

What to do, if your use or application does not appear to be covered by the listed exposure scenarios?

One of the significant changes which come out of REACH is that it is no longer the authorities which have to prove that an operation is unsafe; it is now the responsibility of industry to provide authorities with scientific evidence that all uses are safe!

In case you suspect that you have a use or an application which has not yet been covered by the listed exposure scenarios, our first advice is to start a dialog with your supplier or to contact the ISOPA office. REACH does not use the normal terminology that everyone in the industry is familiar with. Often several use scenarios are clustered and your missing application might be hidden behind some REACH jargon, your supplier or the ISOPA office might be able to help you spot where your application is, in fact, already covered.

It may also be that your use does not require an Exposure Scenario because it relates to a substance which is exempted from REACH. Polymeric raw materials like pMDI, many polyols and pre-polymers do not have exposure scenarios because of an exemption provided by the regulator. The same applies to substances that are not classified as dangerous. Again, your supplier or the ISOPA office may be able to help clarify if this is the case.

In case you really do have an application or use which has not been covered then a new exposure scenario will need to be developed. Development of a new scenario is a complicated matter and the regulator allows only 12 months to accomplish the work.

- Development of a new exposure scenario usually requires information on the conditions of use and on exposure as well as emissions data. The number of measured data points and the quality of the measurement protocol are critical to success. In some cases, combining measured data from several downstream users can decisively improve the statistical evidence. You should be aware that the risk assessment might turn out to be negative which would mean that the current way of working is deemed unsafe, forcing you to change your way of operating
- ➤ It is possible that the current RMMs (Risk Management Measures) are, in fact, excessive. In order to revise the RMMs the quality and quantity of measured data provided to support the case can help to develop an update to an exposure scenario, eventually justifying a less stringent set of RMMs.
- The regulation does provide downstream users with an option to add an application or use directly with the European authorities. Even in this case we would still advise you to enter into a dialog with your supplier or the ISOPA office. The better you understand the existing exposure scenarios the better you can focus on your additional needs.

Time is critical.

The regulator allows only 12 months for accomplishing this work. The clock is not running from the 1st December, 2010, but from the day that you receive the extended safety data sheet from your supplier. In anticipation of the fact that you will have many extended Safety Data Sheets to consider we have chosen to provide you a preview of a draft version of the Exposure Scenario section of the eSDS for aromatic isocyanates and polyols on the ISOPA website. We would advise you to make yourself familiar with these drafts and to start collecting any data you might need as early as possible.

Isopa can not be held liable if a risk assessment would lead toward dis-continuation any downstream operation.

Isopa can not be held liable for any sanction imposed by authorities in cases of non-compliance with REACH regulation.