

REACH BRIEFING NOTE

INTERNATIONAL PIG IRON ASSOCIATION (IPIA)

Purpose: Guidance for IPIA and its members on background and actions to take to ensure that pig iron continues to be supplied under the REACH regime.

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1 Preamble

An understanding of the roles and definitions under REACH is essential to identifying and implementing the duties that fall to companies; an explanation of relevant terms is included in the text and others have been listed in the appendix. Where possible the relevant article (in the REACH text) is included for completeness; where this is not identified such definitions come from guidance documents (from REACH Implementation Projects (RIPs)) prepared by the European Commission and the European Chemicals Agency (ECHA). This document assumes a basic understanding of the requirements of REACH as set-out in the briefing note already made available to IPIA members.

2 Understanding of the issue

Pig iron will have to be registered under REACH to ensure its continued supply. There are basically three forms of pig iron (basic pig iron, haematite pig iron, and modular pig iron) but all have at least 92% Fe and the presence of carbon, silicon, manganese, sulphur and phosphorus make up the remainder. What is important is that none of the constituents other than Fe are large (i.e. > 20%) so that pig iron appears to meet the definition of a “well-defined mono-constituent substance”.

As pig iron has an EINECS number [EINECS number 265-998-4] it meets the definition of a “phase-in” substance. As long as an EU manufacturer or importer (M/I) (or ‘only representative (OR) – appointed by a non-EU manufacturer to cover the REACH duties of all their EU importers (who become downstream users in REACH terminology)) of pig iron pre-registers it within the pre-registration period (1 June 2008 – 1 December 2008), and with the required information, the M/I can benefit from the delayed registration deadlines in REACH. For example, pre-registered phase-in substances manufactured or

imported in quantities of 1000 tonnes or more per year do not have to be registered until 1 Dec 2010.

This report assumes that IPIA members are already manufacturing or importing pig iron. First time manufacturers or importers can benefit from 'late pre-registration' but this is not addressed in this report.

3 Potential roles under REACH, the process and actions to consider

3.1 Understanding the different roles

It is critical to understand the potential roles under REACH as they determine what actions to take – or even which actions are possible to take – and how to do so. Some are explained here and further explained in the Appendix.

Manufacturer (M - see Appendix): this is any natural or legal person established within the Community who manufactures a substance within the Community. From a registration perspective the manufacturer (M) has to register the quantity manufactured.

Importer (I - see Appendix) means any natural or legal person established within the Community who is responsible for import. From a registration perspective the importer (I) has to register the total quantity of the substance they import (this means that the tonnage of the same substance imported in different preparations has to be aggregated).

Only Representative (OR - see Appendix): Only Representatives are natural or legal persons appointed by non-EU manufacturers (this can mean the actual manufacturer of a substance or the formulator that incorporates the substance into preparations) to fulfil the obligations of all of their importers of the substance. Only natural or legal persons: (i) established in the EU and, (ii) having sufficient background in the practical handling of substances and the information related to them, should be appointed as ORs. This means that the OR takes up the role, in REACH terms only, of the EU importers and fulfils their registration and other REACH obligations. The importers become 'downstream users' (DUs) in REACH terminology and have to meet the duties placed on DUs. From a registration perspective the OR has to register the total quantity of the substance imported by all the importers covered by the OR agreement. If an OR is appointed by two or more non-EU manufacturers for the same substance then the tonnage is aggregated for registration purposes; this can have a negative impact if this means that the registration is at a higher tonnage band than anticipated by a non-EU manufacturer but also a positive impact as the registration costs will be shared.

N.B. IPIA itself could potentially act as an OR for some or all non-EU manufacturers. Another option would be for IPIA to appoint a legal entity to act for some or all non-EU manufacturers. Either option would be very cost effective as the costs would be spread between many and the tonnage band would not change (assuming it would be 1000t anyway for one or more non-EU manufacturer). In effect IPIA and/or its appointed representative could manage a consortium of pig iron manufacturers and importers; this would be an efficient and effective way of managing the duties REACH places on pig iron manufacturers and importers.

