REACH restriction on the placing on the market and use of polycyclic aromatic hydrocarbons (PAHs) in the extender oils of tyres

Guidance for industry
November 2010
**REACH restriction**

The REACH Regulation (EC) No. 1907/2006 (as amended) is an EU Regulation that is directly applicable to all European Union member states. Annex XVII of the Regulation contains a list of chemicals that are subject to restrictions. Such restrictions apply to the manufacture, use and/or placing on the market of certain chemicals in concentrations equal to or exceeding the limits stated in the regulation.

A REACH restriction on the placing on the market and use of **polycyclic aromatic hydrocarbons (PAHs)** in the extender oils of tyres came into force on 1st January 2010. The full restriction, as an excerpt from Annex XVII of REACH, is provided in Annex 1.

Tyres, and treads for retreading, manufactured after the 1st January 2010 are banned from being placed on the market if they contain extender oils exceeding the following limits:
- More than 1 mg/kg (0.0001% by weight) Benzo(a)pyrene (BaP), or
- More than 10 mg/kg (0.001% by weight) of the sum of all PAHs listed in the restriction (See Annex 1 for the complete list)

**Placing on the market** means any supply of tyres or making them available, whether for payment or free of charge, to a third party.

**Import** is deemed to be placing on the market.

An EU-based company is defined as a tyre ‘importer’ if it imports tyres from outside the EU (comprised of 27 Member States and European Economic Area members Norway, Iceland & Lichtenstein); e.g. an Irish company importing tyres directly from China, Russia, the USA or Switzerland is an importer.

An EU-based company that is sourcing its tyres from another country within the EU is a tyre ‘recipient’; e.g. an Irish company importing tyres from Germany, UK, the Netherlands or Belgium.

An EU-based company supplying tyres to the EU market is a tyre ‘supplier’.

It is important to note that one company, depending on the nature of its business, may be all of the above.
The Health and Safety Authority is one of the enforcing authorities for the REACH Regulation. Under the Chemicals Act 2008, as amended, the Authority has the power to request information and to take enforcement action for failure to respond or for responding with a false declaration. Inspectors of the Authority may also take appropriate enforcement action against non-compliance with REACH restrictions. Enforcement action may mean the issuing of enforcement notices or prosecution. Prosecution may lead to a fine or imprisonment (or both). A link to the Chemicals Act 2008 is provided in the ‘legislation’ section of the HSA website, www.hsa.ie.

**Polycyclic aromatic Hydrocarbons (PAHs)**

PAHs are a group of over 100 organic chemical substances of poly-aromatic structure. They may be formed during a range of activities, including incomplete combustion of carbon-based fuels and other industrial processes. PAHs are contained in oil, coal and tar deposits and may be formed in the environment by natural processes such as volcanic eruptions and forest fires.

**Use of PAHs**

There are very few intentional uses of PAHs. However, some are used in the manufacture of certain dyes, pigments, plastics, pharmaceuticals and pesticides. They also may be present in some extender oils used in the production of tyre rubber. In Europe concentrations of certain PAHs are now restricted in these oils and associated products (tyres and treads for retreading).

**PAHs and human health**

PAHs are toxic by inhalation, ingestion and on contact with skin, and several have been classified as carcinogens by the International Agency for Research on Cancer (IARC), including the eight named in the REACH restriction. EU legislation classifies PAHs as category 2 carcinogens, mutagens and reproductive toxins.

**PAHs and the environment**

It is estimated that the average passenger tyre will lose 1-2Kg of its mass throughout its lifetime due to friction with the road surface. This results in fine particles containing PAH being released to the environment. PAHs are persistent organic pollutants and can accumulate in plants and animals. They break down slowly and are insoluble in water, and they can travel long distances through the atmosphere. Because of this, PAHs are pollutants of global concern.
**Obligations on tyre importers and suppliers**

REACH places a restriction on the concentration of Benzo(a)pyrene (BaP), as well as the sum total of all eight PAHs listed in the restriction, in the extender oils of tyres and treads for retreading. The full list of restricted PAHs is provided in the table in Annex 1.

Irish companies involved in the supply of tyres (i.e. placing tyres on the market) to the Irish or the EU market are responsible for ensuring that the products supplied comply with the REACH restriction.

