



REACH Compliance : Maintaining your EU markets

Strategy – Business - Compliance

Demarest & Almeida, São Paulo
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Today's presentation

- I REACH within broad corporate strategy
REACH complexities and new business environment
- II REACH : managing compliance post pre-registration



REACH within broad corporate strategy

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➤ REACH means:

➤ NO DATA



NO MARKET

REACH – Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals

- Scope: Chemical substances manufactured and marketed in, or imported into the EU whether on their own, in preparations/formulations or in finished products (‘articles’) where substances are intended to be released
- Key policy objective: Responsibility **on industry** for proving safety of existing and new chemical substances on EU market through provision of specified data
- EU market access: Unless exempted or deemed registered under REACH, substances must be registered with ECHA to be legally marketed on the EU (‘no data, no market’) from June 1, 2008

REACH Compliance Can Be An Opportunity

- REACH is a SYMPTOM, not an end in itself
- REACH reflects growing social and thus political concerns regarding the impact of chemicals on the environment and human health
- REACH compliance programs can be an opportunity for businesses to position themselves as a leader

Scope Of Internal Compliance Activities

- A company in the forefront of REACH compliance will:
 - √ Identify all « REACH-relevant » products
 - √ Involve those who understand the science
 - √ Involve those who understand the markets
 - √ Involve those who understand legal perspectives
- Assign clear responsibilities for implementing the agreed corporate strategy

Corporate Positioning In A Competitive Market

- REACH imposes obligations through the value chain
 - √ Customers need suppliers to provide information
 - √ Customers welcome supplier support in meeting their own requirements
- **An opportunity to gain competitive advantage**
- **An opportunity to enhance customer loyalty**

Product Assessments

An example:

- REACH may make continued marketing of some products unprofitable
- BUT continued production could enhance customer loyalty
 - √ Opportunity to reach out to customers
 - √ Engage actively in tailoring products to customer needs
 - √ Implement product stewardship programs

Product Stewardship Through REACH Compliance

- Opportunity to be « best in class » - product development reflects sensitivity to environmental/human health concerns: contribute to scientific assessments and use to promote product safety in the global arena
- Opportunity to take industry leadership through
 - √ High level of compliance
 - √ Active communication leading to recognition in the market
 - √ Outreach programs to customers
 - Identify customer needs (products and data)
 - Implement customer service programs

REACH And Product Stigmatization

An example:

- « SIN » list – **Substitute it now:** list of SVHCs that NGOs and Internat'l Chemical Secretariat propose be priorities for authorization
- Market awareness leads to pressures from consumers/commercial initiatives to restrict use of listed substances, among which today:
 - √ Nickel monoxide, nickel dioxide, nickel sulphide

Government Relations

- REACH compliance can enable companies to be a reference for local/national government: industry leadership
- REACH is influencing regulators in other world regions: companies can leverage their knowledge to influence evolution elsewhere
 - √ US, China: expect initiatives to emulate REACH
 - √ « SIN » list used by California to launch call for state/federal legislation

Brazil – EU Strategic Partnership

Opens opportunities for Brazilian companies:

- Rio presidential summit on 22 December 2008
- Joint action plan includes sustainable development
- 3-year life span, with revisions prior to summit in 2011
- Regular meetings at ministerial level
- WTO objectives including seeking together a successful conclusion to the Doha round

Ex: Nickel classification issues on agenda of Rio summit in December

Ensure That REACH Presents Opportunities – Not Threats – For Business

- Ensure clear responsibilities for compliance activities
- Involve businesses to understand commercial ramifications and implement appropriate programs
- Be a leader in the sector in
 - √ Product stewardship
 - √ Communicating with customers (reinforce loyalty; avoid product stigmatization)
 - √ Engaging with government: local legislation/worldwide initiatives – be a national leader; leverage influence to advocate for appropriate regulations – as a company, as part of an alliance within industry sector



REACH: Managing Compliance Requirements Post Pre-Registration

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Introduction: Current REACH Compliance Priorities

- Failed to pre-register "phase-in" substances? Options
- Preparing for November 30, 2010 registration deadline for pre-registered high volume / dangerous substances
- Is someone in your supply chain taking responsibility for REACH?
- REACH does apply to finished products/end use products
- Enforcement - are you prepared?

