Briefing the Committee on COM (2023)395: Proposal to amend Regulation (EU) 2017/852 on Mercury

Dr. Graeme Munro-Hall, Chief Dental Officer World Alliance for Mercury Free Dentistry
wafmfd-uk@steeps.net

1. Introduction:

The amended EU regulation to stop the use and export of amalgam does not qualify for using the Stormont Brake for the following reasons:
1. It will not have a significant adverse impact on everyday life in Northern Ireland.
2. It is not an exceptional circumstance requiring the Stormont Brake to be used as a matter of last resort.

The use of dental amalgam as a restorative material is damaging to health and the environment and alternative dental filling materials are:
"Available, Affordable & Effective." (Swedish Chemical Agency 2010)

A ban on dental amalgam has been in place in Northern Ireland since July 1st 2018 for children under 15 and pregnant and nursing mothers.
The EU regulation is an extension of this existing ban to the rest of the population.

2. Background:

Amalgam is a dental restorative material containing 50% mercury and has been a controversial material on health and functional grounds since its inception.

The Minamata Convention was started by UNEP to address the problem of mercury in the environment, the first meeting was in Stockholm (INC1) in 2010.
The World Alliance for Mercury Free Dentistry has been involved with the Minamata negotiations since the outset.
The scope of the negotiations was increased to include the health aspects of mercury exposure at the request of member countries and an expert group was established to investigate this.
The CDO of the World Alliance was a member of the group and has written reports on the adverse effects on health and the environment from dental mercury.
These reports are available on the Minamata Convention's website.
https://minamataconvention.org/sites/default/files/documents/submission_from_organization/WAMFD_Comparison_report_DentalAmalgam.pdf.

3. Adverse health effects of dental mercury:

Mercury is constantly released from amalgam fillings as vapour throughout the life of the filling.
Eating, hot drinks and brushing increase the amount of mercury released as do other metals in the mouth such as crowns, implants etc. 20 seconds after inhalation the

mercury is deposited in all major organs of the body but especially the brain where it penetrates the blood-brain barrier.
Amalgam wearers absorb between 10 and 20mcg mercury daily on a cumulative basis.

According to Dreisbach Handbook of Poisoning dental, mercury can cause the disease conditions Lichen Planus and Mercurialism.
Lichen Planus is a pre-cancerous allergic response to direct contact with mercury which resolves after amalgam removal.
Mercurialism can exhibit varied symptoms predominantly neurotoxic such as depression, anxiety, irritability, amnesia, insomnia, intellectual mental deterioration, loss of IQ, cognitive and behavioural problems. There is a risk of developmental defects during foetal development causing attention deficit and behavioural delays during childhood. Kidney dysfunction can occur as well.

Mercury has no threshold below which adverse effects do not occur. (WHO 2005)

There have been numerous Risk Assessments done for dental amalgam which concluded that dental amalgam is an unsuitable filling material. The most comprehensive Risk Assessment (G.M. Richardson 2010) showed that an adult with four or more amalgam fillings is at risk from an adverse health event from the release of dental mercury.
The health risks identified were impairment to the central nervous system, kidney function, immune system and foetal development especially of the nervous system.

Composite filling material, the alternative to dental amalgam, was also tested in the same Risk Assessment and was found not to pose a risk to human health.

The United States FDA, Food and Drugs Administration, issued a warning in 2020 that dental amalgam should not be used in certain groups of the population because of the potentially harmful effects of mercury exposure from dental amalgam.
Amongst these groups were:
“People with pre-existing neurological disease such as multiple sclerosis, Alzheimer’s disease or Parkinson’s disease and people with impaired kidney function.”

Dental mercury crosses the placenta into the foetus. There is a direct correlation between the number of maternal amalgam fillings and the foetal load of mercury.
The CDC estimate that placental cord levels of mercury in 1 in 7 babies in the USA are high enough to cause a loss of IQ. Studies have shown that prenatal exposure to mercury can alter brain structure and reduce the number of neurons. Even one maternal amalgam filling has the potential to expose the foetus to levels of mercury shown to cause abnormal brain development.
Dental mercury is also transported in breast milk to the nursing child increasing the mercury load which can result in a deficit in motor skills and cognitive as well as psychological/behavioural disorders.

