REACH - ONE COMPANY'S VIEW AND RESPONSE TO THIS IMPORTANT INDUSTRY CHALLENGE

Peter Megaw

Croda International Plc.

REACH is coming. It is coming fast, and when it arrives it will be here to stay with us for a long time.

As I write this pre-print the latest available official text of the legislation is the "Common position adopted by the Council with a view to the adoption of
a Regulation of the European Parliament and of the Council concerning
the Registration, Evaluation, Authorization and Restriction of Chemicals
(REACH) … … …" of June 2006. However it is expected that this text already indicates the major elements of what will within a few months be adopted as European Union Legislation.

It is already evident that the legislation represents a revolution in chemicals control in Europe, and one whose requirements the legislation itself foresees will have to be implemented largely by chemicals manufacturers, suppliers and down-stream users, rather than by the regulatory authorities themselves.

I am not going to try to review the whole of the legislation here. Instead I am going to consider how companies should be preparing by reference to specific selected elements of the legislation. What they will need to do, what they can do in advance, what it is unreasonable to expect can be done now, what we will be expected to have done already. I am going to consider some of the issues that are of special interest to cosmetic ingredient suppliers and cosmetic ingredient users. I will give examples of actions that Croda, as a company supplying significant quantities of ingredients for cosmetics and personal care, has taken and is taking.

Pre-registration.

The article on "entry into force and application" (the last Article – 140 - in the text of June 06) indicates that the Regulation in general will come into force 20 days after publication in its final form and Title II (Registration of substances) will come into force 12 months later. If we do nothing in advance, this means that we would need a full notification dossier for all substances we put on the European market 12 months after coming into force (this could be as early as spring 2008 therefore!). To avoid this, and take advantage of appropriate 3, 6 or 11 year "extensions" of time allowed for "phase-in" substances (i.e. those already in the European Inventory of Existing Chemical Substances [EINECS] or of similar status) companies must pre-register their interest in a substance.

Who needs to pre-register?

Essentially **anyone** manufacturing a substance in Europe **or** importing the substance into the European market needs to pre-register. This includes importers of materials as components of preparations. Note that in this context most cosmetics are "preparations" as defined in the REACH regulation and not "articles".

What is needed to pre-register?

The requirements are given in Article 28 of the June 2006 text.
These include:
"

(a) the name of the substance as specified in section 2 of Annex VI , including its EINECS and CAS number or, if not available, any other identity codes; …

(b) his name and address and the name of the contact person and, where appropriate, the name and address of the person representing him …

(c) … the envisaged deadline for the registration/tonnage band;

… 2. The information referred to in paragraph 1 shall be submitted within a time period starting on [… 12 months after entry into force] and ending on [… 18 months after entry into force …] *.

3. Registrants who do not submit the information required under paragraph 1 shall not be able to rely on Article 23"
.[Article 23 gives 3, 6, 11 year transitions for full registration].

What should we be doing now?

It is clear from the above that we need to know which substance we manufacture in, use in, import into the European Union – and even those we might wish to manufacture in, use in or import into the European Union. We need to know the identity of these substances sufficiently well to assign a specific CAS registry number, and we need to know for how much of these materials we have each of the roles of manufacturer, first importer of the substance or first importer of the preparation(s) containing each substance. If we think we are not the importer we need to know who is – are they pre-notifying? Do they know their volumes? Have they identified their substances?

Compared to much of the 1000 pages or so of the full REACH regulation with its annexes this is relatively easy data to gather and relatively cheap but it matters – NOW! – because there will only be a 6 month window to pre-register, the 6 month window opens 12 months after entry into force.

Are cosmetics (and their ingredients) not exempt?

According to Article (2) paragraph 6 on "Application" the provisions of Title IV (information in the supply chain – safety data sheets) shall not apply to:

"(b) cosmetic products as defined in Council Directive 76/768/EEC1;"

Also according to Article 14 "Chemical safety report and duty to apply and recommend risk reduction measures":

"5. The chemical safety report need not include consideration of the risks to human health from the following end uses:

... ... b) in cosmetic products within the scope of Directive 76/768/EEC."

