

Current WHO position concerning thiomersal- preserved vaccines

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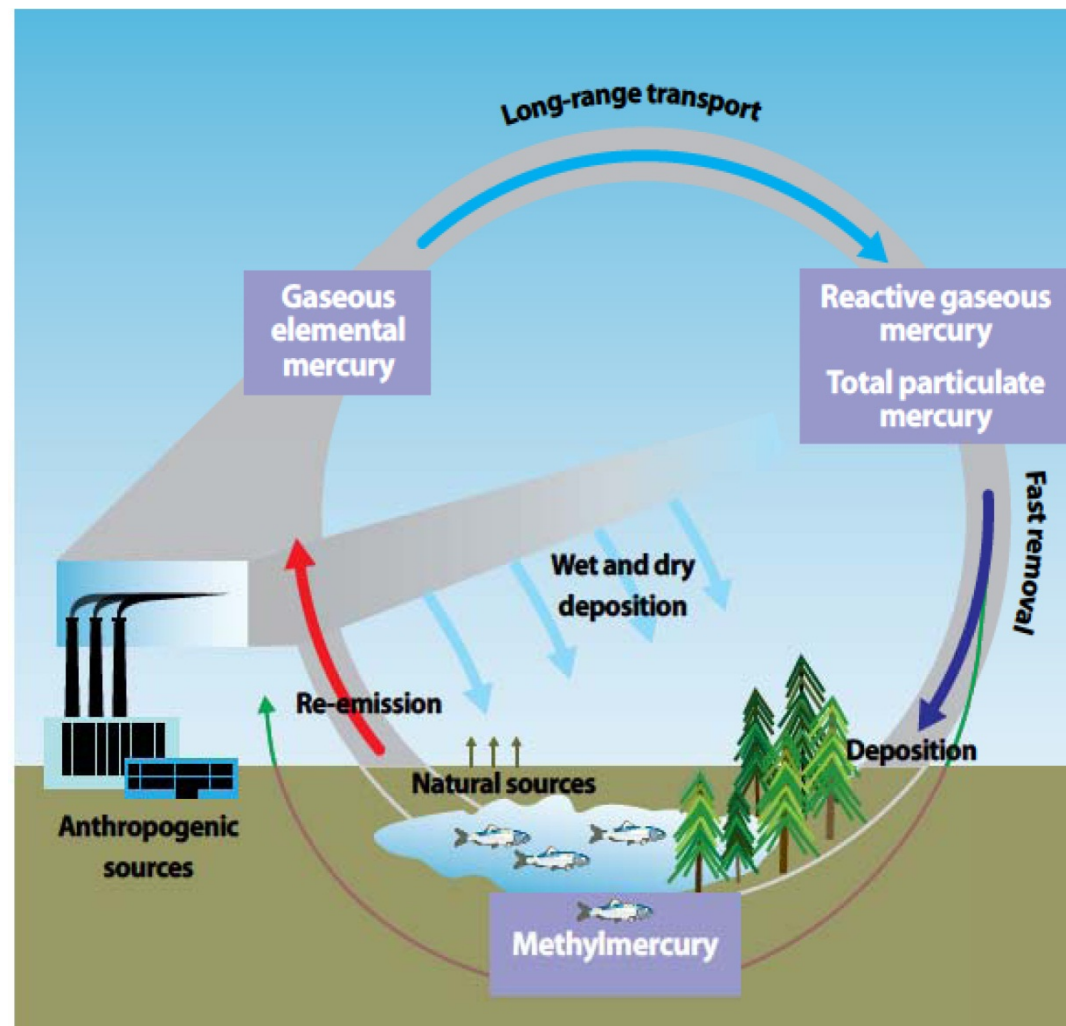