REACH – The Basic Regulatory Framework And Compliance Requirements

- Pre-registration prior to December 1, 2008
 - √ Extended registration deadlines according to hazard profile and volumes manufactured/imported into EU
 - √ No pre-registration: limited options (sales illegal from June 1, 2008)
- Mandatory cooperation between competitors ((pre-)SIEF)
 - √ Joint registration (OSOR)
- Authorisation and restrictions
 - √ SVHC candidate list
 - √ Eventual prior authorisation requirements
 - √ ECHA may place restrictions on manufacture, use or marketing
- Supply Chain Communication (‘new culture’)
 - √ Communication for registration and risk management
 - √ Manufacturers, formulators, article producers, importers, distributors and downstream users

Non-EU Suppliers Under REACH

- Compliance options:
 - √ Rely on EU importer (CBI disclosure, no control on EU supply chain)
 - √ Appoint OR (impossible for non-EU traders / where toll manufacturers used)
 - √ Rely on suppliers or non-EU customer's OR
- OR appointment required by Downstream Users?
- OR paper trail vital if compliance investigation:
 - √ Separate OR appointment contract between each separate non-EU company entity and the OR
 - √ If appropriate, evidence of agreement between each entity and its non-EU customers that OR covering their volumes (indirect exports)
- Already informed importers (directly or through non-EU distributors) of OR appointments?

You Failed to Pre-register?

- No-one in your supply chain pre-registered your EU export volumes:
 - √ Exports to EU since 1 June 2008 illegal until full registration (sanctions for you and DUs)
 - √ Inevitable marketing gap whilst registration organized
- Take advantage of late pre-registration provision (Article 28(6)) ('manufacture in or import into EU for first time after December 1, 2008')
 - √ Appoint new importer who has not imported prior to December 1, 2008
 - √ Change to a non-EU supplier whose OR has pre-registered your substance at a sufficient tonnage threshold to accommodate your tonnage

You Failed to Pre-register?

- √ Create new manufacturing entity in the EU (tax considerations?)
- √ Cannot appoint a new Only Representative if appointor already sold substance in EU prior to December 1, 2008
- Swap to an existing importer who has pre-registered your substance at a sufficient tonnage threshold to accommodate your tonnage (pre-registration numbers for sale?)

The Next Stage of REACH Compliance

November 30, 2010

- Earliest registration deadline for pre-registered:
 - √ CMR substances (e.g. nickel)/ R50-53 substances exported to EU in volumes ≥ 1 metric tonne per year
 - √ Other substances exported to EU in volumes ≥ 1000 metric tonnes per year
- Otherwise ‘No data, no market’

Task List Prior To Registration (I)

- In next 18 months, following internal requirements for REACH responsible in supply chain for EACH substance:
 - √ Obtain business approval for REACH compliance strategy
 - √ Appropriate in-house resources/capabilities?: technical, legal, supply chain management and administrative support for appointed OR
 - √ Decide level of involvement in pre-SIEF partnership and SIEF
 - √ Internal data audit
 - √ Necessary documents in case of enforcement (OR, importers)

- In next 18 months, following compliance obligations (non-exhaustive list!) necessary prior to registration for EACH registerable substance:
 - √ Sameness discussions
 - √ Agreement on structure of mandatory cooperation in SIEF (data and costs sharing, data generation, join consortium)?

Task List Prior To Registration (II)

- √ Preparation and submission of:
 - Joint registration of hazard data as/through Lead Registrant
 - Individual dossier
 - Joint or individual CSR
 - √ Classification and Labelling
 - √ Supply Chain Management
- Post pre-registration – **paradigm shift** in resources needed for REACH compliance

Obligations (Other Than Registration)

Applying Below 1 Tonne

- Substances and preparations exported to EU:
 - √ New format SDSs, including for substances not previously required (enforcement!)
 - √ Other risk management information to be passed ‘up and down supply chain’ where no SDS required
- Marketing and use restrictions
- Requirement to obtain ECHA authorisation of candidate list substances

Obligations re Finished Products ('Articles')

- REACH creates OBLIGATIONS for "articles" (finished products)
- Registration of substance intended to be released from articles under normal or reasonably foreseeable conditions (as part of functionality of article)
- SVHCs in candidate list (a moving target):
 - √ From 2011, notify to ECHA certain concentrations in articles where possibility of exposure to humans
 - √ On inclusion in list, article supplier to provide recipient (industrial/professional/downstream user/distributor), and any consumer which requests, with substance information
- Packaging is itself an article!

