



Northern Ireland  
Assembly

## Windsor Framework Democratic Scrutiny Committee

# OFFICIAL REPORT (Hansard)

Regulation (EU) 2024/1849 of the European Parliament and of the Council of 13 June 2024 amending Regulation (EU) 2017/852 on Mercury as regards Dental Amalgam and Other Mercury-added Products Subject to Export, Import and Manufacturing Restriction

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**Members present for all or part of the proceedings:**

Mr Philip McGuigan (Chairperson)  
Mr David Brooks (Deputy Chairperson)  
Dr Steve Aiken  
Ms Joanne Bunting  
Ms Connie Egan

**Witnesses:**

Ms Caroline Barry	Department of Agriculture, Environment and Rural Affairs
Ms Ashleigh Evans	Department of Agriculture, Environment and Rural Affairs
Ms Caroline Lappin	Department of Health
Mr Michael O'Neill	Department of Health

**The Chairperson (Mr McGuigan):** Our witnesses are Caroline Barry, head of chemicals and industrial pollution branch in the natural environment policy division (NEPD) of DAERA; Ashleigh Evans, senior scientific officer in the NIEA chemical compliance team in DAERA; Caroline Lappin, Chief Dental Officer, Department of Health; and Michael O'Neill, head of general dental and ophthalmic services in the Department of Health. You are welcome arís — welcome back again. I hand over to you.

**Mr Michael O'Neill (Department of Health):** Thank you, Chair. I will make a short statement to kick things off.

**The Chairperson (Mr McGuigan):** OK.

**Mr O'Neill:** Thank you again for the opportunity to brief the Committee. Members will recall the oral evidence that we provided on 18 April 2024 and last week on the anticipated impacts of the new EU law published on 10 July 2024. The Committee will also be aware that, on 19 July, the day after the Committee agreed to hold an inquiry, the European Commission published a notice outlining a significant and material derogation for Northern Ireland. In short, the derogation sets out an arrangement that would allow Northern Ireland dentists to continue to use dental amalgam until 31 December 2034 or until the date agreed by the global Minamata Convention on Mercury to which the UK is a signatory — whichever date is earlier. There are a number of conditions attached, mainly around reporting and showing continued progress in reducing the use of amalgam that are achievable and are in line with our longer-term policy objectives.

The derogation addresses all the significant concerns that the Department had about the application of the law in January 2025. The key and most meaningful benefit of the derogation is that the deferral of the phase-out to 2035, rather than 2025, is much more in line with the current trajectory in the UK on the longer-term reduced usage of dental amalgam. The 10-year derogation means that the Department can better plan a more gradual phase-out of dental amalgam, working with practitioners in Northern Ireland to ensure that the conditions are met in a proportionate and effective manner.

In addition, the derogation gives a significant period in which to effect change in overall population oral health, which, in turn, could reduce the overall use of restorative materials, including dental amalgam. Whilst the more gradual transition to alternative materials may still incur costs in the longer term, the immediate impact on practices and service delivery is averted. Similarly, in respect of capacity, whilst the eventual destination will be the use of a material that takes longer to place, the derogation gives practitioners time to plan for the changes and absorb any benefits arising from improvements in materials and techniques in the meantime.

DH and DAERA have undertaken an initial review of all the conditions outlined in the derogation and concluded that none presents a significant challenge in implementation. Caroline will say a few words from DAERA's perspective.

**Ms Caroline Barry (Department of Agriculture, Environment and Rural Affairs):** Good morning, Mr Chairman and Committee members. Thank you for inviting us to provide further evidence on the potential impacts on Northern Ireland of the new EU mercury regulations.

On 18 July, as Michael indicated, I presented DAERA's assessment of the impacts on Northern Ireland of the amendments to the 2017 EU mercury regulations. For the areas that come under DAERA's remit — mercury-added lamps and crematoria reporting — our assessment was that the amendments would have minimal impact, due to the fact that the lamps are already restricted under EU and UK legislation and that crematoria are already regulated by our district councils, with updated guidance due to be published this year.

As you are aware, the UK Government and the EU have agreed a derogation for Northern Ireland in relation to dental amalgam. The derogation relates only to the health professions, not to the areas for which DAERA has policy lead. Our assessment remains the same in relation to mercury-added lamps and crematoria reporting: there is no significant impact on Northern Ireland from applying the new regulation.

As Michael set out, the derogation contains a number of conditions that Northern Ireland must comply with. Officials from DH and DAERA are working together via the recently established Northern Ireland mercury working group to understand the conditions and ensure that they are implemented. DAERA officials are also engaging with our Whitehall counterparts to assess what changes, if any, are needed to the current UK-wide mercury enforcement legislation to facilitate that.

