Subject: Response to the proposal by Botswana and Burkina Faso to amend Part I and Part II of Annex A to the Minamata Convention on Mercury on dental amalgam.

Dear Parties and Signatories to the Minamata Convention on Mercury,

FDI World Dental Federation (FDI) – the official representative body of over one million dentists worldwide, through its membership of 200 national dental associations and specialist groups – and the International Association for Dental, Oral, and Craniofacial Research (IADR), which represents over 10,000 researchers around the world with a mission to drive dental, oral and craniofacial research for health and well-being worldwide fully support the Minamata Convention on Mercury. This includes its nine provisions on the phase down of use of dental amalgam defined in Annex A, Part II of Article 4 as well as the amendments agreed at COP-4 that will come into force on 28 September 2023.

FDI and IADR are committed to improving the oral health of populations globally and ensuring this is done in an equitable and evidence-based way. We, therefore, support the continued phase down approach to dental amalgam and the maintenance of the current provisions of the Minamata Convention. We provide some rationale and arguments, as to why this should be the case and address some of the items mentioned in the submission by Botswana and Burkina Faso below.

Response to the Background, explanatory notes and references section included in the proposal

1. We must learn from the GEF7 Phasing Down Dental Amalgam Project and adapt strategies and provisions according to the evidence garnered.

FDI and IADR are co-financing partners of the UNEP project set up to 'Accelerate implementation of dental amalgam provisions and strengthen country capacities in the environmental sound management of associated wastes under the Minamata Convention' (GEF 7 Phasing Down Dental Amalgam Project), which is funded by the Global Environment Facility (GEF), with the World Health Organization (WHO) as the executing agency. The three-year project will bring Senegal, Thailand, and Uruguay together to align their policies with international best practice, improving technical capacity on mercury disposal and waste management methods, while encouraging an enabling environment for the increased use of mercury-free alternatives through engaging private sector professionals in the industry.

Given this 3-year project kick-started in March 2023 it would be premature to consider a phase out date for all Parties to the Minamata Convention Mercury before the results and lessons learnt are known. Therefore, dental amalgam should not be included in Annex A, Part I as proposed.
2. The 194 WHO Member States have already made a global commitment to “By 2030, 90% of countries have implemented measures to phase down the use of dental amalgam as stipulated in the Minamata Convention on Mercury or have phased it out” through the WHO Global Oral Health Action Plan¹.

We call for national Ministries of Environment to work together with the Ministries of Health, and national dental associations to ensure alignment of efforts to help deliver on previously agreed goals. Any amendments to Annex A Part I and II would go against the mechanisms agreed by countries to date and be detrimental and disruptive to the progress being made.

3. Prevention of dental caries should be prioritized.

The Minamata Convention presents a unique opportunity for the prevention of caries, reducing the overall demand for restorative materials (including for dental amalgam). Investing in public health measures and strengthening health systems to include oral health promotion, including public regulations to reduce sugar intake, must remain a priority of Annex A, Part II in line with commitments made in WHO’s Global Oral Health Action Plan¹.

4. More research on alternative materials is needed.

As outlined in WHO’s Global Oral Health Action Plan¹, evidence on the health and environmental impact of new restorative materials is needed. There is a lack of available information on mercury-free materials, especially around the safety profile and biocompatibility of certain materials. For alternative materials to be considered as viable replacements to dental amalgam, data on their similar clinical longevity under different clinical conditions and cost-effectiveness is needed as well as an assessment on their safe disposal. Data and evidence is especially needed for alternative materials to be used under difficult clinical conditions such as high caries rate, lack of compliance e.g. because of medical conditions or disabilities and in extended cavities. Establishing a global phase-out deadline before such evidence is available would be premature and detrimental to public health, and even to the environment.

5. Alternative restorative materials including glass ionomer cements and composites are not practical for all clinical settings or in settings that lack a reliable source of electricity or other necessary equipment.

