

Business Guide to Safer Chemicals

Fourth Edition



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Who is Chemical Watch?

Chemical Watch provides the global business community with the facts and perspectives it needs to achieve safer chemicals in products.

With a team of expert journalists keeping you abreast of global policy and business trends, our ultimate goal is to help you meet your responsibilities under chemicals legislation worldwide, including regimes such as REACH, GHS and TSCA. We are not tied to any trade associations, governments or campaign groups, which means we are able to offer objective news and analysis for all sectors.

Alongside our authoritative news coverage, we also support your [professional development](#) with our intensive courses, premium webinars and eLearning offering. Together they provide you and your teams with the training you need to manage the risks of chemicals in the workplace, through the supply chain, and in products.

To find out more about Chemical Watch and our coverage of regulatory developments in your sector, feel free to have a look at our [sector pages](#), or take a [free trial](#) to get full access to all our coverage for two weeks.

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BPA could get canned

A major can coatings producer has worked with other stakeholders to develop an alternative to bisphenol A-based epoxies

Bisphenol A (BPA)-based epoxies have become the default option in the coating of metal cans for food packaging over the last 60 years. About 80% of all metal packaging uses it, according to Thomas Mallen, technical director at Sherwin-Williams Packaging, which was known as Valspar until its acquisition by the coatings giant in June 2017.

BPA was put on the REACH candidate list of SVHCs due to its Category 1B reprotoxic properties in January 2017. Since 1 March 2018, all manufacturers, importers, or suppliers have had to classify and label mixtures containing BPA in this way.

In June 2017, Echa's Member State Committee also voted to identify BPA as a SVHC because of endocrine disrupting properties which cause probable serious effects to human health, giving rise to an equivalent level of concern to carcinogenic, mutagenic and reprotoxic (CMR) substances. Finally, the BPA entry was also updated to include endocrine disrupting properties causing adverse effects to the environment.

The substance has been banned from infant feeding bottles across the EU since June 2011, while three member states have banned it in other materials that come into contact with food intended for infants and children under three years. France has banned it in all food packaging, containers and utensils. It is still permitted in food contact materials, but with maximum migration limits that the European Food Safety Authority (Efsa) is re-evaluating.

Thus, there is a clear regulatory driver towards removing BPA from the epoxies used in can coatings. However, doing this without making compromises in terms of safety, performance and high speed application is a huge challenge, Mr Mallen says. There are a number, of reasons technical, regulatory and societal, why this is so.

First, BPA is used twice in the synthesis of these epoxies, so two steps are impacted by any changes. Secondly, a means has to be found to achieve a high molecular weight linear (not branched) polymer, in order to preserve the material's flexibility and ability to coat metals, and to ensure the same extremely low level of residuals that might migrate into the food.

"The replacement material must also be free of endocrine activity, to avoid regrettable substitutions," says Mr Mallen. "As we went through material discovery, we soon found that there is no one definition of what an endocrine-active material is, so that was a challenge too. And, once we had discovered one, it was important that society accepts that not all bisphenols

are of concern. Many of them have no endocrine activity at all, but they are also not suitable for making polymers or monomers."

To get to the point where there are no concerns among stakeholders and society involved addressing several problems in the way regulatory agencies work, Mr Mallen continues. Food contact agencies generally focus on conventional safety and risk-based safety assessments, and are concerned with other toxicological endpoints than endocrine disruption. Chemical inventory regulatory agencies – like Echa with REACH or the US EPA with TSCA – require GLP-based procedures for human health and environment.

"Those have limitations in terms of fully utilising tests to look for other endpoints that may be of concern," Mr Mallen says. "And we recognise that there is a gap between testing for compliance and getting a more comprehensive answer that is sustainable in the long term."

In addressing this problem, Sherwin-Williams borrowed the concept of 'Safety by Design' from the pharmaceuticals industry. This is generally conceived as a funnel through which a large number of potential products is whittled down in stages through investigation of their regulatory characteristics until a much smaller number is left but with a much higher degree of confidence about the probability of success.

In its product development, Sherwin-Williams starts out with early material investigation, to find out if a product contains any chromophores or structural alerts that would give rise to concern later down the line. The next stage was "to impose on our R&D group endocrine testing for the components, as well as the materials that they make with those components – which is not a trivial issue".

Thus, many materials could be eliminated before the company needed to get further down in the process to toxicological assessment and migration testing, which are needed in order to do a risk assessment. "Eventually we started talking to regulators and others about these materials, submitting dossiers and notifications," Mr Mallen says.

Once Sherwin-Williams had a dataset it was comfortable with as a potential BPA replacement for can coating, it started reaching out to others to get their take on the dataset, its methods and anything missing to see what would convince them the materials were truly not endocrine active. They included:

- academic and state research bodies, such as Tufts University, Texas A&M University, UMass Amherst, Baylor College of Medicine and the UK's Food & Environment Research Agency (Fera);
- NGOs, such as ChemTrust, Breast Cancer Action, the Natural Resources Defense Council (NRDC), Clean Production Action (CPA), ChemSec and the Centre for Science in the Public Interest; and
- regulators, including the US Federal Drug Administration (FDA), Health Canada and France's French Agency for Food, Environmental and Occupational Health & Safety (Anses).

Tufts and Baylor have already published on the material Sherwin-Williams developed and the company has conducted a GreenScreen evaluation for them with CPA. It also engaged with ChemSec and was invited to put its new material on the Swedish NGO's Marketplace, which it saw as "a business-to-business opportunity for transparency," Mr Mallen says. "It really does help innovation to get noticed."

The product, ValPure 70, is described as a next-generation coating technology with epoxy-like performance. It is now being adopted in North and Central America and is being evaluated in Europe.

The monomer for this product, tetramethyl bisphenol F (TMBPF), had been registered under REACH by other companies in a substance information exchange (Sief) but only at low volumes and with little detail. Sherwin-Williams has therefore had to generate and send more information to the lead registrant (LR) to make the dossier acceptable at the highest volume level needed.

The epoxy was not pre-registered, so the company took that on itself, becoming LR for the Sief which others have joined. It is now going through the same process of testing and submission to Echa.

"One of the key things for us to develop trust between the stakeholders in society was to be transparent and put all the material from us and others on a dedicated website," Mr Mallen says. "We feel like we met the challenge, although of course the journey continues."

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