As discussed last week, the Control of Mercury (Enforcement) Regulations 2017 are used by the Northern Ireland Environment Agency to enforce rules on the trade and use of mercury in Northern Ireland. They supplement Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury by establishing offences, penalties and enforcement powers relating to that regulation.

I will hand over to Ashleigh from the NIEA chemical compliance team to provide you with further information on the enforcement of the current and derogated EU mercury regulations.

**Ms Ashleigh Evans (Department of Agriculture, Environment and Rural Affairs):** Good morning, Mr Chairman and Committee. As Caroline said, enforcement of Regulation (EU) 2017/852 falls to the NIEA, which is an executive agency of DAERA. The regulatory duty is undertaken under the powers conferred on the NIEA by the UK statutory instrument, the Control of Mercury (Enforcement) Regulations 2017. In the case of those whom we regulate who fail to comply, advice and guidance will often be our first route to securing compliance. It is important that those whom we regulate are fully aware of legal requirements and the relevance of those requirements to their activities as well as of how to comply. We work with stakeholders to identify barriers to compliance and to provide clear, unambiguous guidance as necessary. We also seek to educate stakeholders and the public to avoid breaches in the first place.

Compliance is assessed through inspection, testing and audits. Resources are applied to the activities and locations that present the greatest risk of harm through non-compliance. The choice of enforcement action taken depends on a range of factors and on the circumstances of each case. The

form or forms of enforcement action that DAERA may use will therefore differ, depending on the particular nature of the non-compliance, the harm caused or likely to be caused and the history of the responsible person, including any previous non-compliance or criminal convictions. Where non-compliance is detected, enforcement is carried out on a risk-based and intelligence-led basis. It is firm, fair and reasonable and in accordance with the DAERA enforcement and prosecution policy.

The Control of Mercury (Enforcement) Regulations 2017 provides the NIEA with powers to issue enforcement notices and to take more formal enforcement action through the courts, should that be required. Additional powers are provided to DAERA. That role is undertaken by the NIEA as the market surveillance authority for the mercury regulations under the Market Surveillance (Northern Ireland) Regulations 2021, which implement aspects of the Regulation (EU) 2019/1020 on market surveillance and compliance, which came into force on 16 July 2021. Market surveillance aims to ensure safe and compliant products on the market. NIEA will work collaboratively with colleagues in DAERA policy, the Department of Health, the Department for Food, Environment and Rural Affairs (DEFRA) and other UK and Irish Government environment agencies to develop the regulatory programme for mercury dental amalgam, following the publication of the derogation last week. NIEA aims to work collaboratively and find practical solutions to ensure a high level of understanding and compliance with the derogation.

**The Chairperson (Mr McGuigan):** Thank you very much. All three of you used the word "derogation" quite a lot. Are both Departments confident that the notification received last week from the EU is, effectively, a derogation?

**Mr O'Neill:** That is our guess. The biggest impact was the ban on the use of amalgam, in the main, from January 2025, but that has been derogated until December 2034 or a reliance on Minamata — whichever comes earlier. It is a full derogation from the use of amalgam, but there is a range of conditions that we must meet in respect of reporting and ensuring progress towards that destination. We are content that the concerns that we have raised have been addressed by the derogation.

**The Chairperson (Mr McGuigan):** And from DAERA's point of view?

**Ms Barry:** We definitely agree with that position. Obviously, we are working closely together to look at the conditions and what measures need to be put in place. As I said, we will look at whether changes need to be made to enforcement regulations and such things. Yes, we are fairly confident that the conditions that have been put in place are not overly onerous, and we think that they can be met.

**The Chairperson (Mr McGuigan):** Michael, you said that you are assessing the conditions from a health perspective. What conditions are those? Whilst I understand that you are assessing them, what is the initial assessment of impact?

**Mr O'Neill:** We have had an initial assessment to work out if any of them will cause us significant problems to implement and, in respect of the Committee's remit, if any of them will present a significant impact beyond the Department having to carry out a range of measures. The first condition is that we take necessary measures to ensure regular and consistent progress towards full compliance by 2034. We will have to plan for that. It restricts the use of dental amalgam to UK residents. We have a range of new conditions, so we are working out how we will implement them. However, our initial assessment of the conditions is that none of them is insurmountable. We can do them, but we want to make sure that we do them in a proportionate way and in a way that reduces the administrative burden on practices and that type of thing. We already collect a lot of data on how much amalgam is used and how many fillings are used on a weekly and monthly basis. We want to make sure that, where possible, we use the information that we already get from practices, rather than placing any new burden upon them.

**The Chairperson (Mr McGuigan):** Thank you.

**Mr Brooks:** That was one of the questions that I was going to ask around the reporting that you will have to do and the impact of that. I will preface my other questions by making the political point that Northern Ireland should not have to rely on the good grace of the EU to avoid cliff edges when it comes to legislation that could have such a significantly harmful effect on the health of our population. There needs to be a longer-term, permanent and durable solution to the imposition of EU law in that regard.