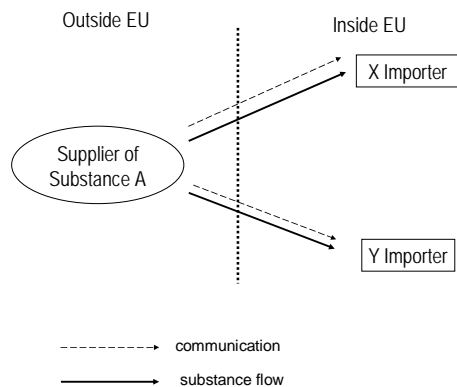
Downstream User (DU - see also Appendix): means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Importers covered by an OR agreement are treated as DUs.

IPIA Membership

The membership of IPIA falls into two groups: Producer Members and Trader Members. For the readability of this document no overlap between them is taken into account, but it is noted that each member should carefully check their role under REACH as they may belong to both groups. In Figure 1 the situation is shown with direct communication between supplier and importer (for the sake of simplicity only one supplier and two importers are shown). In this situation the importers X and Y are responsible for registration of their own imported tonnages.

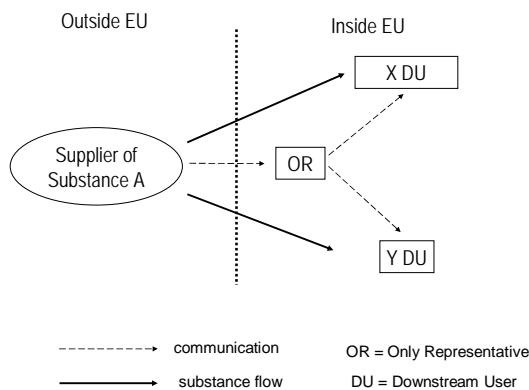
Only Representative

To potentially simplify the registration process for non-EU manufacturers, it is possible for them to appoint an 'Only Representative' (OR) who will be responsible for the registration in the EU of the substance on behalf of all the non-EU manufacturer's importers. If a non-EU manufacturer decides to take this approach it has consequences for the EU importer. Whilst they are still the importer they become a DU for their duties under REACH (for the substance in question); see figure 2. Note that the OR may never actually handle the chemical but has REACH related responsibilities.



N.B. registration is by tonnage per importer.

Figure 1 Situation without appointment of Only Representative



N.B. registration is by tonnage aggregated between importers covered by the OR agreement.

Figure 2 Situation with appointment of Only Representative

If a company is a downstream user (see Appendix) of a substance it does not need to register that substance. However it needs to make sure that its use is addressed in the registration up the supply chain (the Chemical Safety Assessment (CSA), required for registrations of 10 tonnes or more per year, should cover all 'identified uses').

N.B. if a DU owns data on the properties of a substance they can input this data into the deliberations of the Substance Information Forum (SIEF) set-up to agree a single hazard data-set for each pre-registered substance and potentially receive compensation for its use by other registrants.

Legal Entity

The identification of potential registrants under REACH needs to consider when they are a legal entity. When a phase-in substance is manufactured, imported or used in the production of an article by several EU legal entities belonging to the same company group, each legal entity has to pre-register separately. This means that if a holding company has 'daughter' companies in different EU Member States (MS) (possibly acting as importers) and if each is a different legal entity, each legal entity must pre-register the phase-in substances that they manufacture or import. Manufacturing sites that do not have legal personality are not required to pre-register; however, for manufacture to continue their 'parent company' must pre-register and subsequently register the substance.

However the REACH-IT system will provide a function to allow a parent company or head office to submit pre-registrations for several legal entities belonging to the same group provided that all legal entities are informed by the parent company or head office and have access to the information submitted in the pre-registration. However, pre-registration remains specific for each legal entity and the duties still apply to the individual legal entities. Given the membership of IPIA this possibility should be seriously considered by IPIA members as a means of simplifying their workload.

However, at present it is not envisaged that this can be done in a similar way for the actual registration. This means that each legal entity should make its own registration; subject to SIEF formation, agreement on the hazard data-set and joint submission (see section 3.3 below).

For IPIA as a trade organisation this means it cannot take over the pre-registration and registration responsibilities for its member companies; the only exception to this would be if IPIA sets itself up as the OR for one or more non-EU manufacturers.

Importer or Only Representative?