In Norwegian infants the incidence of cleft palate quadrupled if amalgams were placed in the first two months of pregnancy.

A study into perinatal deaths in Norway over a 9-year period involving over 72000 births concluded: “The current findings suggest that the risk of perinatal death could increase in a dose-dependent way based on the mother’s number of teeth filled with dental amalgam.” To put it simply, the more amalgam fillings a mother had, the greater was the chance of still birth after 22 weeks or death within 7 days of birth.
It was estimated that among mothers with more than 12 teeth filled with amalgam, 57% of the cases of perinatal death were attributable to amalgam.

Dental assistants exposed to mercury experience blurred vision, increased anxiety, reduced cognitive function, psychoticism and generally increased distress as well as reduced fertility rates.

Dentists using amalgam are particularly at risk from mercury vapour and particulate when placing and removing amalgam fillings. Increased levels of depression, anxiety, attention deficit and reduced memory function are apparent compared to non-mercury using colleagues.

Mercury is also connected to cardiovascular disease in a variety of ways. Exposure to chronic low dose mercury vapour causes high blood pressure for example and it can also alter the electrical conductivity of nerves.
More examples of cardiovascular pathology from mercury can be found are on P22 of the Minamata report.

4. **Adverse environmental effects:**

Even with BPM (Best Practice Management) systems in place only 34% of dental mercury is captured by separators and waste units. 38% walk out of the door with the patient and 28% is unaccounted for. So at least 66%of the dental mercury will end up in the environment via excretion and at the end of life in the soil and eventual ground water by burial or as vapour after cremation unless special filters are in place at the crematorium.

The effect of this can be seen in Sweden, where after over 50 years of amalgam use, the fish from Swedish lakes have been declared unfit to eat due to mercury released from dental surgeries.

The Concorde report for the EU in 2012, “The Real Cost of Dental Amalgam” estimated that each amalgam filling cost society 60-80 USD per filling when considering environmental, health and socioeconomic factors.

5. **Alternative materials**:

The main alternative material is composite resin.
Composite fillings have practical advantages to amalgam fillings.
Dental amalgam is mechanically held in place via undercuts in the prepared cavity and this requires healthy tooth structure to be removed.
Composite does not require healthy tooth structure to be removed as it is adhesive and is "glued" in place. This means that composite fillings are less destructive to healthy tooth substance and the overall effect is a stronger tooth compared to an amalgam filled tooth and last longer.
Risk Assessments have shown composite to be a very safe material whereas 4 or more amalgam fillings in an adult is likely to cause an adverse health event.
Dental manufacturers have made a composite that handles exactly like amalgam and at a similar cost to amalgam on a filling for filling basis.
The cost of mercury and silver, both components of dental amalgam, have seen significant rises in recent years and since the Minamata Convention came into force it is expected that mercury prices will continue to rise.
Across the world dental schools have ceased to teach amalgam fillings to their students.
A report from Norway in 2012 on their experiences following cessation of amalgam use noted there were no problems at all.

Overall, considering both time and cost, composite has an advantage over amalgam.

6. **Dental Industry position on dental amalgam:**

In 2013, the European Dental Manufacturers Association held a meeting titled:
"The End of the Amalgam Era".
The only speaker in favour of amalgam was the spokesperson for the BDA.
The dental industry recognised the liability risks posed by amalgam and wanted to cease production. Degussa in Germany ceased amalgam production in the 1990s after a class action by patients.
In the USA the dental industry is ceasing or has ceased amalgam production.
The main suppliers of amalgam are now China and Australia.

7. **UK Government Position on dental amalgam:**

In 2012, the then Chief Dental Officer of England wrote to the BDA stating the Governments intention to follow the Danish example and stop using amalgam, with certain exceptions, by 2016. A copy of this letter is attached.
Why was this policy not adopted?
Obviously, it was the opinion of DEFRA and the Chief Dental Officer that ceasing the use of amalgam was both desirable and possible in the UK including NHS dental services.

