

IDNUMBER 200805140019
PUBLICATION: The Ottawa Citizen
DATE: 2008.05.14
EDITION: Early
SECTION: News
PAGE: A3
BYLINE: Sarah Schmidt
SOURCE: The Ottawa Citizen
WORD COUNT: 451

Silicone gel implants may lose approval; Key chemicals could be declared toxic

Health Canada may have to reverse its controversial 2006 decision to allow women to get silicone gel-filled breast implants if it proceeds with a plan to declare key chemicals found in them to be toxic, experts say.

Health Canada is expected to announce Friday its plans for synthetic chemicals found in silicone fluids as part of a risk assessment of 200 chemical substances, identified as top priorities for action because they are potentially harmful to human health or the environment.

It has already written to industry, explaining that "in the absence of additional relevant information," the government is "predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic (under the) Canadian Environmental Protection Act."

A toxic declaration about the Cyclohexasiloxane family, also known as D4, D5, D6, would start a process that could lead to a ban in certain products, as with bisphenol A in baby bottles.

"The different departments at Health Canada have been a bit of a dysfunctional family that don't listen to one another. If the environmental assessment decides this should be toxic, there should be a duty of the medical devices branches to study whether it should be taken off the market," said Dr. Kapil Khatter, scientific adviser for Environmental Defence.

Silicone implants were pulled from the market in 1992 amid concerns they were unsafe for women. Fourteen years later, Health Canada changed course and made them freely available to women with the caveat that "no medical device is 100 per cent safe."

Health Canada said it reviewed more than 65,000 pages of evidence submitted by manufacturers and more than 2,500 scientific articles in reaching its decision to grant licences to two companies to market silicone implants.

Until then, only breast implants filled with saline were licensed for sale in Canada. The October 2006 decision came just months after Health Canada's scientific advisory committee said questions "had not been sufficiently addressed" about potential health risks if the gels leaked into women's bodies and about whether the implants increased the risk of auto-immune diseases in the long term.

In May 2007, as part of its chemicals management plan, Health Canada asked industry to prove D4, D5 and D6 were safe. The chemicals also were found in cosmetics and other personal care products.

Health Canada flagged D4 as a priority because the European Commission has listed it as a reproductive toxin. D5 and D6 were prioritized because of environmental concerns.

Dr. Kapil said he was hopeful a toxic designation would result in better departmental co-ordination at Health Canada. "This will create that conversation," he said. "Through this program, there will be something overarching that will push the Health Canada departments that regulate cosmetics and medical devices to look at toxic substances in their area."

Health Canada also will announce Friday its decision about vinyl acetate, commonly used as a base in chewing gum.