



The FDA classifies mercury amalgam fillings as “moderate risk”

According to European and American NGOs this represents an important step forward for the recognition of amalgam dangers, but it is not enough

For Press Release - 1st August 2009 – The FDA (Food and Drug Administration), the U.S. agency that regulates medicines and therapeutic devices, eventually reclassified dental amalgam, the controversial material used for dental fillings containing, by weight, about 50% of elemental mercury and 50% of other metals in powder like silver, copper, tin, zinc (and sometimes traces of other non declared metals such as nickel or cadmium).

The FDA was forced to conclude its evaluation process of dental amalgam by a civil court ruling in June 2008¹, which gave reason to the request made by a group of consumers and amalgam victims, such as *Moms Against Mercury*,² *Connecticut Coalition for Environmental Justice*,³ *Oregonians for Life*⁴ and *Consumers for Dental Choice*.⁵ These NGOs had requested a reclassification of amalgam since the early '90s and they wanted FDA to go faster with the reclassification, especially in consideration of the growing scientific evidence of potential harms posed by amalgam fillings to human health.

Up to now there was a classification of the two separate group of ingredients of amalgam (that is to say elemental mercury and other metal powder) but FDA had not issued a separate regulation classifying the combination of the two, namely dental amalgam.

The FDA concluded that amalgam is not toxic and that the mercury vapor released from amalgam fillings do not pose any hazard to health when, already in 1991⁶ and in 2003, the World Health Organization confirmed that mercury contained in dental amalgam is the greatest source of mercury vapour in non-industrialized settings, *exposing the concerned population to mercury levels significantly exceeding those set for food and for air*. In 2005 the WHO Policy Paper, *Mercury in Health Care*, precised that the concerned population is exposed to an average of 3-17 mcg of mercury vapour from dental amalgams in normal conditions.⁷

The U.S. agency passes this material from Class I, which indicates a "low risk", to Class II, which indicates a "moderate risk" and provides special controls more than the general ones applying to all medical devices. "We are quite dismayed by this conclusion – Francesca Romana Orlando, Vice President of A.M.I.C.A. comments – since the September 2006 meeting called and organized by the FDA as an 'expert panel to

¹ <http://www.infoamica.it/articolo.asp?a=9&sa=54&art=481>

² www.momsagainstm Mercury.org/

³ www.environmental-justice.org

⁴ www.oregoniansforlife.org/

⁵ www.toxicteeth.org/

⁶ <http://www.who.int/ipcs/publications/cicad/en/cicad50.pdf>

⁷ www.who.int/water_sanitation_health/medicalwaste/mercurypolpaper.pdf

evaluate dental amalgams' voted 13 to 7 to NOT accept the white paper prepared by the FDA Dental Branch which concluded that amalgams were safe. We expected a more severe regulation".

Moreover, the FDA had published on its website more cautious statements as a result of the agreement following the ruling of June 2008: "*Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetus.*" and "*Pregnant women and persons who may have a health condition that makes them more sensitive to mercury exposure, including individuals with existing high levels of mercury bioburden, should not avoid seeking dental care, but should discuss options with their health practitioner*"

These warnings are not present in the new labelling requirements of amalgam and there is mainly the recognition of the risks for people with allergy and the obligation for dentists to warn their patients about the presence of mercury in this dental material.

The FDA recommends this information on the amalgam labelling:

- WARNING: CONTAINS MERCURY
- Warning: May be harmful if vapours are inhaled
- Precaution: Use with adequate ventilation
- Precaution: Store in a cool, well ventilated place
- Contains [...] % mercury by weight

FDA warns dental professionals to use adequate ventilation during processing of dental amalgam and wants the patients to receive enough information about benefits and risks of dental amalgam, including the risk of inhalation of mercury vapour.

According to the NGOs **the new classification is insufficient because it does not take into account various scientific aspects**: first of all, it doesn't consider the inadequacy of studies based urine tests used to determine the effects of exposure to mercury vapour or to other metal of amalgam. Several experiments on sheep and monkeys, in fact, have shown that a significant amount of the dental mercury is absorbed by kidneys, liver, brain and the jaw bones, where, according to many scientists, it may interfere with the neurological and immune system; secondly, the mercury in urine test, often used in pro-amalgam studies, may not be indicative because the minor presence of mercury in urine could be caused by a poor ability to metabolize this toxic element⁸; thus, paradoxically, lower levels of mercury in urine may indicate a state of toxicity and not a state of health.

"At least one percent of those who have dental amalgam could be negatively affected by mercury", Servando Pérez Domínguez, university teacher of the Spanish patients organization MERCURIADOS, said. "We try to tell people and politicians that there are safer alternatives; in the end it will be a political decision".⁹ In May 2009 the *Consejo General de los Colegios Oficiales de Químicos de España* (General Council of Official Colleges of Chemists in Spain) wrote to the Ministry of Health of Spain, saying that "both from a health and an environmental point of view, mercury amalgams should be substituted by other less harmful materials, available nowadays".

"To pay attention only to allergic or sensitive people is a paradox when you consider that most of patients do not know their genetic susceptibility to mercury and do not have any sensitization before they get exposed to this substance", the Vice-President of A.M.I.C.A. comments.