Companies in this supply chain include
- Manufacturers
- Importers
- Wholesalers
- Distributers
- Retailers

All of the companies in a supply chain may be committing an offence if tyres are supplied that contain PAHs above the limits stated in the restriction. **It is your responsibility to ensure that the products your business supplies are compliant.**

There are a number of steps that can take to help you determine compliance with the restriction.

**Steps to ensure compliance**

**Step 1**
The first thing to check on tyres that you are placing on the market is the date of production of the article. The tyre should have an identification or serial number moulded on to the side wall, which will include the production date code. The production date code is the last part of the identification code (before the type approval mark, i.e. the E-mark or e-mark) and is two digits for the week of the year plus two digits for the year for tyres manufactured after the year 2000. For example, a production date code of 0710 indicates that the tyre was manufactured in the 7th week of 2010.

Tyres and retreads for tyres that are known to have been manufactured before 1st January 2010 are not affected by the restriction under REACH.
**Step 2**
If you determine that you have batches of tyres for sale that were manufactured **after 1st January 2010**, the PAH content and compliance with the REACH restriction should be determined by requesting information from your non-EU or EU manufacturers/suppliers.

Table 1 provides a summary of the obligations of different companies in the supply chain.

**Table 1: Summary actions to take in assessing compliance**

<table>
<thead>
<tr>
<th>Action</th>
<th>By who</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis of the extender oil or tyre to determine PAH concentration</td>
<td>Manufacturers of tyres must conduct analysis of the extender oil every six months or after every major operational change</td>
</tr>
<tr>
<td>Extender oils: IP346:1998</td>
<td>Any company in the supply chain may opt to conduct tyre analysis</td>
</tr>
<tr>
<td>Tyres: ISO 21461</td>
<td></td>
</tr>
<tr>
<td>Liaise with the manufacturer/supplier</td>
<td>Importer, wholesaler, distributer, retailer</td>
</tr>
<tr>
<td>Provide written declaration stating compliance with the REACH restriction concerning PAHs</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Keep records as evidence of compliance</td>
<td>Every company in the supply chain</td>
</tr>
</tbody>
</table>

**Analysis**
The restriction states that extender oils (and tyres subsequently made with the extender oil) are compliant if:

- For extender oils, the polycyclic aromatics (PCA) extract is less than 3 % by weight as measured by IP346; **and** the manufacturer or importer assesses compliance with the limit values of BaP and of the listed PAHs, and the correlation of the measured values with the PCA extract, every six months or after each major operational change.
- For tyres, the vulcanized rubber compounds do not exceed the limits of 0.35% Bay protons as measured and calculated by ISO 21461.
Manufacturers of tyres who conduct either of these analyses should provide this to their customers as evidence that their products are compliant.

Any laboratory analysis to establish if a product is compliant must use the appropriate test method as stated in the restriction (IP346 for extender oil or ISO 21461 for tyres). Alternative methods are unlikely to be comparable.

The laboratory conducting the analysis should be reputable, reliable and accredited for the test method used.

If your supplier is conducting the analysis, ask for a copy of the analysis report and confirmation of:

- what products were analysed;
- the date this occurred;
- the method used; and
- the name of the laboratory that ran the tests.

If the analysis relates to extender oil, you should request information about what tyre brands and sizes are manufactured using the extender oil. You should also ask for an interpretation of the results in relation to the restriction.

Even if your supplier is conducting analysis, you should consider regularly obtaining your own independent analysis of products to be confident that they are compliant. Please contact the HSA if you need the contact details of laboratories in the EU that are accredited to conduct analysis of tyres to the methods stated in the restriction. You should check that any laboratory that carries out analysis on your behalf has a current accreditation for the method.

**Liaison with suppliers/manufacturers**
If you are an importer or a recipient of tyres, you should establish regular, on-going contact with the manufacturer/supplier of the products that your business deals with.

You should establish:

- what steps they have taken to ensure the products are compliant
- what evidence they can provide that shows the products are compliant
- an agreement that you will be supplied regular copies of analysis reports
- an agreement that you will be kept up-to-date of any changes to the production process or product ingredients and that you will be informed immediately of any issues that may impact upon compliance
• an agreement that you will not be supplied products unless they are compliant with the restriction
• what future plans they have to maintain compliance

If possible, you should visit the factory where the product is made to make sure you are satisfied that the products are compliant.

