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 restrictions

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Members present for all or part of the proceedings:
Mr Philip McGuigan (Chairperson)
Mr David Brooks (Deputy Chairperson)
Ms Joanne Bunting
Mr Stephen Dunne
Mr Declan Kearney
Ms Emma Sheerin
Mr Eóin Tennyson

Witnesses:

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

The Chairperson (Mr McGuigan): I welcome Caroline Lappin, Chief Dental Officer, Department of Health; Michael O'Neill, head of general dental and ophthalmic services, Department of Health; Caroline Barry, natural environment policy division (NEPD) head of chemicals and industrial pollution branch, DAERA; and Helen Lewis, principal scientific officer and Northern Ireland Environment Agency (NIEA) head of chemical compliance, DAERA. Fáilte; I welcome you all. I hand over to you to brief the Committee in whichever way you have agreed to do so.

Mr Michael O'Neill (Department of Health): I have a short statement to make, Chair, if that is OK. Thank you for the opportunity to brief the Committee. The Committee will recall the oral evidence that DH provided on 18 April and the three documents outlining the Department's analysis of the health-related impacts of the new EU law in question, the most recent of which is the completed template that we provided to you on Tuesday, following publication of the regulations. The Committee is aware of the policy background to and the purpose of the proposed regulations as well as the detail of our concerns regarding their impact. I will be brief in my comments before handing over to Caroline Barry from DAERA.

There is no doubt that the direction of travel across the globe is significantly reduced usage of amalgam, and members will note that the British Dental Association (BDA) articulated that view when it addressed the Committee in April. A key concern of ours relates to the proposed timescales and the resultant impact on practices and patients. The Northern Ireland preferred policy position, which has been reiterated in recent months, remains to phase down rather than phase out. That position was

publicly stated in a joint letter to the BDA from the four UK chief dental officers in December of last year.

The proposals will mean that, for the vast majority of our patients, amalgam, which is a widely used and effective material, would no longer be an option. Whilst we already use alternative materials, such as composites and glass ionomers, for adults, they are generally used only for smaller fillings and front teeth. The Department's concern is primarily about larger fillings and back teeth. In short, we are concerned about, first, the impact on service capacity, which has not recovered to the pre-pandemic level, and, secondly, both the cost to taxpayers, which we estimate at £3·6 million of a budget of around £100 million, and the £2·9 million cost to patients. It should be noted that our cost estimates do not take account of the fact that the new materials do not last as long and therefore need to be replaced more often, neither does the total include the cost of the loss or displacement of private fees for white fillings, which the BDA estimates to be in the region of £20 million. An initial bid for funding was refused by the previous UK Government, and, whilst we continue to make the case to Treasury, there is no guarantee that we will be fully funded in the event that the regulations come into force.

In addition to their cost, composite fillings take longer to place, with an inevitable impact on activity and capacity at a time when activity remains at around 75% of pre-COVID levels. While practices in other member states can plan with certainty for January 2025, uncertainty remains for dentists and patients in Northern Ireland, and we do not underestimate the difficulties that that causes for practices. Whilst we expect significant impacts in January if the law comes into force, practices' short- and medium-term planning arrangements are already being impacted.

Ms Caroline Barry (Department of Agriculture, Environment and Rural Affairs): Good morning, Chair and Committee members. Thank you for the opportunity to provide you with further background on the new EU mercury regulations and their potential impacts in Northern Ireland.

I am head of the DAERA chemicals and industrial pollution team, and I am joined by my DAERA colleague Helen Lewis, who heads the NIEA chemical compliance team and is responsible for the enforcement of the current EU mercury regulations under the Control of Mercury (Enforcement) Regulations 2017. As you are aware, DAERA has overall policy responsibility for mercury; however, the Department of Health has an interest in it and takes the lead on any health-related matters. The EU mercury regulation implements the provisions of the Minamata convention, an international environmental agreement with an objective to:

> *"protect human health and the environment from [man-made] emissions and releases of mercury and mercury compounds".*

The UK is a party to the Minamata convention and implements domestically the decisions adopted under the convention. As set out in the pro forma that we and our Department of Health colleagues provided, the impacts of the key amendments to the regulation of mercury are different for DAERA and the Department of Health. We consider the amendments that fall within DAERA's policy responsibility to have minimal impact in Northern Ireland. We believe that the addition of six mercury-containing lamps to annex 2 of the regulation, which will prohibit their export, import and manufacture from specified dates, will not have a significant impact for the following reasons.