"In case of chronic mercury intoxication the informed patient travels through whole Germany to find a well trained physician, who is able to make a proper diagnosis, to safely remove the amalgam fillings and to develop a therapy for the excretion of the stored mercury. Uninformed patients are in danger to be treated as psychosomatic or psychopathic cases." – Reinhard Lauer of the German patients association BBFU comments.

The FDA has a clear mandate, namely to research and evaluate pending evidence of health risks, and the FDA document published on July 28th 2009 about amalgam takes explicitly the distance from the position of countries - such as Sweden,¹⁰ Norway¹¹ (and soon Denmark) - that decided to ban mercury amalgam fillings in order to protect their citizens in accordance with the *Principle of Precaution*.

⁸ <http://www.infoamica.it/articolo.asp?a=9&sa=38&art=249>

⁹ www.reuters.com/article/reutersEdge/idUSL2319134520070725

¹⁰ www.sweden.gov.se/sb/d/11459/a/118550

¹¹ <http://www.regjeringen.no/en/dep/md/press-centre/Press-releases/2007/Bans-mercury-in-products.html?id=495138>

In Italy the law of 2001 prohibits the use of dental amalgam in pregnant women and in people with allergy to mercury or with kidney problems but A.M.I.C.A. has just launched the Petition "Stop dental mercury!" (see www.infoamica.it) to ask to the Minister of Health of Italian Government for a complete ban of amalgam fillings in order to finally **put an end to this terrible chapter of modern medicine**.

In Spain the National Health System has been taken to court for placing dental amalgam in patients without, at least, *Informed Consent*.¹² Moreover, on July 10th 2009 the public Citizens Defender (called *El Defensor del Pueblo*) accepted the MERCURIADOS claim against the National Health System about the dental mercury issue.

On an international congress in Luxembourg, 10th of November 2007, the European Academy for Environmental Medicine (EUROPAEM) in cooperation with Aktionsgruppe für Umwelttoxikologie (AKUT asbl) Luxemburg proclaimed the "Luxembourg Appeal". Scientists, researcher, doctors specialized in environmental medicine, physicians, and dentists as well as politicians, NGOs, and patient groups, since long, ask for a ban of mercury in dental amalgam. Subjects of this congress were the scientific evidence from observations of health damage in dental medical offices, toxicity of mercury, allergic reactions to dental amalgam and especially health damage to the fetus and children of mercury-burdened parents. In a resolution end of the congress a "Luxembourg Appeal" was declared and signed in order to exert political pressure on European Union and national health authorities in Europe.¹³ "Until today, EUROPAEM and AKUT got over 20000 signatures to this appeal stressing the ban of dental amalgam", reminds Dr. med. Peter Ohnsorge, Managing Chairman of *EUROPAEM*.

In Germany, Max Dauderer, Director of the Tox Center in Grünwald, former Prof. of Toxicology at the University of Munich, and author of a 22,000 pages Handbook of Toxicology of amalgam¹⁴ based on the experience on about 25.000 cases, claims that this particular material is responsible for neurological damages (ranging from behavioural abnormalities to Multiple Sclerosis, Schizophrenia, Amyotrophic Lateral Sclerosis, Sudden Infant Death and Alzheimer's Disease) and immune damages (ranging from immunodeficiency to lethal bacterial or viral infections, kidney failure or cancer). In March 2008 he presented to the European Court of Human Rights an Accusal of the Federal Republic of Germany for Violation of Article 2 of the German Constitution regarding "Right to life and physical integrity".¹⁵

"We have a duty as parents to protect our children. Mercury is a well known toxin, in fact, the third most toxic substance on the planet! Children, especially the foetus are particularly vulnerable to the 'cumulative' effect of mercury and research studies have shown a significant correlation between maternal mercury-blood levels and mercury-blood levels in the newborn infant." Rebecca Dutton of the UK organisation for amalgam patients – Mercury Madness, says¹⁶.

Moreover, according to Anna Zuccheri, MD, President of the Italian organization for Electro-Magnetic Hypersensitive patients, the amalgam fillings, like any metal, amplify the effects of Electro Magnetic Fields (EMFs) at a cellular level so there may be cross-exposure effects between EMFs and amalgam.

The NGOs believe that to **consider dental mercury a "moderate risk" clearly contradicts the basics of preventive medicine** because mercury from amalgam is absorbed into the body at a rate of 3 to 17 mcg/day (WHO 1991 Health Criteria 118).¹⁷

Moreover, the use of mercury in dentistry has also serious implications on the environment. Only in United Kingdom, annually 7.41 tonnes of mercury from dental amalgam are discharged to the sewer, atmosphere or land, with another 11.5 tonnes sent for recycling or disposed with the clinical waste stream. Together, mercury contained in dental amalgam and in laboratory and medical devices, account for about 53% of the total mercury emissions.¹⁸

Full report (in English) of the FDA Dental about amalgam:

<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf>

Press release on the FDA classification of dental amalgam, 28 July 2008:

¹² www.mercurymadness.org/getdatafile.aspx?dataid=190

¹³ www.europaem.de/frameset5.html

¹⁴ <http://toxcenter.de/amalgamhandbuch/ama-hb.pdf>

¹⁵ <http://www.toxcenter.de/download/versch/amalgamanzeige.pdf>

¹⁶ <http://www.mercurymadness.org/>

¹⁷ www.inchem.org/documents/ehc/ehc/ehc118.htm

¹⁸ www.who.int/water_sanitation_health/medicalwaste/mercurypolpaper.pdf

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173992.htm>

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