REACH Registration 2013

Shanghai Chem Summit 2012

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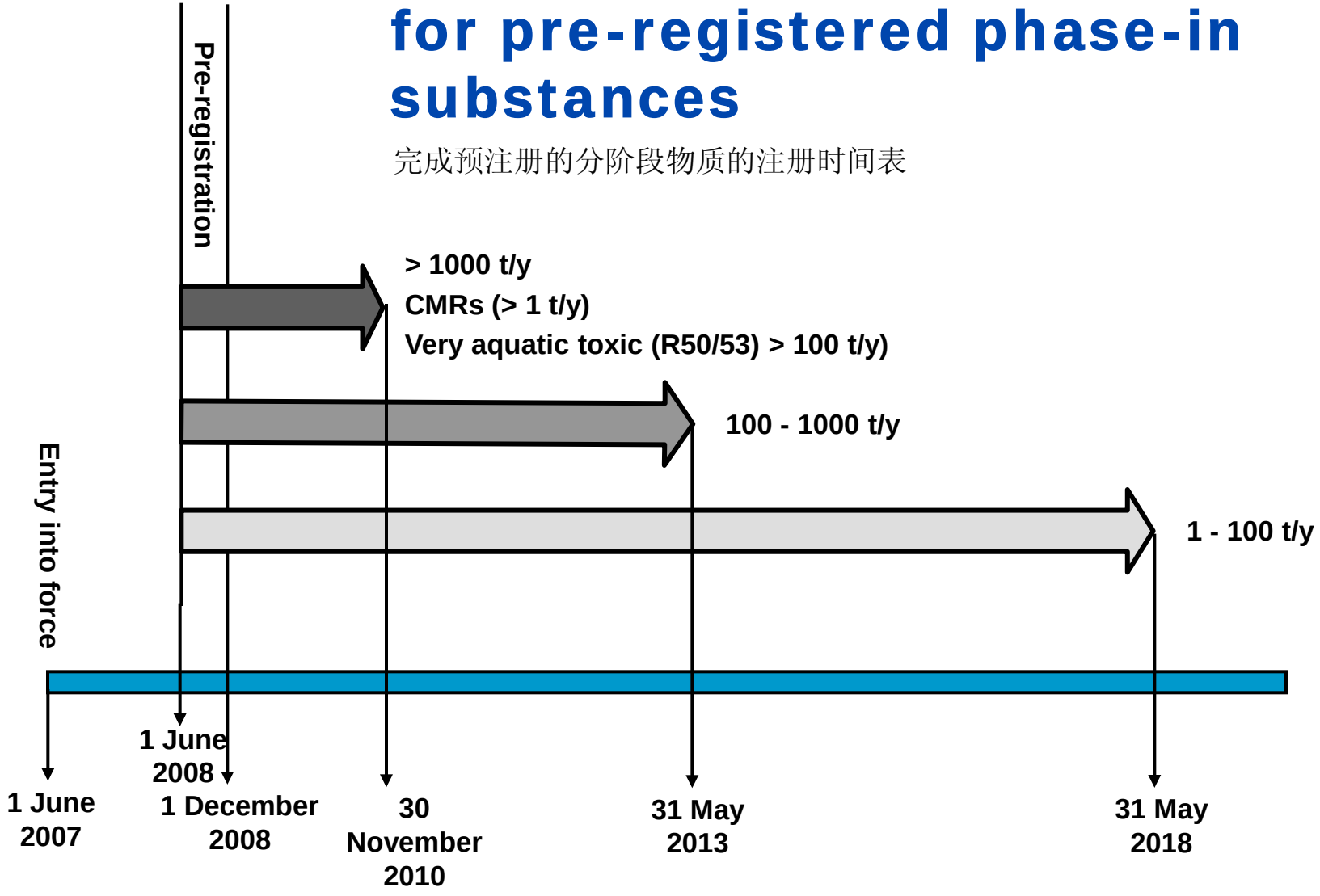
REACH Registration 2013

- **Current status**
- Registration key messages and expectations
- Steps to successful registration
- Only Representatives
- REACH Enforcement

- **注册现状**
- 注册要点及展望
- 成功注册的步骤
- 唯一代表（OR）
- REACH监管

Timelines for Registration for pre-registered phase-in substances

完成预注册的分阶段物质的注册时间表



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Just over one year to the next deadline!