One of the most important decisions for companies exporting pig iron into the EU to make in the next few months is whether to pre-register (and subsequently register) importer by importer or through an OR. This is not necessarily a straightforward decision. Issues to consider include:

- Are individual importers competent to manage the pre-registration and registration process?
- What support would importers need from the 'parent' company?
- What is the tonnage being imported by each importer? What does this mean for registration deadlines?

- Would the aggregation of tonnages across importers mean that you would change tonnage band for registration purposes?
- What tasks would you want an OR to perform? For example, submission of the registration dossier or preparation of the registration dossier, full representation in the SIEF or watching brief only?
- Is a suitable OR available?
- If an OR acts for two or more non-EU manufacturers of the same substance then the tonnage will need to be aggregated for registration purposes; does this impact the registration deadline? Does the cost saving of a 'joint' registration outweigh any additional registration costs?

IPIA could have an important role in helping non-EU manufacturers make decisions about whether to appoint an OR and if so to identify suitable ORs. This is indeed a role that IPIA could take on if the resources and expertise is available. IPIA could also consider managing directly or through an agent a consortium of some or all importers and manufacturers of pig iron.

Information

Information is vital to meet the objectives of REACH. This can be data held by those with specific roles and duties under REACH but also by others (third parties) holding data. They could be trade or industry organisations, NGOs, universities, (inter)national agencies, etc. and also non-EU manufacturers who do not export into the EU. A third party holding information belongs to a group called data holders. For IPIA as a trade organisation it may hold data which could or should be brought into the registration process after closure of the pre-registration period. If it has such data then this should be made known to the ECHA shortly after the end of that period. It should be pointed out that data holders do not have an active role in deciding on studies for joint submission and on classification and labelling proposals. It can of course demand cost sharing for the data supplied if it is used by registrants.

Communication in the supply chain is vital to the effective implementation of REACH. In order to prepare their registration dossier it is important that the registrant communicates with his DUs. In particular he will need information about their uses ('identified uses') and the risk management measures they have already put in place. The registrant needs to address all identified uses in the CSA; the outcome of the CSA will be a Chemical Safety Report (CSR) which will include Exposure Scenarios (ES) for all identified uses. ES set-out the risk management measures necessary for the use identified to be adequately controlled. Following registration the main communication tool is the Safety Data Sheet (SDS) provided by the supplier to all downstream users and distributors; ES is/are attached as an Annex to the SDS.

IPIA could have a role in developing exposure scenarios and CSAs for key uses of pig iron for use by all relevant members in their registrations.

Having covered the main roles and elements, this document continues with the various steps of the REACH process, and any related actions and considerations.

3.2 Pre-registration

Pre-registration is non-committal, i.e. the pre-registrant does not have to proceed to registration. However, there have been calls to be prudent and not to overload the system unnecessarily by knowingly only pre-registering as this has consequences for the formation of SIEFs (see section 3.4). The only advantage to pre-registering a

substance you do not intend to register appears to be that you can remain on the EU market until the appropriate tonnage deadline is reached (this appears to be an unlikely scenario for IPIA member companies).

Who Pre-Registers:

- Manufacturers and Importers of phase-in substances on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;
- Producers and Importers of articles containing substances intended to be released under normal or reasonably foreseeable conditions of use and present in those articles in quantities of 1 tonne or more per year;
- “Only-representatives” of non-EU Manufacturers where the substance(s) will be imported in quantities of 1 tonne or more per year (aggregated tonnage for all importers covered by the OR agreement(s)).

Pre-registration must be made by each legal entity that will be required to register (see section 3.1). This means that if a holding company is composed of different legal entities in Europe, each legal entity must pre-register the phase-in substances that they produce or import. Manufacturing sites that do not have legal personality are not required to pre-register; the tonnage manufactured should be covered by the pre-registration and subsequent registration of the parent company. In practice it means that pig iron manufacturers need to check who their legal entities are within the EU.