‘Indirect’ Requirements of REACH

- Your continuing access to EU markets may depend on REACH compliance of other actors in your supply chain
- Are they aware of, and addressing, their compliance requirements?
- Risk of disruption in supply network? Switch to compliant supplier/DU?
- Customers insist on ‘REACH compliance clause’ in purchase orders stating supplier guarantees, accepts liability/indemnities:
 - √ Substances supplied pre-registered/registered
 - √ Continuing information on SVHCS in articles
 - √ Continuing notification of SVHCS in articles to ECHA
 - √ Commitment to discuss approach to authorisation application

‘Indirect’ Requirements of REACH

- Is your company in a position to accept such clause if customer insists (or risk losing clients)?
- Products defence/stewardship requirements:
 - √ Strategic commercial, not legal, requirements
 - √ Result of candidate list ‘blacklisting’ provisions of REACH:
Duty to inform and notify SVHCS, authorisation requirements
 - √ Avoid ‘deselection’ of your products by the market (encouraged by NGOS)
 - √ Interaction with policy makers and your customers
 - √ Reformulate or support

Pre-SIEF: Level Of Activity Per Substance (I)

- What is the Pre-SIEF?
 - √ Period between end of pre-registration window (December 1, 2008) and pre-SIEF participants' agreement on substance sameness
 - √ Requires close monitoring now of correspondence from 'pre-SIEF partners' for same substance on REACH IT webpage
- Commercially sensitive information:
 - √ Substance distinction on basis of impurity and consequent disclosure of manufacturing process
 - √ Composition and/or raw materials disclosed
- Need to enter into confidentiality commitments:
 - √ Non-disclosure and non-use outside pre-SIEF of information disclosed within it
 - √ Agreement restricting access to certain staff only (bound by confidentiality agreement)
 - √ Appointed independent third party trustee (bound by confidentiality agreement)

Pre-SIEF: Level of Activity per Substance (II)

- First consideration: Decide level of activity for each substance ('pre-registrant status') re registration effort (CEFIC SIEF codes)
- Dormant/inactive or active/passive registrants
- SIEF Formation Facilitator ('SFF') (becoming lead registrant?):
 - √ Proactively drive registration process (to company's advantage?)
- Resist dominance of EU companies!
- ECHA/CEFIC concern over high level of Pre-SIEF inactivity
 - √ CEFIC: "SIEF not working" – consortium alone insufficient for compliance
 - √ "non-EU only" substances where no consortia
 - √ Time running out to register and protect EU markets
 - √ Too far behind timetable to make 2010 deadline? (incomplete long term studies?)
- Be careful re choice of commercial REACH IT communication provider!

SIEF – What Is It? What Isn't It?

➤ What is a SIEF?

- √ Mandatory communication forum for potential registrants of the same phase-in substance
- √ Not a consortium (consortium voluntary, terms / scope up to members)

➤ Purpose of SIEF:

- √ Avoid duplication of studies (animal testing) required for registration and creates cost efficiencies
- √ Mandatory data sharing of existing studies towards submission of joint registration dossier
- √ Collectively identify and carry out required new studies unavailable within SIEF and necessary for joint registration dossier

Why Consortium? (I)

- No obligation under REACH to form or join a consortium
- Form of mandatory cooperation (data sharing, classification and labelling, joint submission of data towards registration ('OSOR'), election of lead participant and lead registrant) not specified
- Weigh up, on *per* substance basis, whether to join/create consortium
- Factors in favour of consortium membership:
 - √ formalised relationship and binding rules ('safer' re confidentiality, anti-trust concerns)
 - √ multilateral cooperation necessary to share costs of purchasing existing data (especially if mainly data purchaser)
 - √ dedicated structure the only time and resource efficient way to cooperate in mandatory (and non-mandatory) areas
 - √ increased influence over competitors' approach to registration, key data sharing terms (cost sharing) (key substance? Defend interests?)
 - √ stronger position v. ECHA (including appeals)

Why Consortium? (II)

- Factors against consortium membership:
 - √ Time and costs of setting up and/or participating in consortia
 - √ Economic downturn liquidity issue : later registrants postpone costs by buying data from consortium at later date
 - √ Unacceptable provisions (for example, costs sharing method unsuitable, late entry fee)
 - √ Unimportant substance ?

Actions Regarding Consortia

➤ Existing Consortium:

- √ If not yet member: obtain and review terms of agreement(s) (legal!)

➤ Creation of new consortium needed:

- √ Active/passive role
- √ Do not wait for signature of consortium (1+ year to negotiate) before starting data review (November 30, 2010 deadline!)