距离下一个注册截止期，仅剩1年

- Phase-in substances **over 100 tonnes per annum**
- Preparations should be well underway!
- Non EU manufacturers: make sure that your Only Representative gets ready

- 欧盟境内年生产或进口100+t/a的分阶段物质
- 为需要注册的物质做好充分的准备
- 非欧盟生产商：确保自己的OR万事俱备

Registration key messages注册要点

- Registration is a big but manageable task:

Already 27 333 new registrations under REACH from approx. 6 800 legal entities for 4 639 substances*

- Is your substance already registered?

Already registered: contact the lead registrant to verify substance sameness, make the SIEF agreement and to obtain your REACH-IT member token

Not already registered: contact (pre)SIEF to establish sameness and agree on a lead registrant

- Members still need to submit their dossiers by 30 May 2013. Ensure that you are able to do this

- Registration is a big but manageable task: （注册工作是一项庞大但是也容易完成的工作）

  已经有近6800家法人实体，为463个物质，完成了27333份注册卷宗

- 您的物质（产品）已经完成注册了吗？

已经完成注册：联系领头注册人，确认自身产品是否满足LR发布的物质同一性，签署SIEF协议，获取token以确认联合提交成员身份

尚未完成注册：与(pre)SIEF成员进行联系，确认物质的同一性，并选举LR

- 无论有无LR，100-1000t/a的毒性一般的物质都需要在2013年5月30日之前完成注册。务必确保在此截止期前，您的主打产品可以完成注册

* data as of 6 Sep 2012, excludes transitional NONS registrations

2013 Expectations – Number of substances

Substances relevant for 2013 deadine	**3813**
Of which are 'new' substances to be registered for 2013	*2 943*
Of which were registered for 2010 deadline by a Lead	*870*

'New' substances to be registered for 2013 deadline	**2 943**
For which a Lead Registrant is known to ECHA	2 173
Of which are already registered by a Lead Registrant	246

'New' substances which are not yet registered and for which no LR nomination has been received by ECHA	**747**

Data as of 31-Aug-12

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances/identified-substances-for-registration-in-2013

2013 Expectations – SIEF Activity

2013注册展望-SIEF活动

- To support SIEF activities, ECHA aims to collect the best possible information on the Lead Registrant status
- List of Lead Registrants on the ECHA Website is one of the best possible sources of information concerning the SIEF progress. The list provides information on:
  - Whether a lead registrant has made himself known to ECHA (i.e. SIEF is active)
  - Whether a registration has been submitted by the same lead or by another company
  - Whether a registration has been submitted by the lead of the joint submission.
- ECHA urges companies to continue to actively participate in the Lead Registrant Nomination at the Website to ensure accurate administration and information of the SIEF formation activities for the 2013 deadline.
- Please, when participating, consent to the publication of your identity.

- ECHA会尽可能多的收集关于领头注册人状态的信息已全力支持SIEF运作
- ECHA官网上发布的领头注册人清单是SIEF动态发展行之有效的素材之一。这份清单主要包含以下信息：
  - LR是否已经将自己的身份通告给LR
  - 物质是否已经由领头公司或其他公司完成了注册
  - 物质是否已经由联合提交的LR完成了注册
- ECHA强烈建议企业积极担任领头注册人以便2013注册截止期前更好的管理并提供SEIF信息
- 如果您担任了LR，务必确保您产品的同一性信息能被潜在注册人认可

