REACH Outside the EU

An International Perspective

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An International Perspective on REACH

- Objective: Highlight compliance issues sensitive especially for Non-EU Manufacturers ("NEUMs")

- NEUMs do not have direct REACH compliance obligations, but…

  the substances NEUMS place on the EU market face the "no data, no market" principle. If NEUM does not take responsibility to ensure that its substances are properly registered, liable to substantially damage or lose its EU market (i.e., disrupt existing supply chain / get customers very upset); possible fines under national law

- NEUM has to get compliance right because no one else can fully take care of it for you. (Competitors will enjoy your predicament!)

An International Perspective on REACH

- Practical Areas of NEUM Concern:
  - ✓ Compliance structuring
    - Who should register, and why?
  - ✓ Compliance implementation (early stages)
    - Now pre-pre-SIEF activities as well as pre-SIEF (what the Regulation does not tell you)
  - ✓ Special considerations
    - How do those exemptions actually work?

- Legal Concerns:
  - ✓ Polymers/monomers (is imported monomer in polymer registration "necessary"?) EU / WTO concerns?
  - ✓ EU Competition law – what's really happening in the consortia?
  - ✓ Consequences in other areas of law – anti-dumping impact?

Who is affected by REACH?

- Every EU Manufacturer and Importer of a "substance", whether on its own or in a preparation, and in certain conditions also substances in "articles" → Pre-registration + SIEF activities, Registration, Authorisation of SVHC, potential Restrictions on use …
- (EU) Downstream Users → Information & potential CSR obligations, SIEF activities if "data holder"
- **NEUMs / Exporters to EU Market** (substance, preparation, article) → Compliance Assurance (No Data, No Market); Protection of CBI; Potential Registration through "only representative"; REACH Cost Minimisation
- Other Data Holders → Can join SIEF to offer test data to potential registrants (Industry/trade assoc. & consortia (EU & **non EU**), **NEUM** non-registrants, NGOs, labs, universities, national/int'l agencies
- Many companies fit one and often several roles – REACH has substantial impact on all parties with interests in substances being placed on EU market

1. Compliance Structuring Issues

- NEUM as exporter and "data holder" – choices:

a) Importer(s) registration route

- ✓ NEUM provides own data (data in your "legitimate possession") to EU importer(s) for use in importer's registration and SIEF/consortium activities
- ✓ Ensure adequate protection of NEUM's Confidential Business Information ("CBI") (risk factor if independent importer also acting as Registrant for imports from other NEUMs/ competitors)
- ✓ Likelihood that NEUM must finance some/all of importer's registration costs (registration fees, any required SIEF data-sharing costs, related consultant/legal fees, potential consortium costs distinct from SIEF activities)
- ✓ NEUM possibility to alter volumes to importers to minimise registration burden (data and deadlines), but mainly with related importers/sales subsidiaries

Compliance Structuring Issues, cont.

b) Alternative Registration route - Designate and provide data to trusted "only representative" ("OR") who substitutes importer(s) registration and other REACH obligations

OR can be:

- one of several related importers/subsidiaries (if any)
- Most trusted of unrelated importers
- external consultant who is experienced (technical and legal support)

= trust relationship to handle REACH and assume any liabilities

✓ NEUM must still provide own data to OR under CBI protection conditions to (pre-)register and actively represent NEUM in SIEF/consortium activities

Compliance Structuring Issues, cont.

- ✓ Need to finance OR's registration fees and costs but if multiple importers then efficiency gained through single OR registration
- ✓ Main drawback: OR cumulates volume of NEUM's exports which may mean greater data required for registration and/or earlier deadline for registration
- ✓ But have single trusted representative to handle especially SIEF data-sharing responsibilities – close cooperation with OR still essential to handle properly any SIEF requests for NEUM data and potential NEUM/OR requests for other members' data.