While mercury-free alternatives exist, they are still less than optimal based on clinical, economic, and practical reasons. The proposal by Botswana and Burkina Faso makes the assertion that “Studies show mercury-free composite fillings can last as long as – and even longer than – amalgam” however there are several studies including meta-analyses that show the opposite to be true²–⁴. The studies used to support the Botswana and Burkina Faso statement have several methodological shortcomings including selected patient groups and a failure to combine cavity size and oral hygiene status with material outcome. Additionally, some of the included references state that their results should be interpreted with caution or contained results that were not significant. Therefore, continued investment is needed to accelerate the development of innovative restorative materials, move them from the laboratory to the market, and to increase their durability and affordability (see Appendix 1).

The success of glass ionomer cement application is highly dependent on a moisture-controlled environment. If the application is exposed to excessive moisture, its effectiveness can be compromised. Cavities that reach below the gum line are hence difficult to keep dry. Therefore, it is crucial that dental professionals apply the recommended technique for optimal results. According to a WHO Briefing Note⁵ glass ionomer cements should only be used in occlusal cavities and not in Class II (approximal) cavities. However, a majority of cavities are those of Class II [A Class II restoration is when a tooth is restored by putting a filling material on the chewing surface and also on the side of the tooth where it touches the
neighbouring tooth. This is necessary, if the tooth decay has extended to these areas, in order to properly repair and protect the tooth.

It is also noteworthy that minimally invasive dentistry is a general approach in restorative dentistry and not limited to glass ionomer cements but is today applied with all restorative materials. The ART technique mentioned in the submission by Botswana and Burkina Faso, is based on the use of glass ionomer cements and has been developed for countries with developing economies to preserve teeth under such special conditions, which otherwise would have been extracted. It may be considered as an option for special patient groups, but it is not regarded as a general alternative for all countries worldwide to other treatment options such as amalgam.

6. **Adequately trained dental professionals are the key to success of any intervention including composite restoration resin.**

   The effectiveness of composite resins for restoration is highly dependent on the competency and training of the dental professionals involved. Therefore, it is imperative to provide adequate training and education to dentists and dental teams to ensure they are equipped to apply the recommended technique correctly.

7. **Alternative materials must be accessible and affordable.**

   Composite restoration resins are used with an adhesive technique requiring additional treatment steps and additional materials (e.g. etching substances, adhesives). Again, this requires a dry operation field and generally additional equipment such as light curing units. Therefore, the use of composite resins to treat caries is more cost intensive compared to amalgam. Furthermore, the longevity of composite resin restorations strongly depends on strictly following dental hygiene standards, because secondary caries (caries adjacent to restoration) is a major cause for the failure of composite resin restorations. This requires an optimal functioning system of caries prevention. It is therefore, critical that these limitations are considered, and reimbursement schemes are put in place for these restorations. Otherwise, there is a risk that people will not seek timely treatment, leading to more tooth extractions and social consequences.

8. **Waste management remains the most important action point even in a phase-out scenario.**

   Best environmental practices for the waste management of dental amalgam must be reinforced, including use of the ISO 11143 standard amalgam separator in dental offices and facilities, taking into consideration the circumstances of each nation. This is still relevant for the recycling of dental amalgam that is removed to avoid mercury releases. Furthermore, not only dental facilities using and/or removing amalgam should have amalgam separators, but waste management infrastructures must also be reinforced to ensure the recycling of amalgam at crematorium. A wider focus on waste management is therefore needed, and similar concerns need to be extended about the disposal of alternative materials.

9. **The phase-down approach is working.**

   Progress in phasing down the use of dental amalgam has been mainly measured by counting the number of countries who no longer use amalgam at all, instead of looking at phase-down indicators (e.g., reduction of amalgam sold). Major producers of dental amalgam have ceased manufacturing, and the dental profession is shifting towards the use of alternative materials, where available and suitable for the restoration.

Untreated caries in permanent teeth is the most prevalent disease worldwide (affecting 2 billion people) and in consideration of the global aspects of the overall challenge to be responsible stewards of the environment while still maintaining access to essential oral health care, it is recognized that there is a wide range of
situations and solutions currently in existence. In countries where advanced alternatives are fully safe, accessible, and affordable, with an optimal caries prevention system for early childhood on until senescence and with adequately trained dental professionals, phase out can be considered. However, this should not be imposed as a one-size-fits-all solution as each Convention Party navigates its own successful path to phasing down the use of dental amalgam adapted to their national context.