https://comments.echa.europa.eu/comments_cms/LeadRegistrantNotification.aspx

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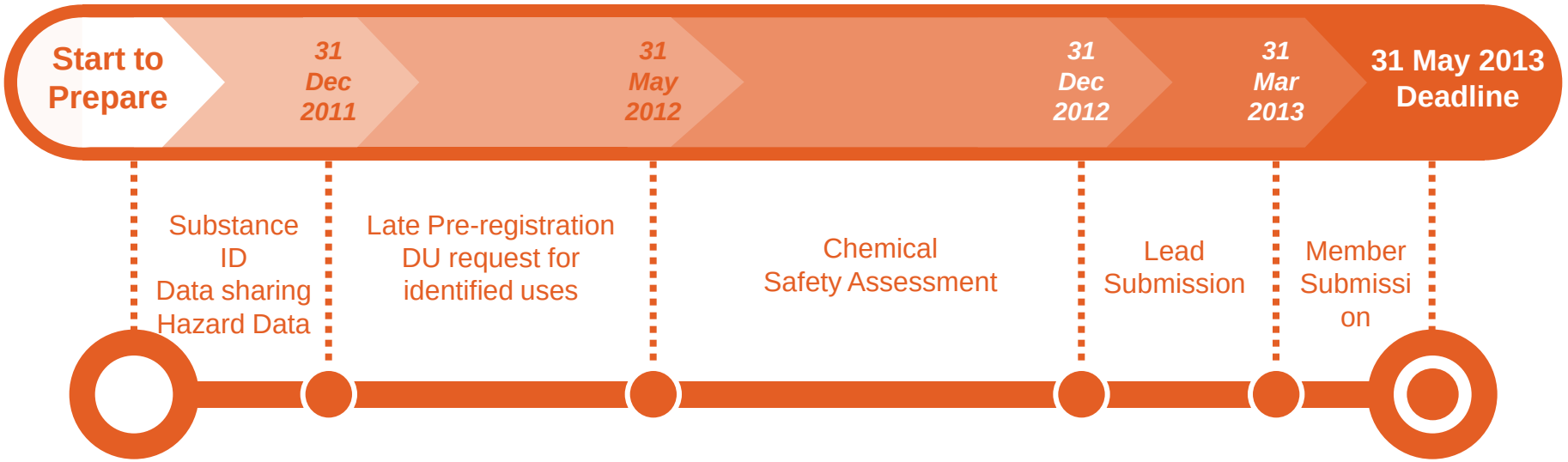
Countdown: optimal situation倒计时：最佳情形



The main SIEF tasks 主要SIEF工作

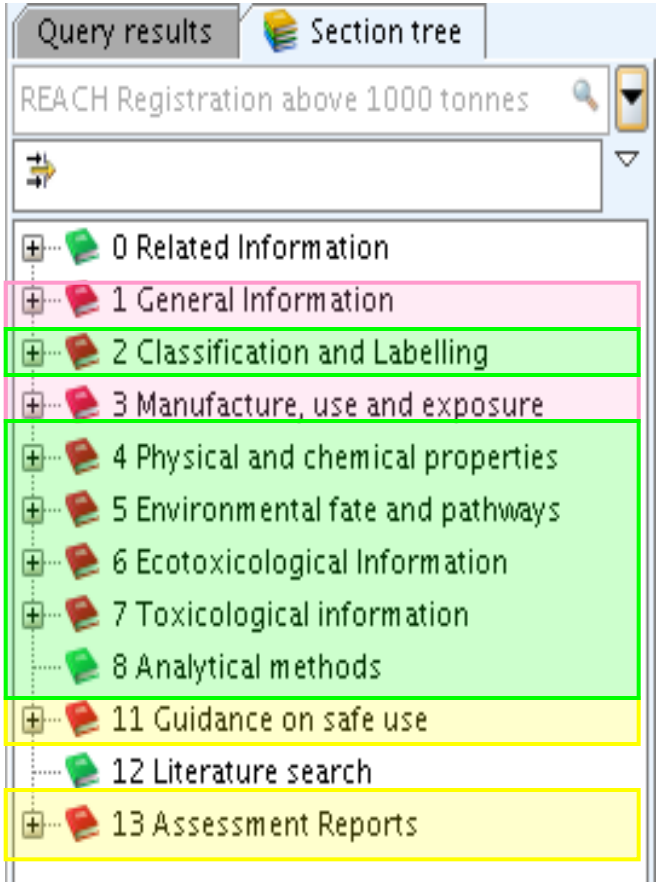
Obligatory steps for SIEF SIEF内必须分步开展的工作	Standard /Recommended practice 标准/执行建议
(SIEF) Agrees on substance sameness (and decide own analytical requirements) 物质同一性的确认	Generate SIEF agreement 生成SIEF协议
(SIEF) Data sharing: vertebrate data must be shared. Other data must be shared if requested 数据共享:脊椎动物数据强制性共享，其他数据如果有需要，也必须共同分享	Generate letters of access 生成数据受权信
(SIEF) Assess data gaps and agree strategy to fill them数据缺口分析并同意填补缺口数据	
(SIEF) Agree on common classification and labelling分类标签信息达成共识	