**Declarations of Compliance**
Any written declarations should **specifically** state that the product complies with the PAH limits stated in the restriction. It should also state what products/brands/tyre sizes are covered by the declaration and the date the declaration is effective from.

You should request that declarations are routinely provided on a regular basis and also after any major changes to the production process.

**Important note:** If a supplier gives you a written declaration that their products are compliant with the PAH limits stated in the REACH restriction, this alone will not be sufficient for you to be confident of compliance. Other evidence of compliance should be sought in addition to the declaration, such as the analytical results as discussed above.

**Record keeping**
It is vital that you keep accurate, on-going and up-to-date records of any steps you have taken to establish the compliance of the products you deal with. Make sure that you keep any correspondence, test results, declarations or any other documentation that can demonstrate how you have assessed product compliance. Accurate records will help you to be confident that the products you handle are compliant with the restriction. In addition, they will allow you to respond quickly to any enquiries from your customers.

The Authority undertakes pro-active compliance monitoring. Keeping accurate records will help you to respond if we contact you for further information about the products your company deals with. This information will demonstrate the steps you have taken to ensure your business is compliant, and allow us to assess those steps without unnecessary delay.

**Step 3**
If you identify tyres or retreads that have concentrations of PAHs above the restriction limits, you should remove them from sale immediately and discontinue the receipt of such tyres from your non-EU or EU supplier. You should also contact
all customers that you have supplied, and inform them that the products are not suitable for sale.

If such tyres are not returned to your supplier and are deemed as waste, you should ensure that you comply with all relevant waste legislation. For information and guidance refer to www.environ.ie and www.epa.ie.

Further Information

If you wish have any further queries in relation to this restriction, please contact the Health and Safety Authority. You can contact Jean Shannon at email jean_shannon@hsa.ie or tel 01 6147079, or Blaithin Tarpey at email Blaithin_tarpey@hsa.ie or tel 01 6147167.
### Annex 1: REACH Annex XVII, Entry No. 50

<table>
<thead>
<tr>
<th>Designation of the substance, of the group of substances or of the mixture</th>
<th>Conditions of restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>50. Polycyclic-aromatic hydrocarbons (PAH)</td>
<td>1. From 1 January 2010, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:</td>
</tr>
<tr>
<td>(a) Benzo[a]pyrene (BaP) CAS No. 50-32-8</td>
<td>- more than 1 mg/kg (0.0001% by weight) BaP, or</td>
</tr>
<tr>
<td>(b) Benzo[e]pyrene (BeP) CAS No. 192-97-2</td>
<td>- more than 10 mg/kg (0.001% by weight) of the sum of all listed PAHs.</td>
</tr>
<tr>
<td>(c) Benzo[a]anthracene (BaA) CAS No. 56-55-3</td>
<td>These limits shall be regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3% by weight as measured by the Institute of Petroleum standard IP346: 1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions – Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limit values of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is controlled by the manufacturer or importer every six months or after each major operational change, whichever is earlier.</td>
</tr>
<tr>
<td>(d) Chrysen (CHR) CAS No. 218-01-9</td>
<td>2. Furthermore, tyres and treads for retreading manufactured after 1 January 2010 shall not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.</td>
</tr>
<tr>
<td>(e) Benzo[b]fluoranthrene (BbFA) CAS No. 205-99-2</td>
<td>These limits shall be regarded as being kept, if the vulcanized rubber compounds do not exceed the limits of 0.35% Bay protons as measured and calculated by ISO 21461 (Rubber vulcanized – Determination of aromaticity of oil in vulcanized rubber compounds).</td>
</tr>
<tr>
<td>(f) Benzo[j]fluoranthrene (BjFA) CAS No. 205-82-3</td>
<td>3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits referred to in paragraph 1.</td>
</tr>
<tr>
<td>(g) Benzo[k]fluoranthrene (BkFA) CAS No. 207-08-9</td>
<td>4. For the purpose of this entry &quot;tyres&quot; shall mean tyres for vehicles covered by:</td>
</tr>
</tbody>
</table>