We look forward to the outcomes of the GEF7 project and learning about the progress made in meeting the dental amalgam targets set in WHO’s Oral Health Action Plan. We urge Parties to keep channeling action and investment into prevention, research into mercury-free alternatives, and waste management. Otherwise, we will witness a negative impact on the provision of quality treatment for dental caries and an increase in tooth extractions, threatening to widen oral health inequalities.

We remain at your disposal if you need any further information.

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Dr Christopher Fox  
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References


This submission was prepared by FDI and IADR and the following organizations are co-signatories:

- Bulgarian Dental Association
- Saudi Dental Society
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Appendix 1

Update on Dental Amalgam Alternatives from the International Association for Dental Research

Research into Dental Amalgam Alternatives

Challenges with current restorative materials

The most popular alternative to dental amalgam is composite resin. While offering the advantage of being tooth-colored and thereby more aesthetically pleasing than dental amalgam, composite resin also has significant disadvantages. In addition to the material itself being more expensive, composite resin also requires maintaining a completely dry tooth in a wet environment, sophisticated equipment for placement, and refrigeration and electricity to store and cure the material, which may not be reliable or even accessible in some settings. The most significant disadvantage, however, is that composite resin restorations are less durable than those made from dental amalgam. Composite resin restorations in permanent posterior teeth are twice as likely to fail and carry a higher risk of secondary tooth decay compared to amalgam restorations.¹ ² Secondary decay occurs after the restoration is placed. Decay at the tooth and composite bonding layer is the most common reason that restorations fail.

One major focus of research on alternative restorative materials is extending the life of the restoration. In 2013, the United States National Institutes of Health/National Institute of Dental and Craniofacial Research (NIDCR) funded six, five-year projects for a total over $13 million through its “Design and Development of Novel Dental Composite Restorative Systems” Cooperative Agreement Program. The goal of this program was to double the durability of current composites by creating new composite restorative systems based on entirely new chemistries.

The following update on research on alternative restorative materials highlights key themes and strategies for addressing their shortfalls as well as the challenges that must be addressed with examples from ongoing projects. Several candidate materials developed by the six NIDCR-funded cooperative projects have demonstrated significant promise in meeting research milestones and are starting to transition out of academic research laboratories to industry laboratories via technology transfer agreements. Overall, it is reasonable to speculate that it takes approximately 10 years to translate this new research to human use and market entry.

These examples are provided without endorsement of one over another. This summary was compiled with input from researchers funded by the aforementioned cooperative agreement program; Dr. Rainer Guggenberger’s presentation, “Amalgam Replacement: The Manufacturer’s Perspective,” at the 97th IADR General Session & Exhibition in San Francisco, CA in 2017; and IADR members Drs. Gottfried Schmalz and Paulo Cesar for perspectives from European and Brazilian dental material scientists, respectively.

The take-home message of this summary is that while this is an active and exciting area of research where significant progress has been made, in the short-term, alternatives to dental amalgam are still less than optimal based on clinical, economic or practical reasons. Therefore, it is important to ensure the access of dental amalgam as a restorative option until investments in research can deliver an alternative restorative material that addresses current shortcomings.

Increased longevity

Composite resins are made of a resin plus filler that reduces shrinkage of the restoration and can lend other desirable physical properties. A commonly used resin in composite restorations is called Bis-GMA (Bisphenol A-Glycidyl Methacrylate). One reason composites have a short lifetime is because the chemical bonds holding the Bis-GMA resin together, called esters, can be broken by water and enzymes in the oral cavity.

One strategy to solve this problem is to change the resin used in the composite from one held together by ester bonds to one held together by a different chemical bond called ether. Ethers are more stable and durable against degradation caused by water and enzymes than their ester-based counterparts. For example, an ether-based resin called TEG-DVBE (triethylene glycol divinylbenzyl ether) has demonstrated no unfavorable interactions with water, which avoids degradation of the material and increases durability.³
Another research group developed a resin system called OASys (Oxirane-Acrylate IPN System). OASys is a mixture of an ester-based resin called acrylate and another molecule called oxirane. Even though acrylate is an ester-based molecule, it has a different chemistry than Bis-GMA resin. This gives the acrylate a high degree of polymerization, meaning that almost every monomer, or unit, of acrylate is linked to another monomer of acrylate, and there are few free monomers of acrylate left in the mixture. This high degree of polymerization means that the resin degrades more slowly. OASys also has half the wear rate – reduction of the material due to abrasive forces – than resin used in conventional composites.\textsuperscript{4} Future directions of this resin system include mixing oxirane with modified acrylates that should reduce the affinity of the resin for water, giving it even more protection from water degradation and increasing its mechanical strength to resist fracture that may occur during chewing.