The main for Lead / Member tasks领头注册人/成员的主要工作

Obligatory steps for LEAD LR必须分步开展的工作	**Standard /Recommended practice** 标准/执行建议
Perform own CSA and document in CSR 开展化学品风险评估并生成CSR	Perform broad CSA and document in joint CSR 开展化学品风险评估并编制CSR
Create REACH-IT joint submission and transfer the 'token' to members 在REACH-IT上生成JS name并将token发送给成员	
Prepare and submit IUCLID dossier 制作并提交IUCLID格式的卷宗	Provide members with IUCLID data set. Co-ordinate 'Guidance on Safe use' section 将IUCLID数据集发送给成员。自行选择安全使用指南是否联合提交
Follow REACH-IT to verify successful submission and payment 确认成功提交卷宗及付款	Give best practice advice to members 给予成员最好的规范新意见
Perform post-registration activities (updates) 开展注册后工作，如卷宗更新等	Use SIEF agreement (or equiv.) to specify post-registration co-ordination e.g. response to compliance check 利用SIEF协议阐明注册后工作，如应对完整性审核

Building the dossier in IUCLID

Lead

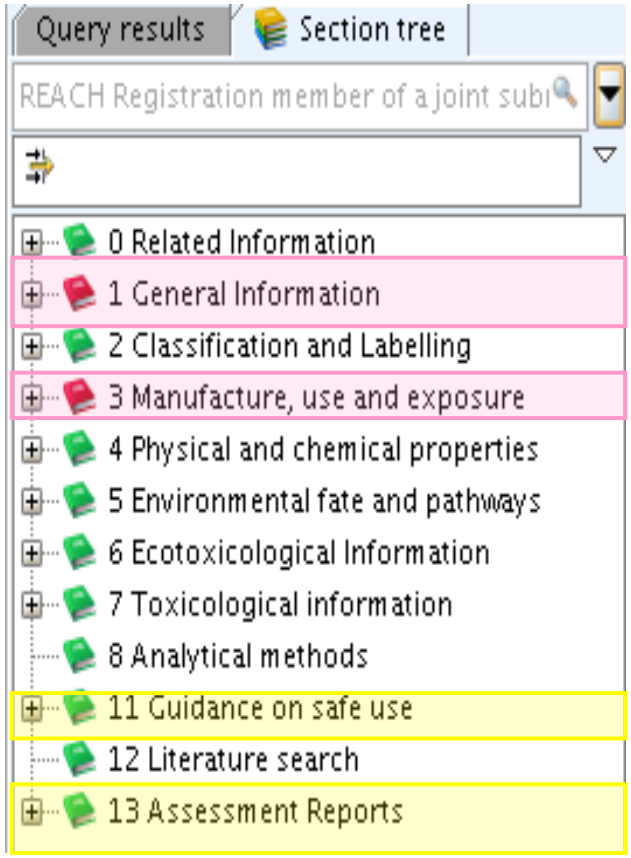


Private data submitted by the LEAD and the MEMBER

Data submitted only by the LEAD (if not opted-out)

Data submitted either by the LEAD or individually

Member



Key steps for ‘member’ registrants
联合提交成员的主要步骤

- Make sure that you are in the correct SIEF and substance ID is sufficiently clear in the registration dossier
- Verify what the SIEF agreement will deliver (previous slides)
- If SME, carefully verify your status: ECHA website > Support > SME’s
- Ensure that you have resources in place to:
  - negotiate within the SIEF
  - prepare and submit the member dossier (making use of the TCC, dissemination and fee calculator IT tools)
  - be ready to pay the fee within the deadline
  - maintain and update the dossier when e.g. new information is received

- 确保您的产品隶属正确的SIEF，注册卷宗中，产品的识别信息明晰
- 确认SIEF协议中传递的内容
- 如果企业是SME规模，根据ECHA官网上SME的介绍，认真审核自身状态是否满足
- 确保您的权利和义务：
  - 在SIEF中进行约定
  - 制作并提交个人卷宗（合理并充分利用IUCLID的插件）
  - 截止日期前务必付费
  - 一旦接收到需要更新卷宗的信息，必须及时更新

Post-registration considerations注册后涉及义务

- **Requirement to spontaneously update dossier include**:卷宗自我更新的要求

Change in status/identity 注册主体身份或状态变更	Change in composition 物质组分信息变更	Changes in tonnage band 注册吨位变更
New identified uses/uses advised against增加新的下游用途或不建议用途	New knowledge on risks (impacting CSR and/or SDS) CSR或SDS中风险更新	Change in classification and labelling 分类标签信息的更新
CSR/Safe Use amendments CSR/安全使用修订	Testing proposal needed 提交测试计划	(Respond to Quality Observation Letter)及时回复质量审查通知