Moving past the politics, there is a condition that dental amalgam can be used only if the patient resides in the UK and by a dental practitioner registered for that purpose in Northern Ireland. There are other similar conditions in that regard. Will there be any impact — I realise that it may be marginal — on children in care, victims of modern slavery, when they are discovered, or victims of crime who may need dental treatment or healthcare? Will we see any impact on them because they will potentially be coming from other parts of the world?

**Mr O'Neill:** The main purpose of that condition relates to a concern about protecting the EU market. It is really about cross-border issues.

**Mr Brooks:** Do we foresee any unforeseen impacts, if you will?

**Mr O'Neill:** We do not. We might have to look at things around the definitions of "resident" or those who are regarded as being resident, but the instances that you mentioned are not the purpose of the condition.

**Mr Brooks:** I understand that, absolutely.

**Mr O'Neill:** We will work with partners to highlight those issues and work around them where needs be.

**Mr Brooks:** You may not want to speak to this matter, and dentists will have their own opportunity to feed into the inquiry. However, obviously, you have consulted dentists through the British Dental Association (BDA) and so on. What is your understanding of their position now that the derogation has been brought forward?

**Mr O'Neill:** We spoke with the BDA on the Friday that the derogation was published. Its response was very positive. It appreciates that the immediate impacts and concerns have been allayed. We very much need to get back to work on making improvements in this area, but it sees significant benefits of the derogation. I think that the BDA has written to its members to say as much and to welcome the news.

**Mr Brooks:** Thanks very much.

**Dr Aiken:** Thanks very much for your evidence. I have an issue with the word "derogation". What is the legal effect of the derogation, and where does that actually reside? We have heard clearly from DAERA and the NIEA about how they will prosecute in accordance with legislation that deals with mercury and the rest of it. We have the dentists thinking, "This is great. We have a derogation until 2034". We have not, however, heard what the legal effect is. Where is the legislation that says, "Thou shalt not go after the dentists because they have mercury or whatever it happens to be", even though the NIEA and DAERA are legally obliged to make sure that there is nothing there. Where does the derogation sit legally, and where does the legal effect lie? I cannot really see it at the moment. Somebody said that it is a derogation, but where does it lie legally?

**Mr O'Neill:** The initial regulation was published on 10 July. It is immediately applicable in Northern Ireland from January 2025.

**Dr Aiken:** That is the legislation.

**Mr O'Neill:** Yes, so that is our default position. On 19 July, the Commission notice was formally attached to the regulation so that it is read in conjunction with the Commission notice. The Commission notice is an official, formal notice from the EU. Our understanding is that the derogation linked to the regulation gives effect to the derogation in law. The initial burden was not really placed on the Department; it was more on dentists in that it said that they were no longer allowed to use the material in that way. That has now been lifted, and, instead, the derogation places a burden or requirements on the Department or, actually, Northern Ireland as a UK member state to comply with the conditions of the derogation. That is the connection between the Commission notice and the regulation in that respect.

**Dr Aiken:** Does that give DAERA and the NIEA legal certainty?

**Ms Barry:** Yes. We are fairly confident. We have not spoken to our legal advisors, but, from a policy perspective, we would —

**Dr Aiken:** The reason that I am intent on this is that it could be the mechanism through which we deal with everything from substances of human origin (SoHO) to other problems as we go forward. We are setting a precedent, and we need to make sure that we have it right. We do not want to say, "It is a derogation", and then for someone to say, "Well, actually, it has not been applied in law, and it does not have legal effect". Can we check with DAERA and the NIEA that, from a legal perspective, they are content that that is what it actually means? It would be useful the Committee to understand that, because, again, it will set a precedent.

**Mr O'Neill:** Those questions were certainly asked. We have been engaging with Cabinet Office a lot over the past number of months, and the specific question of how this will be implemented in practice was asked repeatedly. This is the answer to that question, essentially. It is a Commission notice, so everyone's expectation is certainly that this is the way that it should apply, but I appreciate the point that getting it in black and white is an important part of it.

**Dr Aiken:** Again, with the indulgence of the Chair, this is a particularly important point because we are now setting a formal precedent for a lot of other issues. If the derogation is the mechanism through which we will do it, we need to understand the full legal intent, because we do not want to end up in the High Court with some judge saying, "Uh-uh, I am not happy with that because it does not actually have a legal intent". We need to make sure that you are coming to tell us that, legally, you are content.

**The Chairperson (Mr McGuigan):** There are no other questions, so thank you again for coming before our Committee and taking our questions. Thank you very much.