Yet another research group approached this problem by changing the composite filler instead of the resin. Rather than filling the resin with glass or ceramics, as is typically done, this research group filled the resin with a molecule called thiourethane. The resulting thiourethane-based composite is twice as fracture resistant as the standard material.\textsuperscript{5}

**Reduced shrinkage from polymerization**

As alluded to above, after the resin is placed in the tooth, the individual monomers of the resin have to be linked together through a process called polymerization, or curing. The curing step can cause the restoration to shrink and pull away from the tooth causing stress and even fragmentation of the tooth or gaps at the restoration/tooth margin.

OASys has two polymerization phases – a fast phase and a slow phase. Acrylate and oxirane polymerize independently, i.e., acrylate monomers only bond with other acrylate monomers and oxirane monomers only bond with other oxirane monomers. The acrylate polymerizes quickly, which will allow the restoration to harden quickly in the clinic while the oxirane polymerizes slowly. The slow polymerization phase of the oxirane reduces stress on the tooth from shrinkage.

OASys as well as the TEG-DVBE-based and thiourethane-based composite have all demonstrated reduced shrinkage stress up to 50% of the conventional composite resin.

**Improved adhesive technology**

Composite restorations must be bonded to the tooth with an adhesive that creates a strong bond between the composite and the tooth. Enzymes can cause degradation of the bonding layer between the adhesive and underlying tooth structure and are often the cause of failure for composite restorations. Using the appropriate adhesive is critical to ensuring the durability of the restoration-tooth bonding layer. Choosing the correct adhesive, therefore, adds complexity and lengthens the time needed to place these dental restorations. Adhesive technology has improved and has been simplified to a single bottle of adhesive that can be used with various tooth preparation techniques. Some new materials even incorporate the adhesive into the composite, eliminating the need for a separate adhesive step.

Preparation of the tooth for restoration results in a smear layer of debris that physically prevents bonding of the dentin – the tooth layer just beneath the outer enamel layer – to the adhesive. Currently, three techniques are used to overcome this challenge: etch-and-rinse, self-etch and universal or multi-mode adhesive systems. Using the etch-and-rinse technique, the smear layer is removed with acid that is rinsed away before adding a primer and adhesive. This technique is sensitive to over or under-drying, which can compromise the bonding of the adhesive and the durability of the restoration. Additionally, the acid used in the etch-and-rinse technique can be very harsh and lead to post-operative tooth sensitivity. The self-etching technique is a simplified process that can be reduced to one or two steps and requires less time. It is also less sensitive to moisture conditions and can use milder acids that should reduce post-operative pain. However, the adhesive layer is more permeable to water in this technique, which can ultimately weaken the bond between the tooth and the restoration leading to decreased durability and life of the restoration. Universal or multi-mode adhesives systems can be used either with the etch-and-rinse or self-etch techniques and can be used on either dentin or enamel.\textsuperscript{6}

With respect to adhesive technology on the aforementioned restorative materials, the development of a thiourethane-based composite required the development of a new adhesive. The resulting adhesive again replaced vulnerable ester bonds with material containing a bond less vulnerable to degradation called an amide bond. Laboratory tests showed that the amide bond-containing material maintained its bond strength after six months, whereas the ester-based adhesive did not.\textsuperscript{7} OASys and TEG-DVBE-based composite are able to be used with adhesives currently used in dental practice.
Glass ionomer cement and resin-modified glass ionomers

Glass ionomer cement is another alternative to dental amalgam. Glass ionomers are self-adhering, self-curing and release fluoride and calcium ions to remineralize the enamel but are lacking in strength and wear resistance, especially for larger areas of tooth decay. The strength of glass ionomers can be improved by adding a resin. For example, a newer glass ionomer product reinforced with resin called Cention® N (manufactured by Ivoclar Vivadent) has shown improvements in strength and can be used in primary teeth and to treat certain types of decay.