- **Regulatory updates:**
  - Responding to compliance check (draft/final) decision
  - Responding to request for further information on confidentiality claim
  - Responding to TCC failure of a submitted spontaneous update

- **Be prepared and invest resource in this**
- **常规更新**
  - 处理完整性审核决议草案/决议终案
  - 处理关于保密条款需要提供进一步信息
  - 处理在提交自主更新注册卷宗时TCC失败的情况

- **时刻准备并切实关注**

Post-registration considerations注册后涉及义务

- **Based on experience; proactive spontaneous updates recommended in the following areas:**
  - **Dossier evaluation**: Completeness ≠ Compliance:
    - Read the Article 54 Evaluation Report and invest in a spontaneous update to address potential issues prior to compliance check
    - Take care to correctly enter all testing proposals in the dossier
  - **Intermediate status**: Screening of intermediate dossiers under 'Article 36' provisions showed that 86% of dossiers screened had insufficient information to confirm intermediate status. Formal updates have been requested and work is ongoing.

- **根据经验，以下几种情况可能需要卷宗自我更新**
  - **卷宗评估**：完整性≠应对
    - 仔细阅读ECHA发布的年度评估报告，在卷宗被评估前，对有可能被审核的项目进行自我更新
    - 关注卷宗中所有的测试方案
  - **中间体状态**：中间体注册卷宗的筛选结果表明，86%的注册卷宗不足以确认其中间体状态，因此需要进行更新。中间体注册卷宗评估工作将持续开展。

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Only Representatives – concept and definition

唯一代表（OR）-概念及定义

- In principle, substances imported into EU need to be registered by importers
- However, a non-EU manufacturer can appoint an Only Representative to carry out the registration obligations of the importers
- Non-EU manufacturer then needs to inform all importers of the OR appointment
- OR can be any legal entity established in EU with sufficient background in the practical handling of substances and the information related to them
- A non-EU manufacturer can only appoint one OR per substance

- 原则上，进入欧盟境内的物质，需要由进口商完成注
- 非欧盟生产商可以委托唯一代表（OR）开展注册工作
- 非欧盟生产商有义务就已经委托了唯一代表的事通知其所有的进口商
- OR可以是建立在欧盟境内的，有足够的能力应对化学物质及相关信息背景的机构
- 每一家非欧盟生产商，仅可以为其每一个物质委托一家OR

Only Representatives – responsibilities 唯一代表(OR)的责任

Only Representatives need to:

- to comply with all other obligations of importers under REACH (pre-registration, data-sharing,…)
- to keep up-to-date information on EU importers and the quantities imported which are covered by the registration
- to cover in the dossier all uses of the substance by importers covered by the registration
- If a OR represents different non-EU manufacturers, separate registrations are needed (trough separate accounts in REACH-IT)

唯一代表（OR）必须：

- 履行REACH法规下进口商的所有义务，如预注册，数据共享等
- 实时掌握注册物质下欧盟所有进口商及其进口吨位的信息
- 确保注册物质的进口商其所涉及的所有用途都在卷宗中包含
- 如果一家OR代理多家非欧盟进口商，需要单独开展注册工作（需要为不同的企业在REACH-IT上创建不同的账号）

Only Representatives – SME status 唯一代表(OR)-SME状态

- Reduced fees apply to micro, small and medium-sized enterprises (SMEs)
- In case of ORs, the size of the non-EU manufacturer has to be reported
- ECHA may request evidence of the SME status of the non-EU manufacturer

- 如果申请了微型，小型和中型企业，可以享受费用优惠政策
- 如果注册者身份是OR，公司规模依非欧盟生产商而定
- ECHA有权要求注册者提交非欧盟生产商的SME证明材料

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Outline概述

- Enforcement in EU law
- Competent authorities and enforcement authorities
- REACH and CLP enforcement
- Forum
- Support from other EU legislation
- Conclusions
- 欧盟法律法规下的监管
- 成员国主管当局及监管当局
- REACH及CLP监管
- 论坛
- 欧盟其他法规的协助
- 总结

