



Memorandum

From: R.C.A. Barrington
To: IPIA members
Date: May 3rd 2007
Subject: REACH - an overview

The new REACH legislation was adopted by the European Parliament and the Council of the European Union on December 18th 2006. This is covered by REGULATION [EC] NO. 1907/2006 and DIRECTIVE 2006/121/EC. REACH is the acronym for:

REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS

and will replace the many current directives and regulations covering chemicals in force across the EU countries. It will come into force on June 1st 2007.

The objectives of REACH are:

- protection of human health and the environment
- maintenance and enhancement of the competitiveness of the EU chemical industry
- prevention of fragmentation of the internal market
- increased transparency
- integration of international efforts
- promotion of non-animal testing
- conformity with EU international obligations under the WTO.

REACH will create a single system for both “existing” and “new” substances - substances are now described as:

- “non-phase-in” substances [i.e. those that were not produced or marketed prior to the coming into effect of REACH], and
- “phase-in” substances [i.e. essentially those listed in the EINECS - the European Inventory of Existing Commercial Chemical Substances].

Pig iron is listed as “Iron, furnace” in EINECS [no. 265-998-4] - “the metallic substance produced in a blast furnace or direct reduction furnace which contains over 90% iron.” As such, pig iron will almost certainly come under the auspices of the REACH regulations as a “phase-in” substance [the implications of this will be covered below].

Under the legislation, a new authority, the European Chemicals Agency [ECHA] will be established [to be based in Helsinki, Finland] to manage the technical, scientific and administrative aspects of the REACH system. The ECHA will manage a database, which will contain the registration dossiers and other information generated by REACH and co-ordinate the implementation of REACH.

All EU producers and importers of substances covered by REACH will have to register under the system and all applicable substances will have to be registered and approved in due course. In the case of pig iron, this means that all EU producers and all companies importing pig iron into the EU countries will be directly affected. Other companies in the pig iron supply chain to EU countries will be affected indirectly in that in order for the material concerned to be imported into the EU, the actual importer will have to be registered and the material itself will have to be approved. Thus, producers in Russia and Brazil and traders in Switzerland, for example, will have a vested interest in the successful registration of their EU importer and the licensing of their product.

EU importers and producers will be required to pass the information relating to health, safety and environmental properties, risks and risk management measures down the supply chain to distributors and end users [principally steel producers and foundries in the case of pig iron]. Commercially sensitive information will be excluded from this requirement. The primary tool for transfer of this information will be the Safety Data Sheet, the current requirements for which will be carried over into the REACH regulations.

In short, the process will be as follows:

- June 1st 2008: pre-registration begins - this is a necessary activity for any organisation wishing to achieve “phase-in” status for their substances. The pre-registration period will last until November 30th 2008. Pre-registration is intended to bring together potential registrants of the same substance to avoid duplication of studies. It should be a simple process - not yet finalised - requiring least the following information:
 - name of the substance, including EINSCS and CAS numbers
 - registrant company name, address and contact person and, where appropriate, the name and address of the person acting as its representative
 - the envisaged deadline for the registration [see below for pig iron]
- Pre-registration will allow substances to continue to be produced and imported during the process of evaluation. There will be various deadlines for formal registration and submission of the formal dossiers for “phase-in” substances: November 30th 2010, June 1st 2013 and June 1st 2018. Substances with a volume $\geq 1,000$ tonnes per year [including pig iron of course] will have to be registered by the first deadline i.e. by November 30th 2010.
- After the pre-registration period, the ECHA will compile a data base of substances and registrants with a view to coordination of the evaluation processes and, in particular, with a view to minimising the amount of

animal testing required. This will take the form of a Substance Information Exchange Forum [SIEF] which will identify all potential registrants of the same substance. SIEF participation will be obligatory with the aim of sharing data to avoid unnecessary testing. The SIEF process will also provide a forum in which to agree and carry on further investigative work in order to fill information gaps and agree on classification and labelling and identify potential “lead registrants” for the various substances. In this context, it should be noted that REACH recognises that data have value and will need to be paid for at a fair market rate [procedures and guidance are under development to ensure transparency and equity in data sharing.

- Once a substance has been registered, the ECHA will perform a completeness check of the registration dossier. It will perform a quality evaluation for a minimum percentage of dossiers [currently 5% of them]. All proposals for testing will be evaluated. ECHA, in conjunction with Competent Authorities located in the Member States, may perform substance evaluations [as opposed to evaluations of dossiers] if the substance is considered to be of potential concern.

As already mentioned, the principal mechanism for transfer of the relevant substance information will be the Safety Data Sheet. This should contain the following information:

- identification of the substance and the registrant
- hazards information
- composition / ingredients
- first aid measures
- fire-fighting measures
- accidental release measures
- handling and storage measures
- exposure controls / personal protection
- physical and chemical properties
- stability and reactivity
- toxicological information
- ecological information
- disposal considerations
- transport information
- regulatory information
- other information

There are many documents on the subject of REACH available on the EU and other websites and there are many organisations that have been established to assist companies in dealing with REACH issues. We intend to create a REACH page on the IPIA website and will post relevant documents and links on this page.

Because of the likely considerable cost of gathering together existing data, carrying out the necessary tests and preparing the information for the registration dossiers, it makes sense for the concerned producers and importers of pig iron to combine forces and share costs. In many industries,

groups of companies have formed or plan to form consortia for the purposes of REACH and it may well make sense to do so for merchant pig iron. A trade association such as IPIA cannot apply for registration of substances under REACH, but can act as representative of its members in preparation of the relevant information.

The Management Committee of IPIA is currently considering how IPIA can best serve the interests of its members as far as REACH is concerned and will revert with further information in due course. Whilst there is no need to panic at this stage, producers and importers have about 12 months in which to prepare themselves for the process ahead.