Glass ionomer, however, can be appropriate for some situations. A technique called atraumatic restorative treatment, or ART, has been implemented in various settings, especially developing countries. ART uses highly viscous glass ionomers and does not require electricity or running water. It requires a minimally invasive procedure and is acceptable for children but not adults. ART began in the 1990s with a focus on developing countries and is now used in many countries at various stages of economic development. However, a systematic review comparing ART using high-viscosity glass ionomer cement with conventional treatment— including treatment with dental amalgam and composite resin— showed a higher risk of failure with the former in the primary teeth of children.8

Added antimicrobial activity

The most common reason for failure of composite resin restorations is secondary tooth decay. One way to reduce secondary decay is to supplement materials with antimicrobial agents such as silver nanoparticles. In one study, composite resin synthesized with different amounts of silver nanoparticles inhibited the growth of tooth decay-causing bacteria S. mutans between 50-98% of composite resin synthesized without silver nanoparticles.9

Investigators are exploring the potential of a new antimicrobial agent that may selectively inhibit the growth of acid-producing bacteria, not just S. mutans, at low pH. Subsequently, the antimicrobial agent has been demonstrated to maintain the pH of the oral cavity above 5.5, below which tooth demineralization may take place.10 If added to composite resin restoratives, it may be possible to prevent or reduce the risk of secondary caries.

Another strategy is to create materials with inherent antimicrobial activity. Laboratory tests have shown that the OASys material itself has antimicrobial properties and that supplementing OASys with silver nanoparticles had a negligible effect on antimicrobial activity.

Self-healing technology

Micro-cracks occur in the composite restoration that are difficult to detect and impossible for the dentist to repair. Self-healing composites include microcapsules within the filler containing healing materials. Micro-cracks in the restoration break open the microcapsule, releasing the healing materials which form glass ionomer cement, filling the micro-crack and extending the life of the restorations.11, 12

Safety and Regulation

These novel composites are still in the early development phases. Testing on safety has been limited with more studies planned, and regulatory requirements vary by country. The United States Food and Drug Administration (FDA) requires manufacturers to gain approval before marketing novel composite resins and to show that the novel composite resin is at least as safe and effective as those currently on the market. Manufacturers need to assess and mitigate risks for mechanical failure, adverse effects on tissue and improper use of the composite resin.13 In the European Union, market access of new dental materials will be subject to the Regulation on Medical Devices (MDR), which will come into force in 2020. A number of prerequisites have to be met that show conformity with the basic requirements of the law.14 As another example, the Brazilian Health Regulatory Agency, or ANVISA, requires documentation and testing of any new product before approval even if the product is already approved in the U.S. and Europe. This is a relatively long process that usually takes more than 2 years.

So far, studies of OASys in cells and animal models have not shown any adverse health effects. Thiourethane-based composites increase polymerization of the resin, so there is less leakage than from conventional composites, and they perform similarly to conventional composites in safety tests on cells. TEG-DVBE-based composite is still undergoing safety tests. Although the components of self-healing composites have already been separately introduced into the clinic, clinical testing is still needed for these composites.
Ease of use

The restoration process with composites can be simplified by using bulk-fill and flowable composites. Bulk-fill composites can be placed in a single large increment or just a few smaller increments which simplifies and speeds up placement as opposed to traditional composites, which are placed in several thin layers. However, one problem with bulk-fill composites is that it is difficult to cure the material in bulk, and bulk-curing can cause shrinkage and deformation of the restoration. Flowable composites are less viscous than earlier composites and easier to use.

OASys, thiourethane-based, and TEG-DVBE-based composites can be placed and cured in bulk. OASys is not yet flowable, but that is a future goal for this material. Thiourethane-based composite itself is also not flowable but could be made flowable by the eventual manufacturer.

To encourage dentists to use these novel composites once they reach market, researchers are trying to develop systems that do not have a steep learning curve. Thiourethane-based and TEG-DVBE-based composite do not require dentists to learn new techniques or purchase new equipment. Similarly, with OASys, the dentist can use the adhesive system that they prefer to use whereas previous composites based on this resin required a proprietary bonding agent.