What Information is Required for Pre-Registration:

The information required to be submitted for pre-registration consists of:

1. The name(s) of the substance specified in section 2 of Annex VI, i.e.
 - the names in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature or other international chemical name(s);
 - other names (usual name, abbreviation and trade name,)
 - European Inventory of Existing Commercial Chemical Substances (EINECS) number (if available and appropriate);
 - Chemical Abstract Service (CAS) name and CAS number (if available);
 - other identity code (if available);
2. The name and address of the pre-registrant and the name of the contact person and, where appropriate, the name and address of a Third Party Representative (see below);
3. The envisaged deadline for registration and tonnage band;
4. The name(s) of other substance(s) for which the available information is relevant for performing adaptations to the testing requirements, i.e. use of results from (Q)SAR models (Section 1.3 of Annex XI) and read-across approach.
5. Optionally, the pre-registrant can indicate whether he is willing to act as "facilitator" in the SIEF. This means they would take on the role, if agreed by the rest of the SIEF, of organizer to ensure that the SIEF works efficiently.

Third Party Representative

A pre-registrant may select a Third Party Representative (TPR) to represent them in all the proceedings involving discussions with other Manufacturers, Importers and Downstream Users (Article 4) in a SIEF. This option would normally be taken up if a company is concerned about the release of confidential business information (see below) through the link between their company and the pre-registration of a substance. This means that the link between the Third Party Representative and the company is

known only between these parties and the ECHA; this will not be revealed to the SIEF participants. N.B. do not confuse the TRP with the OR. The TRP does not have any responsibilities for registration whereas the OR does. Anyone can represent a pre-registrant in the SIEF; they do not need to be specifically mentioned in the pre-registration.

It is unlikely that registrants of pig iron would have any need to keep their identity confidential but if they do then IPIA could fill the third party representative role or recommend other agents who could.

When and How to Pre-Register:

The period for pre-registration runs from 1 June – 1 December 2008. It can be done through a plug-in in to IUCLID5 (the software package that must be used for registration purposes) which is being developed, or through a form on the website of the Agency.

Why Pre-Register:

The main benefit of pre-registration is that companies are allowed to continue manufacturing, importing and using phase-in substances until the appropriate registration deadline. In other words, the delayed registration applies. In the case of high volume chemicals (1000 tonnes or more per annum per M/I), CMRs class 1 and 2 (1 tonne or more per annum per M/I), those substances meeting the criteria for classification as R50-53 (broadly speaking those that are seriously dangerous for the environment in quantities of 100 tonnes or more per year per M/I) this means 30 November 2010.

3.3 Confidentiality issues

If a company is concerned about the release of confidential business information it can use a TPR in the SIEF process. If an IPIA member wishes to use this option it should make the necessary arrangements prior to the pre-registration phase, so that this can be included in the pre-registration step since it is not possible to change it after completion of this step. The TPR can handle a range of tasks such as any technical work during the operation of the SIEF including the exchange of data, liaison with a contracting third party, etc.

IPIA could fulfil the role of TPR on behalf of member companies. In practice it is unlikely that confidentiality of the name of a pig iron registrant would be necessary.

3.4 After pre-registration - SIEFs and consortia

Why and who

The aims of the SIEF are to facilitate data sharing for the purposes of Registration, and agree on the classification and labeling of the substance concerned. This sharing of data is designed to prevent duplicate testing, especially testing on vertebrate animals; available information generated through testing on vertebrate animals must be shared, other information must be shared on request of other members of the SIEF. In practice most SIEFs will consider all information available leading to the submission of a Joint Registration covering all relevant end-points. Optionally, a SIEF may also be the basis for the exchange of the data needed to perform the Chemical Safety Assessment (CSA), drafting the Chemical Safety Report (CSR) and agreeing on guidance on safe use that may be part of this joint submission.

The formation of a Substance Information Exchange Forum (SIEF) under REACH is provided to share information among potential registrants (Manufacturers and Importers) of the same "phase-in" substances and in articles intended to be released, and Only Representatives of non-EU manufacturers of a pre-registered phase-in substance, as well as allowing participation of DU and other stakeholders who have data that may be useful for registration purposes.

If a company has identified during pre-registration that they wish to use a TPR, this person will be a SIEF participant but is not the pre-registrant or registrant.

Other stakeholders, such as Manufacturers and Importers of substances in quantities of less than one tonne, Downstream Users and Third Parties who hold information on the substance will be able to submit relevant information on a voluntary basis with the view to providing their information for fair recompense in the SIEF for that substance. Registrants of the same substance that have registered their substances before the extended registration deadlines are mandatory members of the SIEF.