Compliance Structuring Issues, cont.

c) Special considerations

Scenario 1: NEUM is joint owner of data per membership in non-EU industry association/ consortium that has generated/owns relevant data

- Does NEUM have right to use that data for EU REACH registration? What if other joint owners not exporters to EU and not willing to allow? Check right to use data as such, also if right to disclose further under SIEF data-sharing rules to requesting SIEF members (may have to amend foreign industry/consortium contract to allow this and establish terms for disclosure – negotiate early!).

Scenario 2: Non-EU assoc./consortium to become SIEF member directly as data-holder and can control sharing activities as data owner (but likely only if multiple members are exporters to EU and see common advantage in doing this)

2. Compliance Implementation Issues

- Recent guidance from the European Chemicals Agency ("Agency") has added REACH compliance activities not even hinted at in the Regulation. This helps to avoid total chaos but also raises additional issues/activities that NEUMs must address in an ever shorter timeframe

  e.g. pre-SIEF activities and, in reality, also pre-pre-registration activities (esp. consortia formation).
- Impact: Accelerates need for NEUM decision-taking on what external structure they prefer for registration compliance (while EU producers not concerned because they will normally act directly on own behalf).

Compliance Implementation Issues, cont.

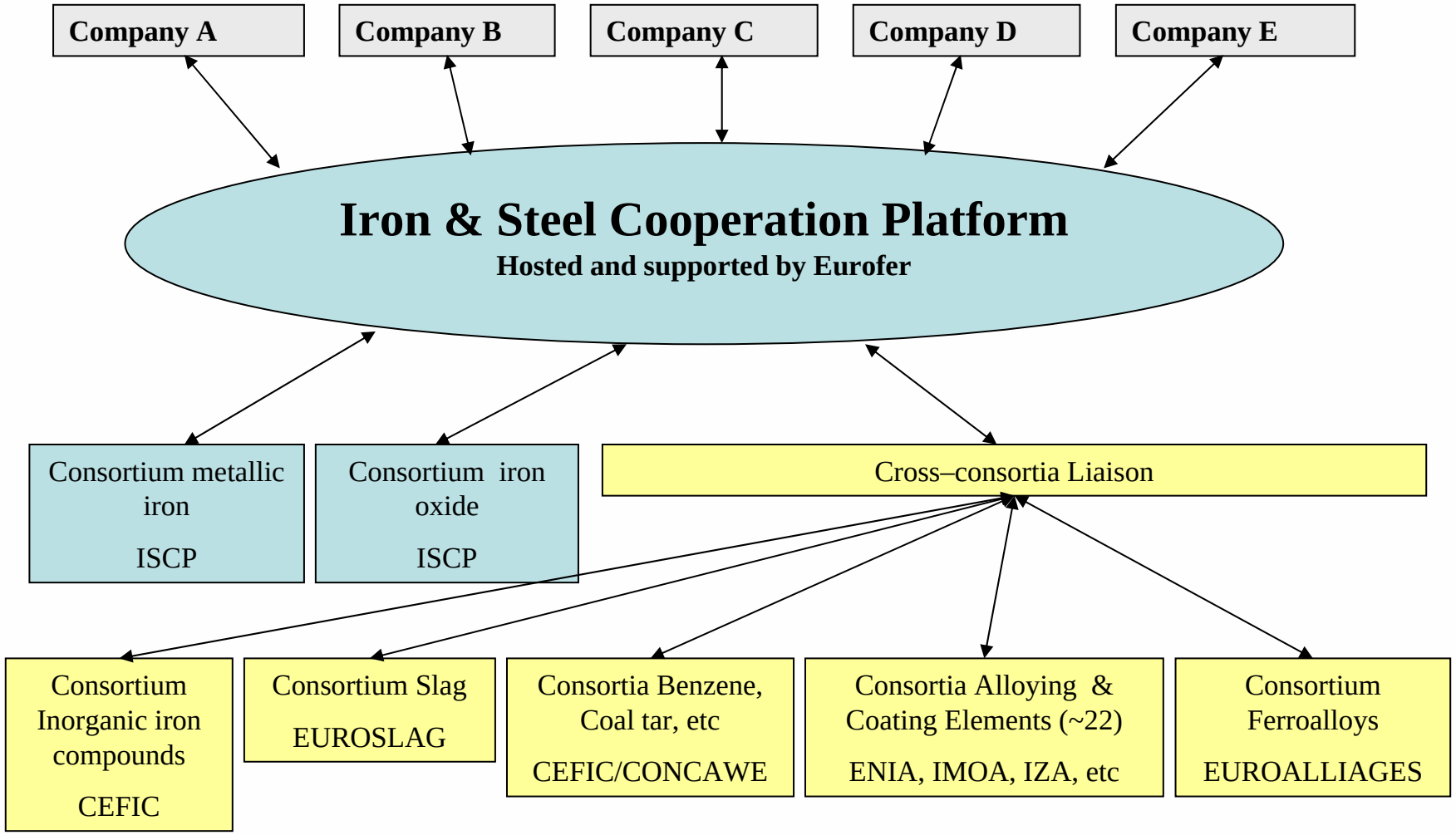
- Pre-SIEF Activities (per Guidance 3.4 - not REACH)
  - ✓ Goal: establish foundation for SIEF formation
  - ✓ Only for pre-registrants (dedicated Agency web-page disclosure) (EU manufacturers and importers, substitute Ors, "third party representatives" who cover identity of actual registrant)
  - ✓ Substance identity / "sameness" (per Guidance on substance identification)
  - ✓ SIEF formation through volunteer "facilitator"
  - ✓ Related consortia formation (voluntary)