➤ Joining consortia for many substances:

- √ Negotiation of terms:
 - Experience on key issues (data valuation and compensation, antitrust) required
- √ Data management:
 - IT system
 - Personnel to attend consortia meetings

Key Issues For Consortium Agreements (I)

- Key issues:
 - √ Relevant to whether to join existing consortium
 - √ Negotiate to protect your position in creation of new consortia
- Internal data audit (any data own/have access to):
 - √ Which studies worth seeking compensation for? Costs of negotiation exceed value recoverable?
 - √ Proof of ownership (paper trail, which company in group compensable?) and valuation (proof of study costs)
- Consider criteria for valuation of existing data:
 - √ Historic value or current value ('replacement value')?
 - √ Additional factors increasing value? Risk premium? Additional administration and management on costs?

Key Issues For Consortium Agreements (II)

- Preferred data costs sharing formula:
 - √ Proportionate to EU export volume tonnage band
 - √ Equal shares
 - √ Exemption for low volume manufactures (for example, 1-10 tonnes)
- Fair consortium management costs
 - √ late entry fee = equal share of sweat equity costs of running consortium prior to joining? Avoid free-riders, but not excessive?
- Adequately protected against allegations of competition law infringement?
- Citation rights only

Key Issues For Consortium Agreements (III)

- Confidentiality provisions:
 - √ Restrict access to certain staff (bound by confidentiality agreement)
 - √ Provisions to deal with breach of confidentiality by data users or if legally required to disclose
- Ensure terms cover communication with SIEF participants outside consortium
- Joint ownership rights (IP) in new jointly developed data and their protection
- When it goes wrong: default and withdrawal of participants, dispute resolution, liability to third parties or between consortium members
- Mechanisms for appeal of ECHA Decisions

Key Issues For Consortium Agreements – EC Competition Law Compliance (I)

- Why you should be wary of infringing EC competition law?
 - √ Lengthy investigations
 - √ Fines up to 10% global turnover
 - √ Void and unenforceable agreements or clauses
 - √ Criminal sanctions in some jurisdictions (for example, UK Enterprise Act 2002)
- Inadvertent infringement
- “Sword” against deliberate anti-competitive / collective dominance tactics of leading consortium members
- REACH Regulation ‘without prejudice to the full and complete application of Community competition rules’ (Recital 48)
- Issue 1: Consortium potential cloak for a cartel – exchange of commercially sensitive information between competitors

Key Issues For Consortium Agreements – EC Competition Law Compliance (II)

- Example of commercially sensitive information
 - √ Margins, profits, discounts or prices charged to customers/ end users;
 - √ Names of customers or customer-specific translation information;
 - √ Key terms and conditions for sales;
 - √ Future strategic, business or investment plans;
 - √ Current market shares and specific sales volumes (tonnage bands OK!);
 - √ Suppliers and input costs for key materials.

- Adherence to Antitrust Policy. All consortium/ task force members to:
 - √ Acknowledge Antitrust Policy before Task Force meeting;
 - √ Limit all discussions during meetings to agenda topics;
 - √ Protest immediately if discussion becomes sensitive;
 - √ Maintain minutes of all meetings;
 - √ Presence of lawyer/ compliance officer to ‘wave red flag’

Key Issues For Consortium Agreements

– EC Competition Law Compliance (III)

- Incorporate Antitrust policy clause preventing members from exchanging market information
- Use independent third party to collect sensitive data
- Issue 2: Avoid Discriminatory Behaviour
 - √ Grounds for refusal of entry to consortium must be objectively justifiable and consistent
 - √ SIEF participants outside consortium must not pay higher fees than consortium members without good reason
- Issue 3: Bundling of Data
 - √ Breach of Regulation: ‘Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements’ (Article 30(1))
 - √ Data owner cannot make sale of required data conditional on other data
 - √ Not required to pay for studies before you actually require them for registration deadline (although may agree to data/costs sharing method)

Registration Obligations

- Significant technical support required for:
 - √ Joint registration of hazard data as/through Lead Registrant
 - √ Individual dossier
 - √ Joint or individual CSR in most cases
 - √ Preparation of (robust) study summaries
 - √ Agreement on harmonized classification and labelling

Appeals Procedure (I)

- 2 options for legal recourse
- Express Appeal mechanism under REACH (Article 91)
 - √ Board of Review (multi-disciplinary panel)
 - √ Appeal to the European Court of First Instance (Article 230 EC Treaty – annulment action)
 - √ Only applies to specific ECHA decisions, including:
 - Rejection of an incomplete registration
 - Permission to refer to data where data holder refuses to share
 - Choice of SIEF member to undertake new studies for joint submission
- General Redress in European Courts against other ECHA decisions (Article 94)
 - √ Article 230 EC Treaty (annulment action)
 - √ Article 232 EC Treaty (failure to act)