As mentioned above, IPIA may be a holder of data on behalf of its members. It is important to establish who the owner of the data is as only the owner of the data can input data into the SIEF and gain compensation for its use. IPIA could have a role in supporting the relevant SIEF(s) in assessing the quality and value of data and in recommending how the relevant costs could be shared between members of the SIEF.

A SIEF is not the same as a consortium. In fact, a SIEF is not a legal entity but merely a forum to achieve particular purposes under REACH as described above. It may be, and it is very likely, that in practice companies organise themselves in consortia. A consortium is a more organised and formal type of co-operation between parties, governed by a contract or other form of agreement. *IPIA could have a role set-out in a contract or agreement to support or manage the work of the consortium.*

How

The first pre-registration of a substance will trigger the creation of a dedicated webpage organised by the Agency which can only be seen by other pre-registrants of the same substance once they have made their pre-registration.

Sameness Check

The first task of all pre-registrants of the 'same' substance is to ensure that the substance they have all pre-registered is really the same. Pre-registration does not require detailed information on composition to be submitted. It is therefore possible, and in many cases likely, that the detailed composition will reveal that the 'same' substance should in fact be treated as being different for registration purposes (for example, a small difference in impurities could change the properties of a substance). A single substance for pre-registration purposes may therefore require several SIEFs to be established. N.B. read across of data from one SIEF to another would still be possible.

IPIA could have an important role in identifying whether pig iron as pre-registered in fact requires several SIEFs to be established and setting out their parameters (e.g. impurities present and ranges).

What

SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for such studies to be carried out (REACH Art 29.3).

IPIA could have a role in gathering, assessing, evaluating and valuing available information. This could be on behalf of individual IPIA member companies, groups of companies, or the SIEF as a whole.

3.5 Registration

Sole or joint registration

Although described as 'options' for registration, the default will be joint submission. This means there is a lead registrant and co-registrants (sometimes referred to as members, stemming from the SIEF process). The information to be submitted then depends on their role in the SIEF, but essentially all members supply information on the identity of the manufacturer or importer, the identity of the substance, information on the manufacture and use(s) including exposure scenarios, and exposure information in the 1-10 tonnage band. The lead registrant provides information on behalf of the joint submission on classification and labelling, study summaries or robust study summaries for key studies for all relevant end-points, and/or proposals for testing (the information requirements for each tonnage band are set-out in the REACH Annexes).

Opt outs are possible from joint registration. The criteria to be met are: (i) it would be disproportionately costly to submit the information jointly; (ii) joint submission would lead to disclosure of commercially sensitive information; or (iii) disagreement with the lead registrant on the information. However, a justification for such an opt-out has to be made to the Agency and a fee paid. The opt-out is also only for the end-point in question and not for the whole registration unless such a case is made. The system is set-up to discourage such opt-outs. IPIA members should consider carefully whether to try to take advantage of this possibility. *IPIA could have a useful advisory role here as well as preparing justifications if required.*

It should be noted that any opt-out does not apply to the data sharing obligations and other SIEF duties. Furthermore, dossiers submitted as a sole registrant rather than as part of a joint submission are much more likely to be scrutinised by the Agency and subject to evaluation.

Duties placed on the registrant relating to communication in the supply chain are covered further in section 5. Suffice it to repeat here the importance to the potential registrant of communicating with the DU about their uses of the substance and the Risk Management Measures and Operational Conditions already in place. These 'identified uses' need to be covered in the CSA/R, if required, and included in the registration dossier. The resulting exposure scenarios (ES) will need to be communicated to the customers of the registrant through an annex to the Safety Data Sheet.

Registration dossier

The registration dossier consists of a Technical Dossier, starting at 1 tonne per year, and a Chemical Safety Report, starting at 10 tonne per year. The technical dossier should contain a substantial amount of information such as:

- Identify of the manufacturer/importer
- Identity of substance
- Information on manufacture and use of the substance
- Classification and labelling
- Guidance on safe use of the substance
- Study summaries – substance properties
- Test proposals (if relevant)
- Exposure information

The Chemical Safety Report should contain a:

- Human Health Hazard Assessment
- Physicochemical Hazard Assessment
- Environmental Hazard Assessment
- PBT and vPvB Assessment

For dangerous and PBT/vPvB substances, an exposure assessment, risk characterisation and exposure scenarios will need to be developed and documented.