World Health
Organization

Health in the mercury instrument

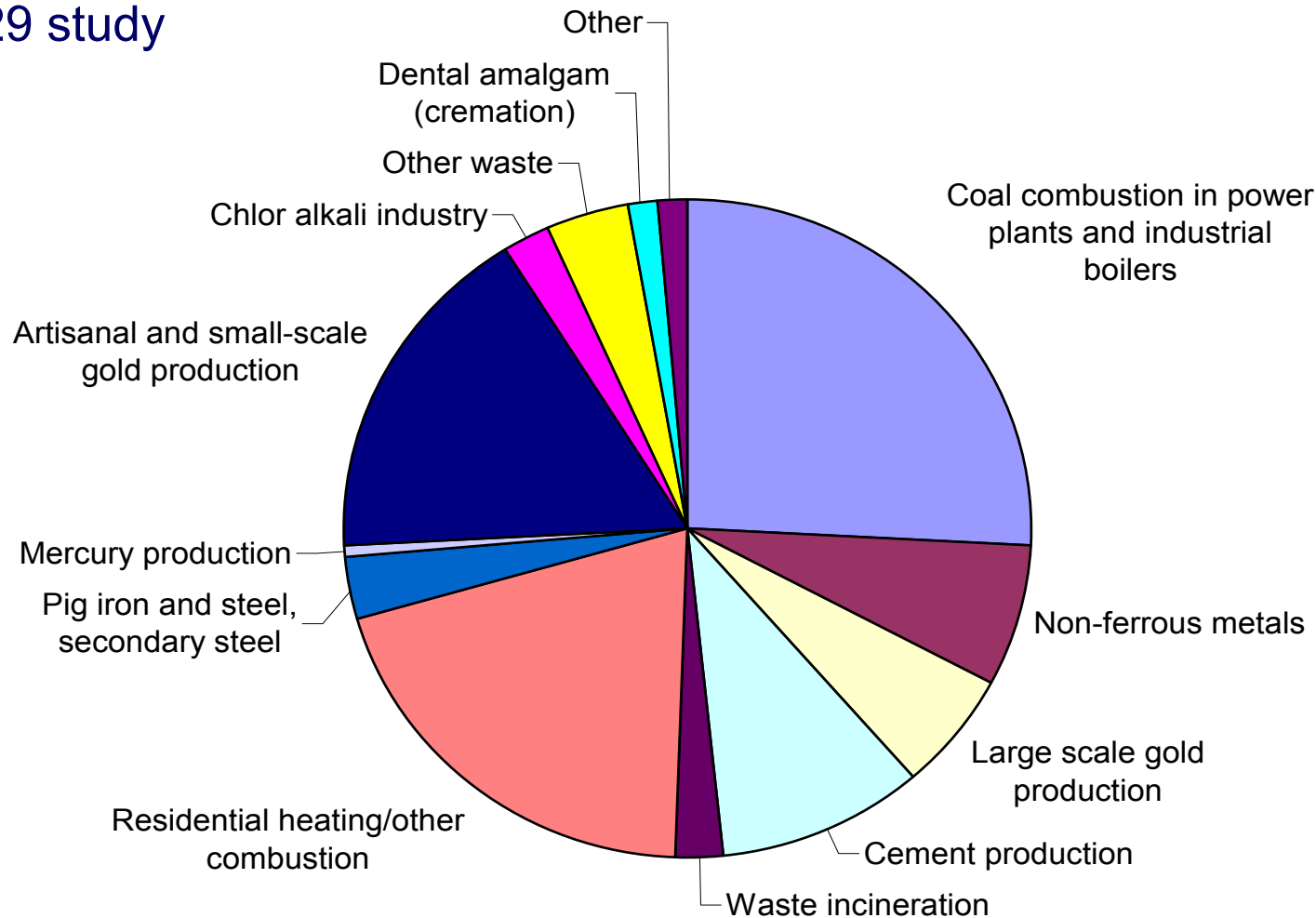
Objective: protect human health and environment by reducing mercury releases.

In subsistence fishing populations, between 1.5/1000 and 17/1000 children showed cognitive impacts



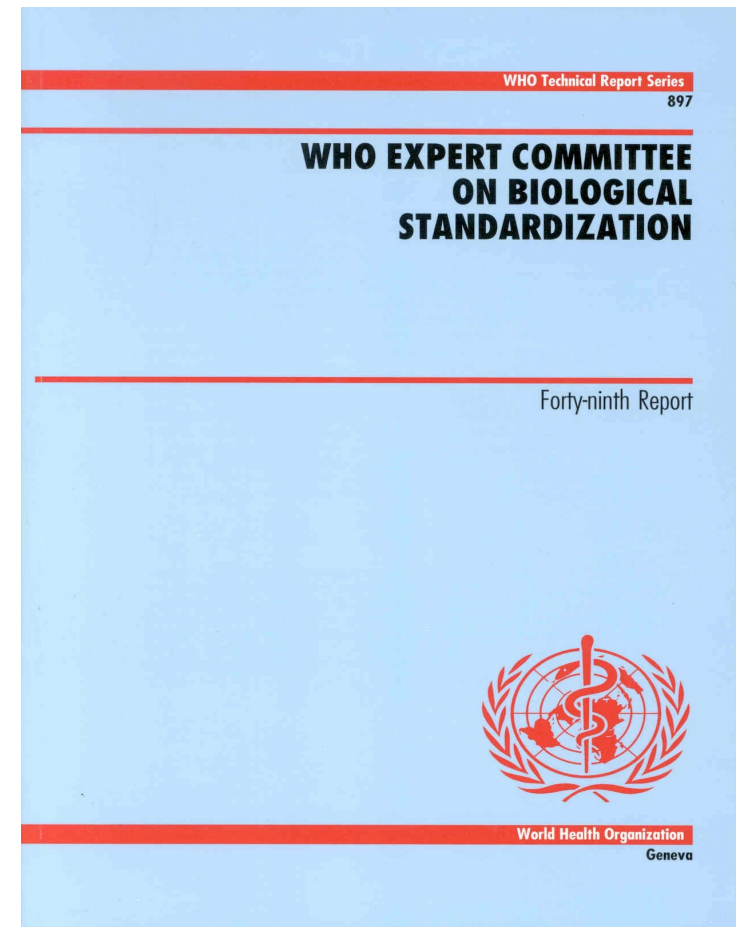
Greatest health gains will be made by addressing the main sources of mercury