First, for five of the lamps specified, the EU is implementing decisions taken at the Minamata conference in November 2022 and November 2023. All signatories to the convention are required to do so, and we understand that the Department for Environment, Food and Rural Affairs (DEFRA) intends to lay appropriate implementing legislation this year for GB. Secondly, it is already prohibited to import all six lamps and place them on the market under the UK regulation as a restriction on the use of certain hazardous substances in electrical and electronic equipment or "RoHS" for short, which you might be aware of, for the 2012 regulations. On manufacturing and export, there is no manufacturing base for those items in the British Isles. Furthermore, light-emitting diode (LED) alternatives are widely available. Finally, DEFRA has consulted the Lighting Industry Association, and no concerns have been raised.

It is worth noting that the new EU regulations will technically introduce Northern Ireland to GB divergence. The EU amendments place prohibitions on six mercury-containing lamps, whereas the Minamata convention and, therefore, GB place prohibitions on five. Similarly, the phase-out dates in the EU regulation are 2025 and 2026, whereas GB, following the Minamata convention, will phase the lamps out in 2026 and 2027. However, the divergence will have little impact for the reasons already stated and, in particular, due to the fact that the lamps are already restricted under UK legislation and are not manufactured in the UK.

The second item in the regulations that falls under DAERA's responsibility is the reporting of mercury emissions from crematoria. The EU intends to report by 31 December 2029 on the implementation and impact of Commission guidance on abatement technologies for emissions of mercury and mercury compounds from crematoria. We do not consider that to have a significant impact for the following reasons. First, the guidance that the UK intends to publish by 31 December 2025 is not mandatory. The three crematoria operating in Northern Ireland are already regulated by district councils under the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013. DEFRA, in consultation with the devolved Administrations, has reviewed the UK guidance for crematoria that was published in 2012. New updated statutory guidance should be published this year. It will include up-to-date technical recommendations on mercury abatement, as well as the management of other pollutants such as particulate matter and nitrogen oxides. On that basis, we believe that the UK is already in a strong regulatory position for the abatement of mercury emissions from crematoria.

I will hand over to my colleague Helen, who can provide further information on the enforcement of the current and new EU mercury regulations.

Ms Helen Lewis (Department of Agriculture, Environment and Rural Affairs): Good morning, Chairman and Committee.

As Caroline mentioned, EU Regulation 2017/852 on mercury is enforced in Northern Ireland through the UK statutory instrument (SI) the Control of Mercury (Enforcement) Regulations 2017. Regulation 5 lists DAERA as the enforcing authority in Northern Ireland. That role is undertaken by the NIEA, which is an Executive agency of DAERA. Scoping of how we intend to ensure compliance and carry out enforcement of the regulations for dental amalgam will commence shortly. The NIEA will work collaboratively with colleagues in DAERA policy, the Department of Health and other UK and ROI environmental agencies to develop the work programme.

If you have any questions about the content of the completed pro forma provided by DAERA or on the enforcement activities carried out by NIEA on mercury, Caroline and I will be happy to answer them.

The Chairperson (Mr McGuigan): Thanks very much to all of you.

Michael, you gave three costs of the impact: there was £20 million for displaced private fees, as well as figures of £3 million and £6 million. Are those yearly costs?

Mr O'Neill: Yes, they are all annual costs.

The Chairperson (Mr McGuigan): OK. Give me a wee bit of detail about what the £3 million and £6 million costs are for.

Mr O'Neill: The cost to the Department would be £3·6 million. That accounts for the more expensive materials. We already provide alternative filling materials. It includes the additional 30% that we are paying for fillings, as part of the Minister's announcement in March. It also includes a 15% additional cost to cover the fact that, when the regulations are in place and the supply of mercury is impacted, there will likely be an impact on the price of mercury and composite materials. It is by no means an exact science, but it is to cover some of the costs around the supply chain issues that may arise. It does not cover the cost arising from the fact that the fillings last less long. It does not cover the longer-term impacts.