This negates the assertion that amalgam can be considered essential, certainly not by the UK Government in 2012.

8. **Other countries' experience on ceasing the use of dental amalgam:**

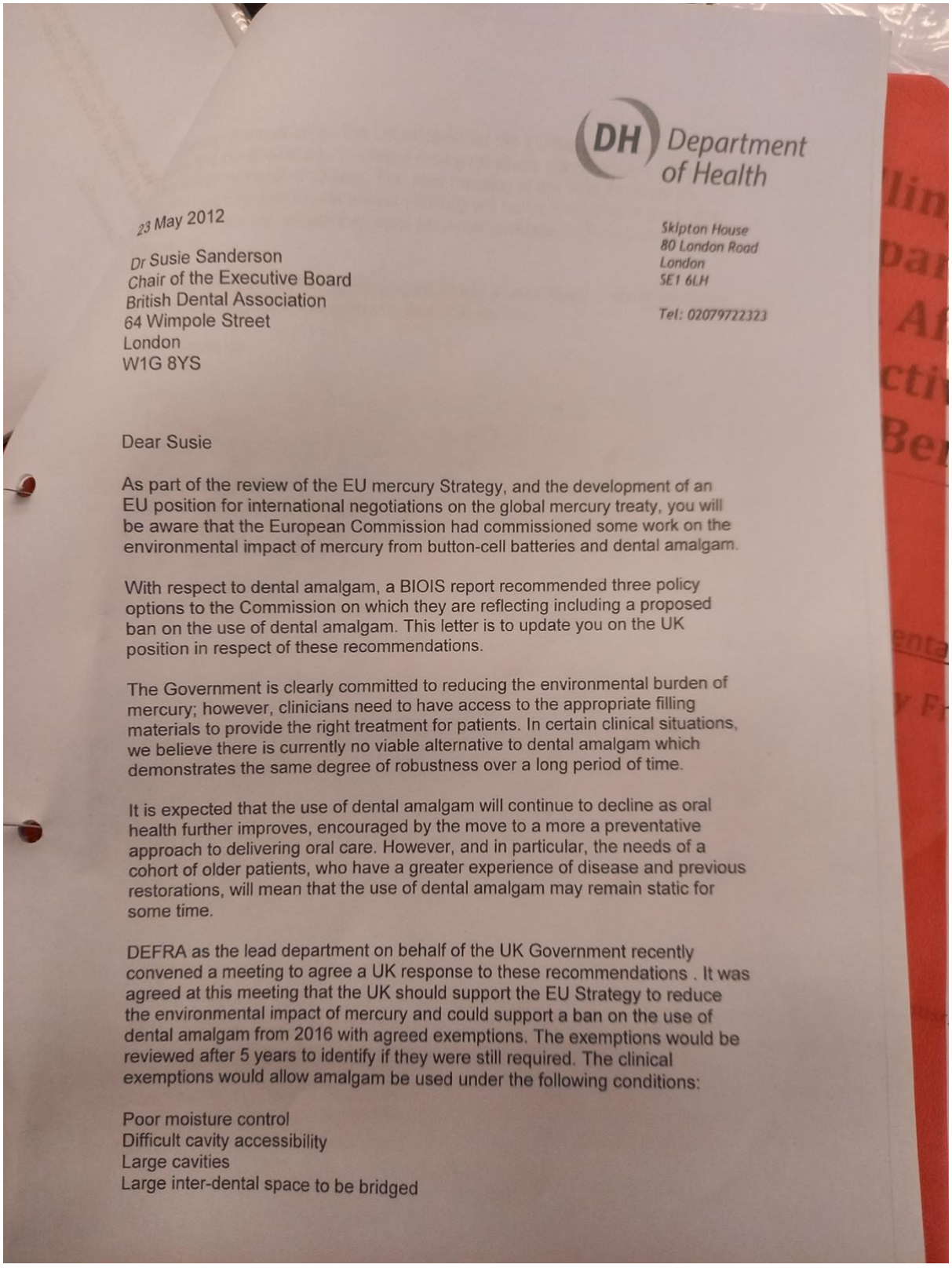
Norway in 2008 followed closely be all the Scandinavian countries banned amalgam on environmental grounds with exemptions. Today there are no exemptions.
No problems have been reported. There are no situations in clinical dentistry where the alternative materials to dental amalgam cannot be used.
Sweden, Norway and Moldova use no dental amalgam in any circumstances.
This shows conclusively that dental amalgam can be consigned to the history books.