Enforcement 监管

- Once a legislation is adopted, there is a need to use/create tools and structures to enforce it
- Vast majority of EU law, enforcement is Member States responsibility
- REACH and CLP are not different in this respect (e.g. penalties, administrative structures)

- 一旦法规正式通过并实施，就必须要有相关监管措施
- 繁复的欧盟法规，监管工作由成员国落实
- REACH和CLP在监管监管方面类似，如处罚，行政机构等

Member States authorities (CA & NEA)

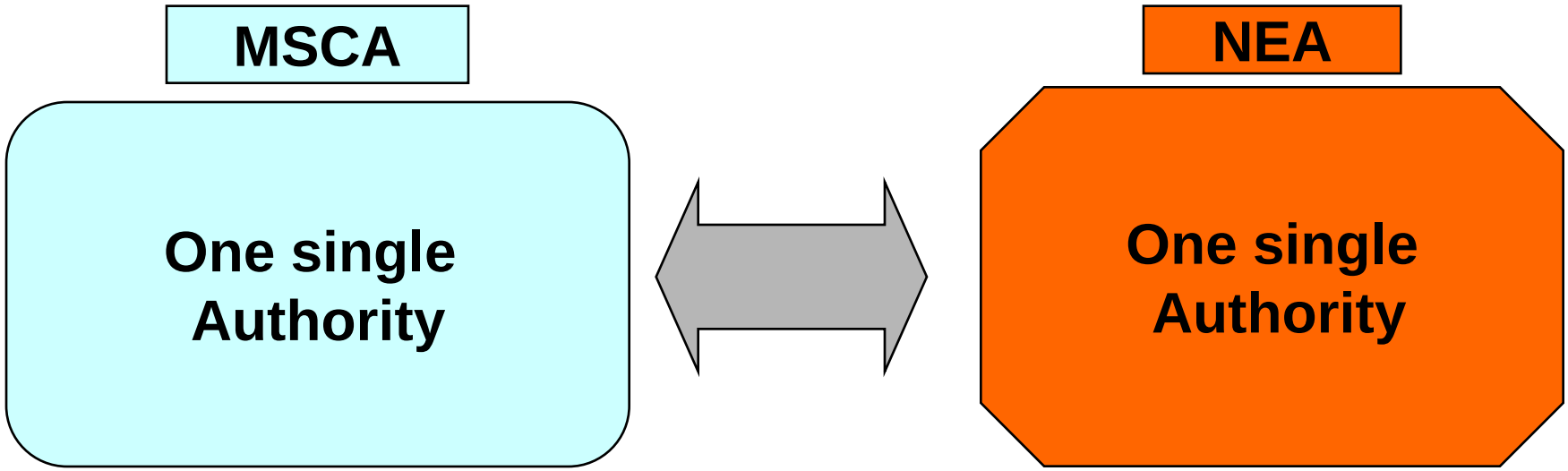
成员国主管当局(CA & NEA)

	One	Several bodies
MS Competent Authorities (MSCA)成员国主管当局	20	10
National Enforcement Authorities (NEA)各国监管当局	6	24

- Administrative structures change from MS to MS
- More bodies are involved in enforcement
- 不同成员国当局设置的行政机构不同
- 监管涉及的机构将越来越多