The guidance resulting from the REACH Implementation Projects (RIP) covering these aspects has not yet been published.

How

To submit a registration dossier, the IUCLID (International Uniform Chemical Information Database) 5 format must be used as there is no other way to submit a dossier to the Agency (IUCLID 5 is available for free download from the ECHA website). Therefore, during the preparatory period, companies who will have to register substances are strongly advised to become familiar with IUCLID5. There is a separate functionality in development for use in SIEFs and consortia that interfaces with IUCLID5 to allow data to be brought in and out of the SIEF/consortia without opening up internal company files.

IPIA could have a role in arranging training for its members in, and support for, the use of IUCLID 5.

The role of industry associations such as IPIA in the registration process cannot be direct. The actual registration can only be done by the manufacturer, importer or producer of an article or OR and cannot be done by any third party including industry associations, unless they act as the OR for one or more non-EU manufacturers.

However, industry associations can provide very valuable assistance to registrants for the preparation of registration dossiers, and can help co-ordinate the process. As mentioned before they may have valuable data on the substance that could be submitted to the SIEF. They could also be appointed to represent a registrant in discussions with other registrants regarding preparation of the joint submission of hazard data and act as third party representative. They can include non-EU enterprises as members of a consortium, who, even though having no direct registration obligations, can provide information and assistance through these associations. IPIA could set-up and manage, directly or through an agent, a consortium of potential registrants to prepare the material for registration by all members of the consortium. This is likely to be a cost effective and efficient way of managing the registration process.

4 Downstream user specific issues

Downstream users have to ensure that the substances supplied to them will be registered. If a substance is not registered when required it should be withdrawn from the market and manufacture cease. Non pre-registration of a phase-in substance would mean that a registration was required immediately (by 1 December 2008); this would greatly increase the likelihood of withdrawal from the market. If a supplier is not going to pre-register a phase-in substance or otherwise register when required a DU needs to know this as soon as possible to enable them to source alternative suppliers.

If a downstream user who has a legitimate interest in a substance finds out that the substance has not been pre-registered it can notify the Agency of its interest. Ultimately the Agency can provide contact details of this downstream user to a potential registrant. This allows the downstream user to find another supplier to pre-register under the late pre-registration procedure. If any of the IPIA members are only downstream users they should keep a close eye on this.

IPIA should stress to its members the importance of communicating with their suppliers to ensure that they are confident that substances they depend on will continue to be supplied. If there is any concern over continued supply alternative suppliers and/or substances should be identified.

DUs could also have relevant data and could act as a data holder in the SIEF. DUs should implement any Risk Measurement Measures (RMM) as set out in the ES attached to a Safety Data Sheet (SDS). When it receives a SDS with an ES attached, the DU should check that its use is covered and implement the, very often, specific RMMs. In the event that its use is not covered, the DU should inform its supplier of that use (ideally this discussion would happen before the substance has been registered to ensure that its use is an 'identified' one) and await the new SDS with updated ESs. A DU is free to conduct its own chemical safety assessment, and notify the Agency. For example, a DU may wish to keep their precise use of a substance confidential for commercial reasons and so has to prepare their own CSA for that use (certain conditions apply).

The obligations on DU listed above are not exhaustive.

5 Communication in the supply chain

5.1 SDS

Safety Data Sheets (SDS) are already used as a means of communication in the supply chain, and under REACH their role is strengthened. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a SDS. In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks. For the same reason, downstream users should manage the risks arising from their uses of a substance.

5.2 CSA/CSR

Manufacturers and importers need to collect or generate data on the substances and assess how risks to human health and the environment can be controlled by applying suitable risk management measures (RMM). The responsibility for the management of these risks lies with the natural or legal persons that manufacture, import, place on the market or use these substances in the context of their professional activities. The identification of measures required to manage risks is an integral part of the safety assessment concept. In general this is the result of an iterative process where the aim is to demonstrate how risks identified for the manufacturing or use processes can be adequately controlled by suitable risk management measures. This process includes an assessment of all available relevant information on the hazardous properties of a substance and on the conditions under which it is used. For all substances that are manufactured or imported in volumes greater than 10 tonnes per year, a more formal Chemical Safety Assessment (CSA) needs to be carried out and documented in a Chemical Safety Report (CSR).