These are the only exclusions – and they apply only to finished cosmetic products, and only in the context of human health.

Are "cosmetic articles" not exempt?

Chapter 2, Article 3 gives definitions including.

"2) Preparation: means a mixture or solution composed of two or more substances;
3) Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;"

Clearly according to these definitions the vast majority of finished cosmetics will be "preparations" and not "articles". The components of such preparations will need to be pre-registered and registered in the same way as any other substances. (Are polymers exempt? – yes as long as their monomers and other starting substrates are registered – and the polymer composition conforms to that given in the regulation).

So what should I be doing as a cosmetics manufacturer in the USA? What should I not be trying to do? (What is Croda doing as an EU-based manufacturer and importer of ingredients?)

Advice on this has been surprisingly consistent from EU-based industry associations. Since 2004 CEFIC (the European chemical Industry Council) has been advising companies to:

"(1) Produce your own inventory of chemical substances that will be subject to REACH
(2) Establish which legal entity of your Group of companies is involved as manufacturer or importer
(3)Identify the CAS numbers of these substances

(4) Establish a list of your customers and what their uses are; also establish whether the substance is being sold to downstream users and/or consumers via distributors... ... ...
(5) Establish whether there are for your substances:
Hazard property information, i.e. any available studies according to Annexes V through VIII of REACH [old numbering] or other types of hazard information, e.g. human data or QSARs, of your own or others, including vertebrate animal tests Classification & Labeling information Safety data sheet (and, if necessary, bring them in line with existing regulation).
Exposure information across the supply chain i.e. exposures of your own workforce and exposures at your customers' workplaces and eventually in final uses."

This has much in common with COLIPA (The European Cosmetic toiletry and perfumery Association) advice from summer 2006, which for cosmetic manufacturers notably adds the further advice " ...establish your company's REACH team ... prioritize your ingredients ... proactively start a dialogue with your suppliers".

What's Croda done so far, what have you learned already?

We have been tracking the development of REACH since publication of the "White Paper" in February 2001. We had even 2 years ago already prepared volume rankings of our finished product range as sold, aggregated by CAS registry number, adjusted for activity, allowing for exclusions of polymers and materials on "Annex IV". This is a significant undertaking by "normal" standards, but one over which we had control of input and timing. Preparation of an inventory of our raw material is still on-going. This is a much more difficult undertaking, for example multiple suppliers of the "same" product turn out to assign different CAS numbers or even mention none on their MSDS, different suppliers have different status for the same material – sometimes we are the importer, sometimes our supplier is, sometimes our supplier is the manufacturer – even for the same substance. Our advice is "if you haven't started your inventory yet, then start as soon as you can".

In terms of responding to customer enquiries we have prepared a position statement that first confirms that we are aware of REACH and that we know what the requirements will be. It refers customers to the current status of the legislation and activities on its implementation. We indicate that we are taking part in industry association activities in preparation for implementation, including identification of possible consortia partners. However we also make it clear that it is not possible to give absolute undertakings that a material will be supported through the REACH process in advance (no association we know of is advising any company that they should be able to reasonably ask for such an undertaking – but this has not stopped customers from asking!).

Hang on – you've largely discussed activities before and up to pre-registration - we've not even got to "R" for Registration yet, what about Evaluation, Authorization?

"Learn to walk before you try to run" the activities described above need to be carried out now! You need a team to start preparing for pre-registration now. There is a lot of information out there about REACH – so much guidance, for example in "Reach Implementation Projects" that you might need guidance on the guidance. The first step is to realize that you need to have a team working on the issue – that team can find more information, and as long as you pre-register and joint a Substance Information Exchange Forum (SIEF) as foreseen by the legislation you should find partners with a common interest in most substances who will be forming consortia to supply shared data and reduce cost.

If you've done all this already – congratulations! You have still a long way to go, but you are ahead of many.