Appeals Procedure (II)

➤ Procedural Hurdles

- √ Decision susceptible to challenge?
- √ Standing? Addressee of decision or ‘directly and individually concerned’
- √ Short window to lodge action

Enforcement

- Enforcement of REACH has already begun!
- REACH requires Member States to adopt ‘effective, proportionate and dissuasive sanctions’ for infringements (Article 126)
- Significant civil and criminal sanctions already adopted in most Member States – example of France:
 - √ 2 years imprisonment and € 75,000 fine (210,000 Brazil Reais) for M/I of non pre-registered substance
 - √ 3 months imprisonment and € 20,000 fine (55,000 Brazil Reais) for failure to provide recipient with SDS
- European level agreement of national inspectorates to focus enforcement on:
 - √ Proof of substance pre-registration
 - √ Accompanying SDS

Enforcement

- Wide-ranging national authority search and seizure investigation powers (customers officials, health inspectors) – example of Rotterdam (NL) customs clearance:
 - √ Pre-registration reports
 - √ SDS
 - √ where appropriate, signed contract appointing OR
- Can you/your importer/your OR/your customs clearance agent produce the necessary documents if shipment investigated? (otherwise inevitable delays in transit)
- “Pragmatic enforcement” policy: no!

REACH: An Illegal Trade Barrier?

- On-going representations by 24 Governments in WTO Technical Barriers to Trade Committee – no substantive case yet
- REACH arguably creates trade barriers because:
 - √ Discriminates against non-EU suppliers exporting substances to EU (Article 2.1 TBT Agreement)
 - √ Unnecessarily burdensome, (not least restrictive measures: Article 2.2 TBT Agreement) complex and unclear, particularly prejudicing SMEs
- REACH is the « biggest » issue in the history of the World Trade Organization's Technical Barriers to Trade Committee » (USTR)
- Non-EU companies:
 - √ Cannot register directly (OR required), unlike EU competitors: need to protect CBI, control supply chain
 - √ Practical effect on non-EU supply chain inadequately addressed in REACH
 - √ 'Third country concerns have not been factored into the legislative process' (U.S. Ambassador to the EU, C. Boyden Gray, 8 June 2006)
 - √ Some trade issues resolved through changes to REACH guidance due to industry pressure

REACH: An Illegal Trade Barrier?

➤ SMEs:

- √ REACH compliance beyond resources and a ‘moving target’ (repeated revisions of interpretative guidance)
- √ Significant SME withdrawal from SME markets

➤ Non-EU companies and SMEs

- √ Excluded from EU market if did not pre-register or miss 2010 deadline

Conclusion (I)

- To avoid heavy sanctions, immediate REACH obligations ?
 - √ Missed pre-registration:
 - cease EU exports
 - consider late pre-registration options
 - √ SDS, where now required
 - √ Information on SVHCs in articles communicated downstream
- Prepare documents needed in case of enforcement inspection
- Significant commercial requirements, distinct from REACH legal obligations:
 - √ Is someone in your supply chain addressing REACH obligations (insist on supplier 'REACH compliance' contract term?)
 - √ Product stewardship to counter blacklisting effect of REACH

Conclusion (II)

- Next stage of REACH requires significant commitment from Brazilian companies in order to ensure uninterrupted access to EU markets
- Sufficient progress on compliance to meet 2010 deadline:
 - √ complying with express REACH obligations (data sharing, submission of dossiers)
 - √ strategic decisions on a per substance basis in order to best protect companies' interests (SFF or not? join consortium? cooperation terms?)
- Skills required:
 - √ technical (sameness discussions, data audit, preparation of registration and CSR)
 - √ legal (reviewing and drafting consortia and data licensing agreements, familiarity with negotiation of data valuation and costs sharing issues, anti-trust issues)
 - √ administrative support (managing communications with other pre-SIEF and SIEF members and within own supply chain, dedicated IT tools, attending consortium meetings)

Steptoe REACH Services

For additional information about our REACH services, please contact csimpson@steptoe.com or visit our website

www.steptoel.com/REACH

Join our next REACH compliance Webinar: 'Next Steps in Registration' on June 23, 2009 at 11.00 am, Sao Paulo time