The conduction of an exposure assessment is required for substances meeting the criteria for classification as dangerous or assessed to be a PBT or vPvB substance and is a prerequisite for conducting a risk characterisation.

The exposure assessment consists of two steps: the generation of exposure scenario(s) (ES) and estimation of exposure for each ES developed. The exposure estimation is based on the ES, which provides a set of parameters that are the main drivers (controls) of exposure. The ES is a placeholder for these parameters and contains specifications of the conditions of the use. The conditions of use cover Operational Conditions (OC) (e.g. the applied amount of substance, duration of use, process temperature, pH etc.) and Risk Management Measures (RMM) (e.g. exhaust ventilation, waste water treatment plant, personal protective equipment), which the registrant has implemented or, where relevant, recommends the Downstream User(s) to implement. When it can be demonstrated that the risks are adequately controlled, then a final exposure scenario is constructed specifying the conditions of use and (RMMS and OCs). This is then communicated in an exposure scenario attached to the Safety Data Sheet that is provided to the user in the supply chain of the substance.

Preparing CSAs is a complex technical and scientific task. IPIA could have a key role in identifying the uses (including EU manufacture) of pig iron and in helping in the preparation of CSAs and ES in particular. It is anticipated that most uses of pig iron are well known and common to many if not all pig iron manufacturers and importers. It does not make sense for all IPIA members to do these assessments individually. IPIA could manage the process for the preparation of exposure scenarios for all IPIA members for the common uses.

6 Final Remarks

At present many trade organisations and bodies are already organising consortia and helping prepare their members for REACH. IPIA can fulfil this role depending on the activities of related organisations. It should be ensured that any consortium adheres to European Competition Law and does not violate WTO rules.

There are many areas where IPIA can help support the work of its members in meeting their REACH requirements and in others IPIA could potentially take a central role. These are indicated in *italics* above.

The key issue for all IPIA member companies now is to identify substances (pig iron and potentially others) that require pre-registration. Coupled with this is the need to decide who will make the pre-registration (importers or only representatives) and whether a third party representative is needed (probably not for pig iron but possibly for other substances that are used in processing etc).

The SIEFs will start to operate from January 2009 so companies should be prepared to operate effectively (in some cases this will mean an active role and in others a 'watching brief') in SIEFs from this date. Many IPIA members will need to register pig iron by the end of November 2010 so will need to be active immediately the SIEFs are formed.

IPIA should carefully consider establishing and managing, directly or through an agent, a consortium of IPIA members to undertake many of the tasks required for registration and other REACH duties. This would be the most cost-effective and efficient way of managing the process.

APPENDIX

Definitions

Substance (Art 3.1): means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Registrant (Art 3.7): means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

Manufacturer (Art 3.9): means any natural or legal person established within the Community who manufactures a substance within the Community;

Importer (Art 3.11): means any natural or legal person established within the Community who is responsible for import;

Downstream user (Art 3.13): means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;

Phase-in substance (Art 3.20): means a substance which meets at least one of the following criteria:

- (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
- (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;
- (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;

Identified use (Art 3.26): means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

Supplier of a substance or a preparation (Art 3.32): means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

Exposure scenario (Art 3.37): means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the

environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

Use and exposure category (Art 3.38): means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

Data holders Third parties or other stakeholders, such as Manufacturers and Importers of substances in quantities of less than one tonne, Downstream Users and Third Parties who hold information on the substances appearing on the list of pre-registered substances will be able to submit relevant information on a voluntary basis with the view to providing their information for fair recompense in the SIEF for that substance. Registrants of the same substance that have registered their substances before the extended registration deadlines are mandatory members of the SIEF.

Only representative (Art 8):

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

Substance Information Exchange Forum (SIEF) (Art 29) is a forum to share information among Manufacturers and Importers of the same "phase-in" substances, as well as allowing participation of Downstream Users and other stakeholders to prevent duplicate testing, especially testing on vertebrate animals.

Abbreviations

CBI	Confidential Business Information
CMR	Carcinogenic, Mutagenic and Toxic to Reproduction
CSA/R	Chemical Safety Assessment/Report
DU	Downstream User
EINECS	European Inventory of Existing Commercial Chemical Substances
RIP	REACH Implementation Project
RMM	Risk Management Measure
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
WTO	World Trade Organisation