Relatively simple structure of MSs

成员国当局相对比较简单的组织关系

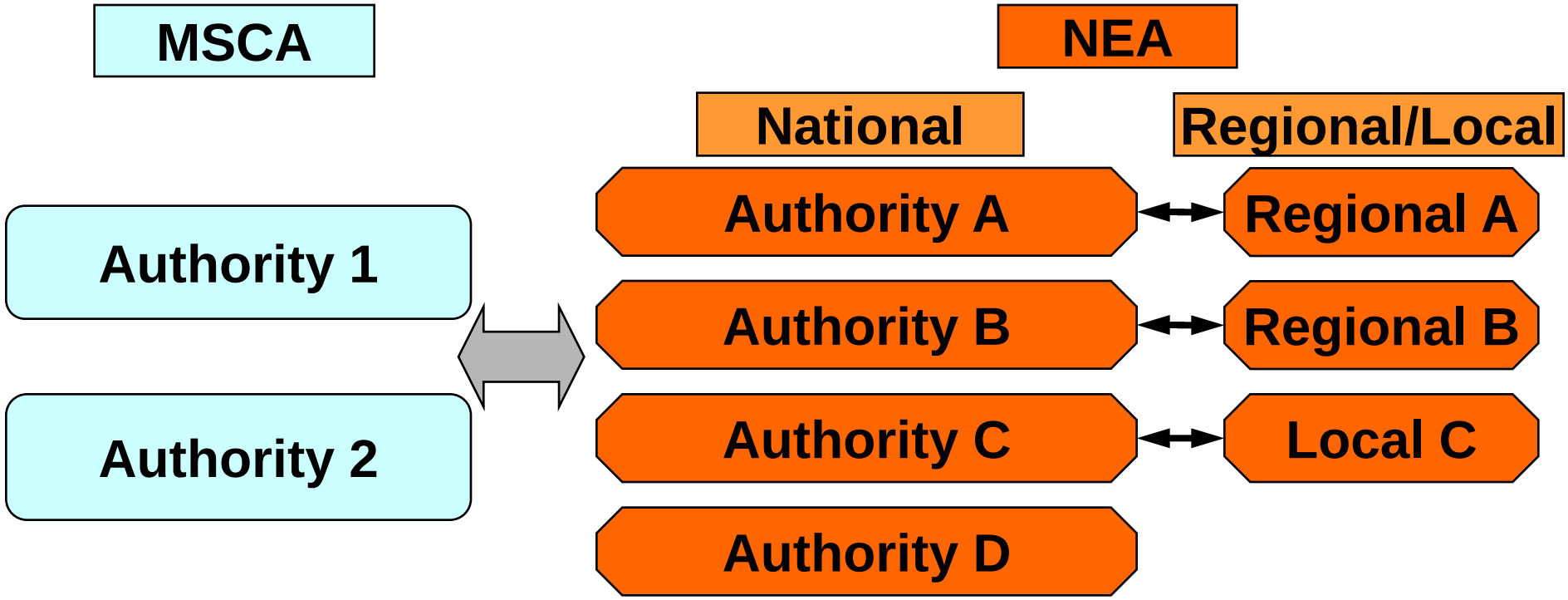


5 Member States have this type of structure

5个成员国拥有这种组织结构

Relatively complex structures of MSs

成员国中相对复杂的组织关系



9 Member States have this type of structure

9个成员国拥有这种组织结构

REACH and CLP enforcement REACH和CLP监管

- Regulations → Directly applicable
- Obligations for MS (e.g. penalties, helpdesks)
- Creation of a new enforcement body: Forum
  'European network of REACH and CLP enforcement authorities'
  !Formal body!
- 法规→ 直接适用
- 成员国责任，如惩罚，helpdesk等
- 成立一个新的监管主体：论坛
  “REACH和CLP监管当局的欧盟网络系统”
  !Formal body!

Why Forum in REACH and CLP?

为什么为REACH及CLP监管设立论坛

- Need to accommodate the MS differences but all of them working on the same legal background
- Need to strength enforcement at EU level
- Spreading good/best practices, harmonised enforcement projects, exchange of inspectors, enforcement strategies, tools and methods
- Liaise with industry and stakeholders
- 尽管各成员国都致力于为法规服务，但是监管仍然存在差异，对此需要调和
- 从欧盟层面上加强监管
- 传递良好地操作模式，统一监管项目，增进审核员，监管战略，工具及方法的交流
- 加强与行业及利益相关者的沟通

REACH and CLP enforcement is not alone

多层面对REACH及CLP的实施开展监管

- REACH and CLP enforcement supported by other EU legislations, some examples are:
  - **Integrate customs legislation to support REACH and CLP enforcement**
  - **General Product Safety Directive (GPSD)**
  - **Restrictions and rapid alert system for dangerous consumer products (RAPEX system)**

- REACH及CLP的监管获得了欧盟其他法规的支持，如 ：
  - 联合海关相关法律法规以协助REACH及CLP监管
  - 通用产品安全指令（GPSD）
  - 危险消费品限制及快速预警系统(RAPEX system)

Conclusions结论

- Enforcement is essential to achieve REACH and CLP objectives
- Respect national differences and integrate them in the Forum work
- Strength enforcement to achieve REACH and CLP objectives

- 监管是保障REACH及CLP法规达到预期目的的必要手段之一
- 尊重各成员国监管方面的差异，并将其整合到论坛工作中
- 加强监管以达到REACH及CLP法规预期的目的

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you.

Let’s work together for another successful deadline!