9. **Prevention Programmes:**

Prevention programmes do not reduce the use of dental amalgam. Whilst any prevention programme is laudable in reducing the burden of disease, such programmes generate more dental awareness in the public leading to more restorations being placed in teeth. Water fluoridation is an ineffective tool in reducing the amount of dental amalgam used. Water fluoridation gives the illusion of preventing decay because, as an enzyme disrupter, it delays the eruption of permanent teeth.

10. **In conclusion:**

- Dental amalgam is unnecessary as the alternatives are available, affordable and effective in all situations.
- From a cost and time perspective, dental amalgam now offers no advantages over alternative materials, indeed the opposite is true.
- Experience in other countries show clearly that a ban on dental amalgam is feasible.
- A partial ban has been in place in the UK for nearly 5 years so dental staff are familiar with the alternative materials to dental amalgam.
- Mercury released from dental amalgam is dangerous to health, especially dental staff, and damaging to the environment.
- Future generations will have to bear the cost of remediation of this damage.
- The UK Government clearly thought that such a ban on dental amalgam was feasible in 2016 so it must be even more feasible now.
- There will be no significant and lasting effects on the everyday life of the population of Northern Ireland after implementing this EU regulation.
- Implementing this EU regulation cannot be considered an exceptional circumstance in view of all the above, so the application of the Stormont Brake is unnecessary.



DH Department of Health

23 May 2012

Skipton House
80 London Road
London
SE1 6LH

Tel: 02079722323

Dr Susie Sanderson
Chair of the Executive Board
British Dental Association
64 Wimpole Street
London
W1G 8YS

Dear Susie

As part of the review of the EU mercury Strategy, and the development of an EU position for international negotiations on the global mercury treaty, you will be aware that the European Commission had commissioned some work on the environmental impact of mercury from button-cell batteries and dental amalgam.

With respect to dental amalgam, a BIOIS report recommended three policy options to the Commission on which they are reflecting including a proposed ban on the use of dental amalgam. This letter is to update you on the UK position in respect of these recommendations.

The Government is clearly committed to reducing the environmental burden of mercury; however, clinicians need to have access to the appropriate filling materials to provide the right treatment for patients. In certain clinical situations, we believe there is currently no viable alternative to dental amalgam which demonstrates the same degree of robustness over a long period of time.

It is expected that the use of dental amalgam will continue to decline as oral health further improves, encouraged by the move to a more a preventative approach to delivering oral care. However, and in particular, the needs of a cohort of older patients, who have a greater experience of disease and previous restorations, will mean that the use of dental amalgam may remain static for some time.

DEFRA as the lead department on behalf of the UK Government recently convened a meeting to agree a UK response to these recommendations . It was agreed at this meeting that the UK should support the EU Strategy to reduce the environmental impact of mercury and could support a ban on the use of dental amalgam from 2016 with agreed exemptions. The exemptions would be reviewed after 5 years to identify if they were still required. The clinical exemptions would allow amalgam be used under the following conditions:

Poor moisture control
Difficult cavity accessibility
Large cavities
Large inter-dental space to be bridged

This position demonstrates the UK support for the EU mercury strategy, whilst allowing the continued use of dental amalgam where it is clinically appropriate as the filling material of choice. The next meeting of the Working Party on International Environmental Issues (WPIEI) will be on Thursday24 and Friday 25 May in Brussels, where the issue of dental amalgam is likely to be discussed.

If you feel it would be helpful to discuss this in greater depth, I would be happy to meet with you as soon as is mutually convenient.

Yours sincerely

Barry

Barry Cockcroft CBE
Chief Dental Officer - England