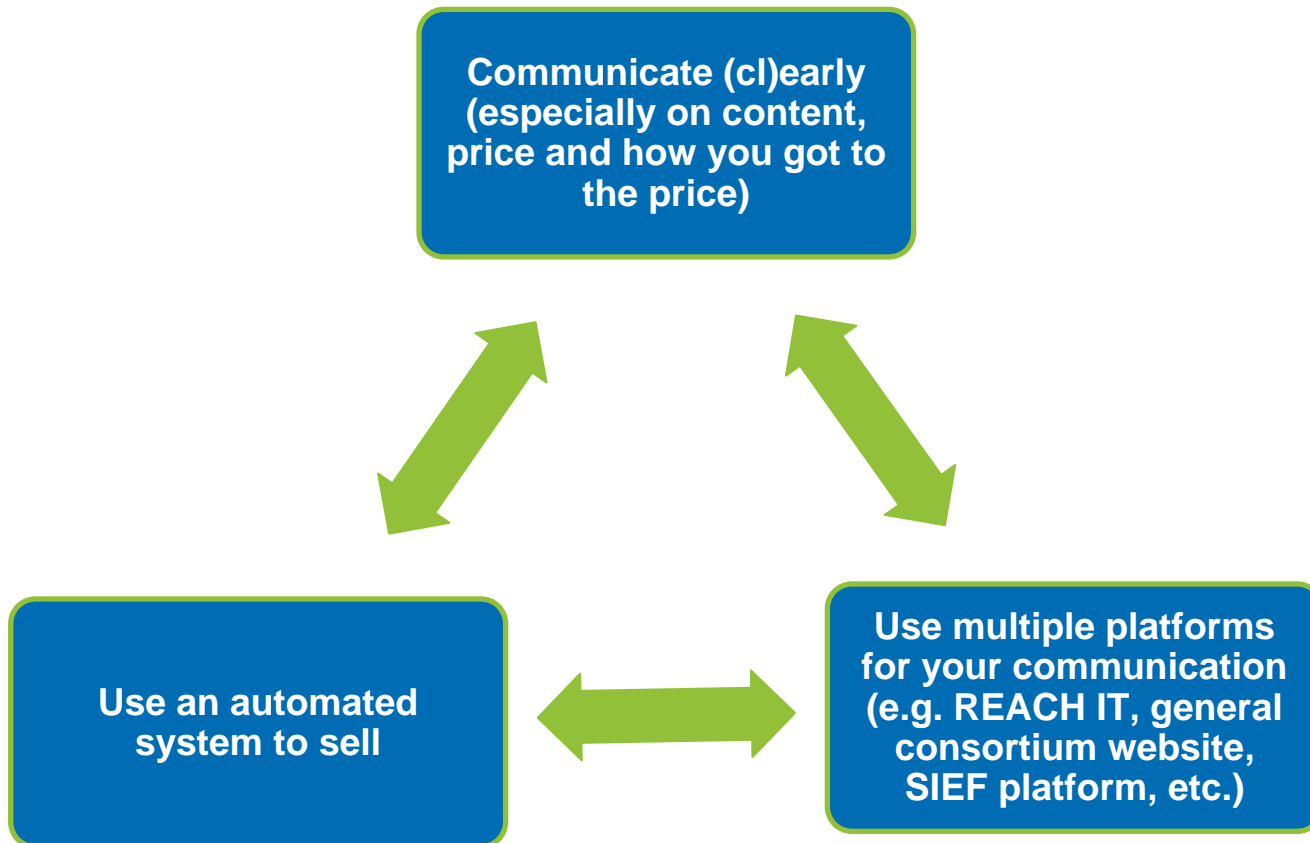
Overview of an electronic system



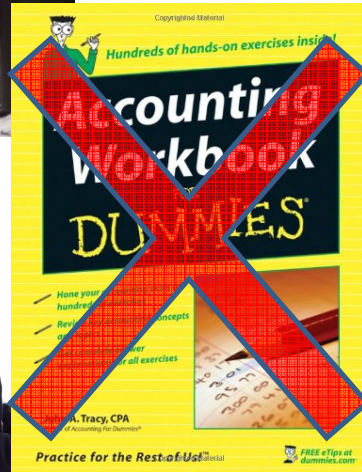
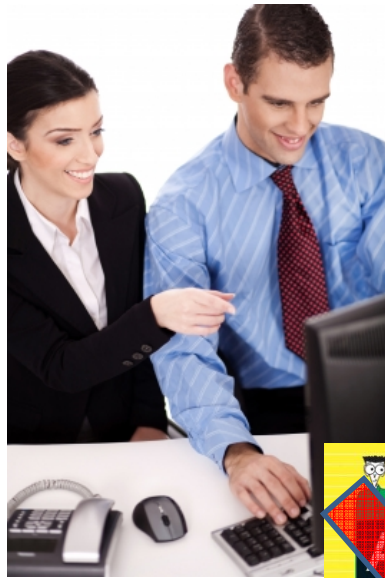
Some other advantages

- **Standardized process**
- **Suitable for other processes, like authorisation, but also other regulations, e.g. biocides**
- **Sales of individual studies, much easier**
- **Costs are relatively low compared to costs for the Lead Registrant dealing with the process**

Letters of Access: conclusion



Aims of the presentation



- *Explain what is involved in regards to LoA's*
- *Explain advantages of LoA electronic sales*
- *Take away concerns in regards to LoA sales as lead registrant*





Turning our REACH expertise into practical help for industry

THANK YOU!

For questions:
mme@reachcentrum.eu

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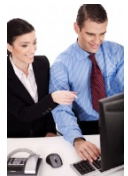
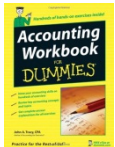


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