UNEP para 29 study



Information to INC3 on mercury in pharmaceuticals

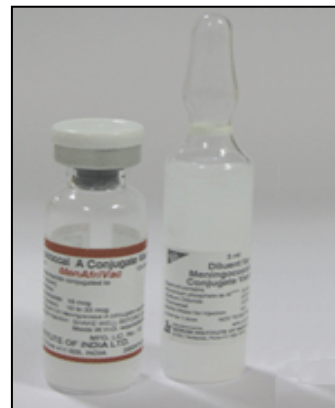
- Vaccines are already highly regulated (by medical health regulators assessing safety, efficacy and quality of medical products before granting marketing authorization/registration)



WHO TRS 926 (2004)
Thiomersal in Vaccines; regulatory expectations

Thiomersal containing vaccines and global public health

- Thiomersal containing vaccines are essential medicines
 - used in over 120 countries to immunize at least 64% of global birth cohort each year
 - protect against four major killers; diphtheria, tetanus, pertussis, and *Haemophilus influenzae* type b disease
 - estimated to avert at least 1 400 000 child deaths per year
- Thiomersal-containing vaccines are also used by developed and developing countries to protect their populations against pandemic (influenza) and epidemic (eg meningitis in Africa) threats



Thiomersal and vaccine safety

- High-quality population-based studies conducted in several countries since 2000 conclusively show that vaccines that contain thiomersal are very safe
- There is no credible scientific evidence that thiomersal-containing vaccines cause autism



The screenshot displays the WHO website's 'Global Advisory Committee on Vaccine Safety' page. The header includes the WHO logo and navigation tabs: Home, Health topics, Data and statistics, Media centre, Publications, Countries, Programmes and projects, and About WHO. A search bar is located below the navigation tabs. The main content area is titled 'Thiomersal and vaccines' and contains several sections:

- Committee reports**: A list of reports from various meetings, including dates and topics related to thiomersal safety.
- Related links**: A list of links to statements, questions and answers, and epidemiological records.
- References**: A list of scientific references, including studies on thiomersal exposure in infants and the relationship between thiomersal and autism.

On the right side of the page, there is a sidebar with a search bar and a 'Good information practices for vaccine safety web sites' section. The bottom of the page features the WHO logo and the text 'World Health Organization'.

Alternative preservatives

- There is very little evidence that a range of vaccines can be preserved with alternatives such as 2 phenoxyethanol
- Extrapolation from a few examples (such as injected poliovirus vaccines) that all vaccines can be switched to an alternative preservative is not supported by evidence

Thiomersal-free vaccines

- Thiomersal-free vaccines would have to be available in 1 or 2 dose presentations, rather than the 10-dose products currently used by most countries
- This will increase the cost of vaccines and the global immunization effort; as immunization will need to continue in the long term, this will be an additional cost long into the future
- A switch to single-dose vials alone would require more raw materials, more energy for manufacturing processes and transport, and more waste



The environmental impact of thiomersal-free vaccines is not negative

International distribution of vaccines

- Vaccines that contain thiomersal are manufactured in no more than 40 countries but used in over 120 countries
- Vaccines require import permits to be traded across international borders
- The introduction of new provisions on vaccines that contain thiomersal will introduce potential technical barriers to trade which may inhibit access to life-protecting products

WHO response on the use of thiomersal in human vaccines

- The amount of mercury involved with thiomersal use in vaccines is very small compared to other sources of mercury
- There is no evidence that suggests a possible health hazard with the amounts of thiomersal currently used in human vaccines
- WHO recommends multi-dose vaccine vials for routine immunization programmes in many countries because they are safe and effective, they limit the required storage capacity and help reduce vaccine costs
- Alternative presentations would incur significantly higher costs in manufacturing procedures and new regulatory approvals, thereby limiting the ability to offer affordable vaccines



Further Information

WHO chemical safety website www.who.int/ipcs/en/

WHO Immunization, biologicals and vaccines website:
www.who.int/immunization/en/