- Pre-pre-registration activities – no basis other than need
  - ✓ Essentially same activities as pre-SIEF plus more per practical need to collectively prepare asap (product characterisation, C&L, data availability, etc.), happening now!

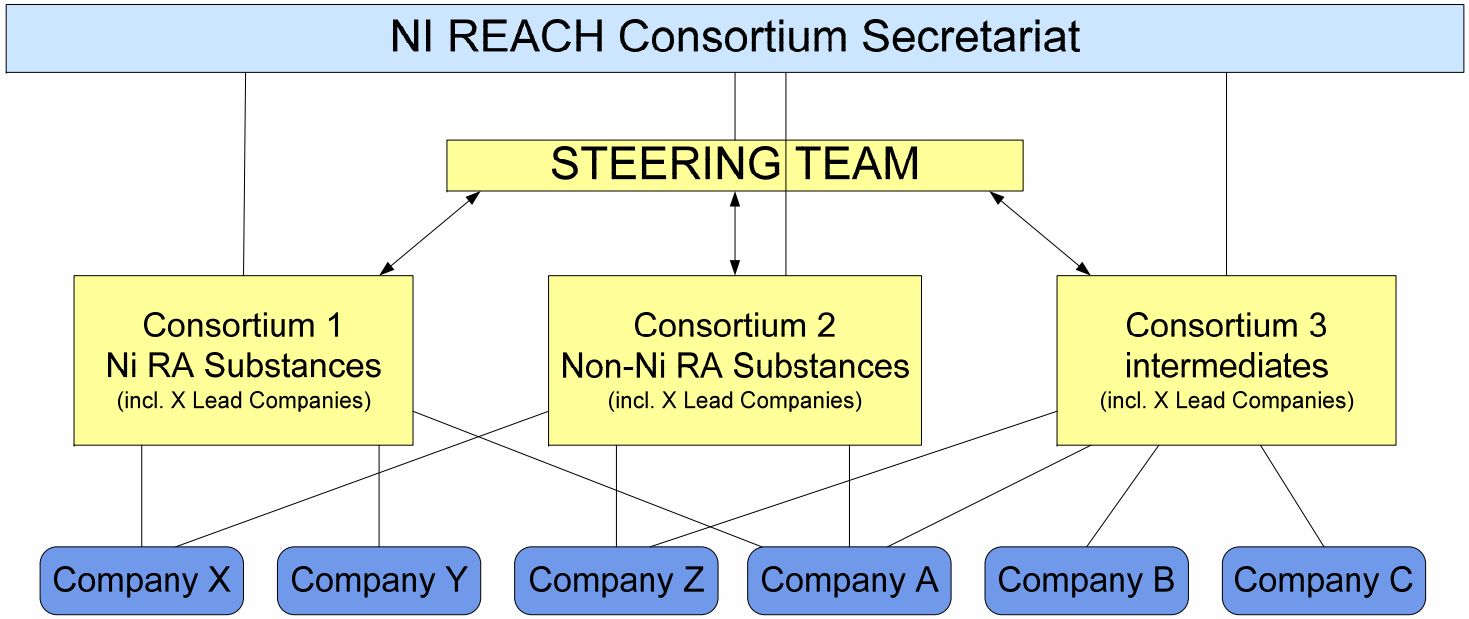
Compliance Implementation Issues, cont.

