Veille Internet sur les phtalates du 15/08/2011 au 4/09/2011

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EC develops tests for phthalate adulteration of drugs, beverages

Phil Taylor

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The European Commission's Joint Research Centre has developed three new methods to detect a plasticiser agent which has been used to adulterate foods, beverages and some pharmaceuticals in Asia.

The JRC has developed and validated three new testing methods for DEHP (diethylhexyl phthalate) - one of the main plasticiser agents implicated in the contamination scandal - at the request of the European Commission.

In late May, the Taiwanese authorities informed the European Commission that significant amounts of phthalates were illegally added to certain categories of sports drinks. Subsequent investigations led to an import ban on various categories of food and beverages, including not only sports drinks but also juices, tea drinks, fruit jams, jellies and syrups and supplements in tablet, powder and capsule form.

More than 200 products from 34 Taiwanese producers were exported to 22 countries. These include some EU member states, in particular Germany and the UK, where some products were withdrawn from the market.

Meanwhile, GlaxoSmithKline was forced to recall its antibiotic Augmentin (amoxicillin and clavulanate) twice in Hong Kong after traces of DEHP and two related agents - DIDP (diisodecyl phthalate) and DINP (diisononyl phthalate) - were found in tablets. Other drugmakers have also been affected (see Hong Kong recalls drugs due to DEHP contamination).

At the moment it is unclear how the plasticisers found their way into the medicine, although at least one case of DEHP contamination has been traced to Taiwanese firm Yu Shen Chemical Co. Meanwhile another Taiwan-based supplier - Pin Han Perfumery - has been accused of adding DINP to clouding agents that can be used in food and pharmaceutical applications.

The plasticisers are in the phthalate class of compounds, which are believed to affect reproductive performance and fertility, and have been linked to developmental problems with children.

The new test methods are freely available on the JRC's website and are intended "to facilitate the work of laboratories in the EU and world-wide involved in the testing of suspected products," said the group in a statement.

Testing laboratories are invited to submit their feedback regarding the performance of the methods to the JRC, which will analyse the findings and improve the methods, if necessary.

Commenting on the case, the IPEC Federation - an international group representing excipient manufacturers and the drugmakers who use them - said that in some cases plasticisers have been added as a low-cost replacement for the more expensive palm oil in what seems to be a clear case of economically-motivated adulteration.

Other phthalates are specifically approved for use in pharmaceuticals, notably diethyl phthalate (DEP) and dibutyl phthalate (DBP) and do not pose safety concerns in these applications, said IPEC.

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http://chemicalwatch.com/8258/us-epa-aims-to-replace-phthalates-with-safer-chemicals

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US EPA aims to replace phthalates with safer chemicals

Agency wants to find alternative substances for certain phthalates

26-Aug-2011

The US Environmental Protection Agency (EPA) has launched an initiative aimed at identifying safer chemicals that can be used as alternatives to certain phthalates. It hopes to achieve this aim by comparing the human health and environmental impacts of the alternative compounds with the phthalates currently in use. The initiative - a partnership between the EPA and interested parties - was launched on 24 August under the auspices of the...

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