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SPECIAL EDITION: RESVERATROL

Regulation: Resveratrol GRAS to novel

By Shane Starling, 11-Sep-2009

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As with many relatively new ingredients, resveratrol's GRAS status is not helping it gain widespread commercial availability in the early 1990s.

Its status therefore varies depending on the type of [resveratrol](#) in question and the region or country.

For instance, Danish supplier Fluxome has self-affirmed GRAS (generally recognized as safe) status in the US for its genetically modified yeast-derived version of resveratrol, but may be waiting years for novel foods approval within the European Union – its GM status obviously not helping in GM-averse Europe.

But product manager, Sami Sassi, says it is in the process of compiling a dossier for submission to the EU's novel foods assessors.

In the EU at least the fact that the most bioactive form of resveratrol, trans-resveratrol, is not derived from the antioxidant's most abundant source, grapes, due to poor concentrations, amplifies this dilemma as a common novel foods approval is not possible.

But for the grape-derived versions, novel foods approvals should be transferable throughout the bloc according to Lorène Courrège, the regulatory affairs director at the European Federation of Associations of Health Product Manufacturers (EHPM).

"I understand that as long as not from a novel source, if it comes from traditional sources such as grape skin etc, it would be OK in the majority of EU states such as Belgium, Netherlands, UK, Italy," she said, noting member states had the right to make their own determinations on individual product formulas.

"But I am not aware of any concerns," she said.

Food supplement products containing natural versions of resveratrol such as those sourced from red wine, mulberries, peanuts and 'knotweed' (*polygnum cuspidatum*), will require Traditional Herbal Medicinal Product Directive (THMPD) registration by 2011 if they wish to make any health claims for demonstrated benefits such as diabetes, heart health, obesity and some cancers.

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Given approvals so far other herbals, it would seem resveratrol products have a good chance of achieving this.

Resveratrol-based health claims for foods and food supplements have not been submitted to the European Food Safety Authority (EFSA), but other antioxidant opinions due soon will be very informative for the resveratrol industry, whichever way they turn out.

US approvals

In the US, approved dietary ingredient status has been difficult to achieve in the past due to safety concerns, but most of the big players have demonstrated safety to the Food and Drug Administration (FDA) and are trading their pure, extracted blend, natural or synthetic versions there.

Knotweed-derived concentrations and blends from the likes of Sabinsa, Blue California, InterHealth, Maypro, Ethical Naturals and Cyvex and Ethical and the likes of DSM which has a synthetic version called resVida, are all doing business, and which it says is also self-affirmed GRAS.

However the situation is complicated by the potential classification of the ingredient as a drug, something Dipak Das, PhD, from the University of Connecticut, believes will happen soon.

How that will affect its GRAS status is unknown, but Sangeetha Srinivasan,

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program manager in the Food & Beverage Ingredients Practice at Frost & Sullivan, noted drug trials were underway that may open the way for pharma approval.

"The key applications are supplements and cosmetics," she said. "Presently, there are a number of clinical trial underway for the development of drugs based on resveratrol. Resveratrol is being considered for its diabetes, anti-aging, anti-inflammatory and anti-cancer properties."

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