- Focus on Consortia issues:
  - ✓ Purely voluntary grouping though can establish legally binding arrangements amongst members
  - ✓ Distinct from SIEF – related objectives but not linked in any legal way
  - ✓ Consortia coverage not necessarily SIEF consistent; can follow treatment of substances within industry/trade association, e.g.:
    - Single substance grouping (like SIEF)
    - Multiple substances with similar properties (similar risk assessment, C&L)
  - ✓ Note: non-EU associations may/may not have strong relations with EU association so treatment of NEUMs may vary
    - May have different interests (preparation vs article; different data sets)
    - If NEUM's own national (non-EU) association not REACH active and EU association not helpful or focusing on your product, then must find leading NEUM companies to start discussions as possible

Eurofer's Proposed Implementation Plan



Consortia models



Compliance Implementation Issues, cont.

NEUMs and EU Consortia:

- NEUM (and importers) may be disadvantaged vis-à-vis early EU manufacturer talks taking place in existing/early REACH consortia or informally (i.e., in pre-pre-registration activities)

Why?

- EU manufacturers talking about key issues to facilitate efficient compliance: “preparation” v. “article” discussions (EU looking to industry input to finalise positions); substance identification/ ”sameness” assessment (more likely to similarly and correctly identify substance at pre-registration / no wasted time from wrong identifiers), review of data availability/quality and potential valuation, early C&L discussions, etc.

Compliance Implementation Issues, cont.

- NEUM non-participation in these early discussions results in organisational/ informational / general compliance disadvantage = less efficient compliance preparation and potentially greater costs to ensure compliance

Why NEUM non-participation?

- NEUM has not yet taken structuring decisions or finalised importer or OR agreements on registration obligations, so they are not in position yet to join such discussions (urgent to speed up decision-taking/ arrangements). Recall option for NEUM to join EU consortium directly if representative arrangements not ready!

- Or, NEUM is ready but dissuaded or not accepted in the EU consortium (some discussions on-going about admitting importers / NEUMs) – must monitor / enquire about entry as possible

3. Special Compliance Considerations

Watch those exemptions!

Legislative principle: Don't REACH / regulate substances already deemed not a risk or which are already adequately regulated under other EU legislative regimes.

Practice: Inconsistencies in REACH text and in Guidance, e.g., Art 15 "regarded as being registered" PPP and BPD substances

Special Compliance Considerations, cont.

- REACH text: "Substances regarded as being registered":
  "Active substances … for use in [plant protection products] [biocidal products] only and …"

- We interpret this legislative text as granting registration exemption only for PPP or BPD actives that are used exclusively for these uses – if also non-PPP or BPD use, then exemption is lost! Simply bad drafting that was not corrected before adoption / inconsistent with other exemptions

- ECHA Guidance on Registration: Ignore the actual REACH text and register as if word "only" does not exist (i.e., register only the quantity for non-PPP/biocidal uses; good result for industry, but bad regulatory interpretation)

- Note: Commission Legal Service (concerning another area of REACH interpretive uncertainty) has said "follow the [legally binding] REACH text even if difficulties arise in application"

Special Compliance Considerations, cont.

- Registrant risk: Guidance may give desired end-result for industry but it places registrants at risk for defective registrations and potential liabilities

- Happy yesterday to hear that UK CA would likely err on the side of the actual REACH text rather than a conflicting Guidance, and this is what we expect your lawyers would advise, too. If we advise to follow the non-binding Guidance and you are caught out, who will be liable then?