Other current advances

Another advance with composite resins has been the advent of universal composites, which can be used in restorations in teeth in front or back of the mouth.

There have also been advances with indirect restorations. Dental amalgam, composite resins and glass ionomers are direct restorations – that is, the restorative material is placed and formed directly in the tooth. Indirect restorations are made and formed outside of the tooth then placed into the tooth. CAD/CAM, which stands for computer-aided design and computer-aided manufacturing, can enable accurate design and production of indirect restorations and may become more widely used as the technology becomes simpler, cheaper and more accessible. Finally, 3D printing holds possibilities for the future of indirect restorations, but high-performing dental materials need to be optimized for 3D printing fabrication techniques.

Future direction of restorative materials research

Generally, future research of restorative materials will focus on multifunctional materials that have remineralizing and antimicrobial activities; can reinforce the underlying dentin structure for more durable bonding; and improve strength, flexibility and the life of the restoration while ensuring safety. For example, a group from Brazil is testing a new composite containing a calcium salt that has shown the ability to remineralize artificial enamel caries in a laboratory setting.15, 16

Fiscal year (FY) 2018 marked the final year of NIDCR’s five-year award. Following interactions with FDA and industry experts organized by NIDCR in 2017, grantees made significant progress to optimize the nanoscale properties of their candidate dental composites by implementing strategic feedback on product development and regulatory requirements. The newly-developed dental materials have shown unique features such as self-healing and anti-microbial properties. Additionally, investigators have demonstrated improvements in mechanical performance, biocompatibility, ease of clinical handling, and durability of candidate dental resins combined with nanoparticle-based materials. In this way, grantees were enabled to accelerate product development activities in 2018 and several groups reported pursuing commercialization strategies via partnerships with industry, product licensing, or via startup ventures. Several patents have been issued to date stemming from this program and future efforts will build on current success towards the clinical translation of novel dental materials with superior longevity and durability. NIDCR’s support towards development of new nanomaterials-based dental composites will continue at least until FY2021.

Lingering challenges

The development of new dental materials will require sufficient and sustained investment in research. However, securing funding for research on new dental materials can be a challenge when competing with other research priorities and because of the belief that this area is the purview of industry. In Europe, several manufacturers have intensive and innovative research programs that involve university research groups, but they are primarily focused on testing new materials that have already been developed and are less interested in the basic research required to create new materials.

To the IADR’s knowledge, only one oral health project was funded within the European Union’s 75 billion Euro joint research program called Horizon 2020, but this project was not focused on materials science. There will be a continuation of this program called Horizon Europe with a planned investment of 100 billion Euros starting in 2020 and...
lasting until 2027. However, there are still a number of uncertainties regarding this program, for example, due to the unresolved questions of the Brexit. IADR members of the Continental European Division and Pan European Region are trying to get a dedicated call within this new program for research related to the Minamata Convention on Mercury and the consequences on the health system.

Once these or other restorative materials are available, practicing dentists will have to be convinced to use a new material, and dental curriculums will have to teach restorations with new materials. Researchers are also working to create and simplify procedures to aid in this transition.

Another challenge is establishing performance standards to ensure quality and high clinical performance. NIDCR has partnered with the U.S. National Institute of Standards and Technology to develop appropriate standards for novel restorative materials.

In at least the short-term, cost will continue to be a barrier. These new technologies will be expensive and may not be suitable in all settings, especially as dentistry becomes increasingly digital. Digitization will make restorations more precise and easier to place, but these technologies will not be available in places that lack a reliable source of electricity at a minimum or access to more sophisticated tools, computers and accompanying software.

**Conclusion**

Researchers are addressing deficiencies of alternatives to dental amalgam in a variety of innovative and exciting ways but require continued investments in research to accelerate development of these products, move them from the lab to the market, and to increase their affordability. Related to the phase-down of dental amalgam, while much progress has been made with alternative restorative materials, they are not practical for all clinical situations or in settings that lack a reliable source of electricity or other necessary equipment. Thus, it is important to preserve the availability of dental amalgam as a restorative option until investments in research can deliver an alternative restorative material that addresses these current shortcomings.

**References**


