Press release

The Greens | EFA in the European Parliament

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Highly toxic substances in medical devices to be labelled under new legislation

Toxic substances

A first reading agreement between the European Parliament and the Council on revising the medical devices directive was adopted by the EP today. Under the agreement, all medical devices that include substances (PVC softeners) which are carcinogenic, mutagenic or damaging to reproductive organs (CMR substances), will have to be labelled to reflect this. Following the vote, Green MEP and shadow rapporteur **Hiltrud Breyer** said:

"Toxic substances should have no place in medical devices, when safer alternative devices exist. Medical devices are in constant direct contact with the body and should not endanger the health of patients.One particular offender is the use of soft PVC in medical devices, which usually contain high concentrations of the toxic softener DEHP (a phthalate that is toxic to reproduction). The EP had originally sought a ban on the use of highly toxic 'CMR' substances where safer alternatives exist and we regret that this was not included in the final agreement, following the resistance of Council.

"The obligation on manufacturers of medical devices containing these toxic substances to label their products to reflect is a silver lining however. Under the agreement, any medical devices in body contact containing CMR phthalates will have to specify this on the label. There will also be a greater burden on manufacturers to justify why they use soft PVC in products used for children or pregnant mothers.

"While these provisions are certainly improvements on the current situation, clearly only a ban on these toxic substances will provide the necessary protection.A draft recommendationalong these lines was finally presented by the Commission this week - as such we are expecting an effective Commission proposal for a phase-out of DEHP in medical devices by the end of this year at the very latest."

Further information:

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