- As usual, you are free to follow your lawyer's advice or not! Our preference is to get REACH properly amended asap.

4. Legal Issues for NEUMs

a) Polymers / Monomers – Potential Unjustified Obligation Affecting NEUMs

While polymers as such are presently exempt from REACH registration (but still subject to provisions on authorisation and restrictions on use), certain reacted monomers and other non-stabiliser additives (pigments, thickeners, compatibilisers, etc.) contained in polymers imported into the EU must be registered like other substances. The need for registration of reacted monomers in imported polymers is highly controversial from both scientific and regulatory policy perspectives.

Very simply, reacted monomer in the imported polymers does not enter the EU market and cannot cause health or environmental risk. Query: Is their registration obligation necessary and proportionate to the risk? Bigger query: Is the regulatory impact falling mainly on non-EU polymer producers who must provide their product data to the importer to enable registration of the monomers?? NO, and YES.

Legal Issues for NEUMs, cont.

- Problem is that the answers to these questions may provoke a potentially even worse scenario, i.e., a registration obligation for polymers as such, sooner rather than later (end of Art 2(9) exemption)

- From REACH policy perspective, current registration exemption for polymers will be reviewed by the EU Institutions "as soon as practical." This review may be accelerated by legal developments concerning above questions. Have to watch closely.

- Anticipate intense government relations activity concerning the criteria to be used for the polymer exemption review. Important for NEUMs to evaluate whether there can be a common position among all polymer manufacturers or if there are differences between manufacturers and/or between those based in the EU and outside.

- A split in interests may be inevitable.

Legal Issues for NEUMs, cont.

- From legal perspective, registration of monomers in imported polymers may have WTO/TBT impact as well as under EU law:

  2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia:* …; protection of human health or safety, animal or plant life or health, or the environment.

Legal Issues for NEUMs, cont.

b) EU – Competition law (Art 81 & 82, EC Treaty)

NEUMs and their representatives (importers or OR) have "defensive" concerns especially re REACH consortia:

Exclusionary or discriminatory actions of consortia that might be accepted now under existing legal frameworks can be penalised under REACH and may incur wrath of EU competition law as well. This will concern especially data-sharing terms and related costs in the SIEF context.

Legal Issues for NEUMs, cont.

c) Other legal considerations … anti-dumping consequences?

Reference already in EU anti-dumping proceeding where question raised whether 3 different product types for commercial purposes nonetheless had same essential characteristics or not?

- Exporter claimed not "same" chemical properties because one type had been registered under BPD Directive while two others were to be registered instead under REACH.
- Commission concluded that the product types were essentially same and that latter two types were to be registered under REACH only because, by comparison to registration under BPD, "registration procedures … could be more cost and time efficiently handled in the wider context of … REACH" !!
- At this time, this seems a very optimistic assessment!

5. Conclusions – Practical Recommendations

a) Internally, NEUMs must speed strategic assessment of compliance structuring/implementation options and take earliest organisational decisions and start preparations accordingly (delay may make compliance more costly)

b) Externally, direct NEUM or representative discussions with likely co-registrants of same substance are urgent – at industry level in EU, as possible / Leading export companies need to meet/share REACH concerns & consider common interests:

- ✓ Article producers → preparation v article; substances therein and released
- ✓ Substance identification → "same" substance
- ✓ Data availability/ownership; Classification and labeling
- ✓ NEUM interests in consortium formation and governing rules

Conclusions – Practical Recommendations

c) NEUMs need to share equal regulatory burdens but also must not be exposed to greater burdens in order for their exported substances to be REACH compliant. “Level playing field” must be the rule, just as EU producers have the right to expect in their export markets.

d) Finally, however, the cost of REACH compliance will probably be greater for non-EU manufacturers than for EU producers, largely because of need for, extra cost and risk associated with having to work through third parties to get the same compliance result.

Comments? Questions?

Thank you!