The Chairperson (Mr McGuigan): Are the alternative or substitute materials an immediate issue, or are they a medium- to long-term issue?

Mr O'Neill: If the regulations are in place from January, we will start to face those costs immediately, because we will start having to pay dentists the higher prices to treat with the more expensive materials. It will also take more time. It is not just the materials; it is the additional time. Patients and the Department will start to face those financial pressures immediately.

The Chairperson (Mr McGuigan): Will the availability of alternative materials be an immediate problem?

Ms Caroline Lappin (Department of Health): We have no indication that it will be a problem. The alternative materials to amalgam are resin-based materials such as composite and glass ionomers. Those materials are in use regularly, so we have no indication at this point that there will be an availability issue. You would wonder whether market forces will play into the costs. The £3·6 million is a bit of a guesstimate of where we will be. We had to base it on our like-for-like usage if we are looking at the direct replacement of amalgam with composite or glass ionomer. It is difficult to know what those costs will be.

The Chairperson (Mr McGuigan): We have done this at different times, but it is important to ask the question again. If the legislation is applied and if, as you have outlined, for some reason the legislation is not applied in the North, what does the Department of Health do to reduce the use of amalgam in the immediate term?

Ms Lappin: We are already on our phase-down trajectory. We have our national plan around reducing our use, in line with the rest of the UK. Through the UK's agreement to the Minamata convention, which is based purely on phasing down, we have already committed to phasing down. We already restrict the use of amalgam. We do not place amalgam fillings in children under the age of 15 or in pregnant or breastfeeding mothers, unless it is indicated that, for clinical reasons, it is the only material that can be used. We have already significantly reduced the use of that. Hopefully, we will keep that going.

The other big factor that would help to reduce our overall use of restorative materials, including amalgam, would be a reduction in levels of decay in Northern Ireland. There is work under way in the Department on how we can speed up the reduction in our level of decay. It is difficult, and it reaches beyond purely dentistry and health. We will work with partners around childhood health and older people's health. All of that has an impact on the overall oral health of the population.

The Chairperson (Mr McGuigan): Four members — David, Declan, Joanne and Eóin — wish to ask questions.

Mr Brooks: I was going to start with the question that the Chair has asked, but I will expand on it. The BDA estimate is £22 million per annum. It says that that includes the displacement of existing private fees for white fillings. Does that explain entirely the discrepancy between the two sets of numbers, or do you think that the BDA's working out of the likely costs is slightly different from yours?

Mr O'Neill: That £22 million figure will include all the things that we have accounted for and the displacement of the private income. There is a conversation to be had about the extent to which that should and can happen, but there is no doubt that the majority of practices in Northern Ireland are a mixture of NHS and private, so it is a real issue that they face. The placement of white fillings is a significant commercial activity for them, so this will have an impact. Their main concerns are that it will have an immediate impact on the commercial sustainability of their practices, assuming that there is no financial input from the Department in that regard.

Mr Brooks: It is not unreasonable to suggest that, while your numbers are an accurate guesstimate, insofar as that can be the case, other unforeseen costs may come along for the industry.

Mr O'Neill: Yes.

Mr Kearney: Thanks for coming along this morning, folks. Will you give us an update on the composition and progress of the joint departmental working group that was tasked with working through any issues arising from the amendments?

Mr O'Neill: Over the last number of months, we have been identifying the impacts. A lot of that work is inputted into the information that we have provided to the Committee in the first instance. The next phase of that work will be with January 2025 in mind. There will be exemptions under the new regulations for people with medical conditions, so it will be about trying to establish in what scenarios people should be exempt from that. The other thing is to work on the statement of dental remuneration. That will have to be updated to ensure that the fees that are paid reflect the cost of providing the service — the larger composite fillings — but also in respect of some of the provisos. Those are the two mains parts of the work. The work of that group over the last number of months has largely been identifying impacts. We have been working with DAERA colleagues on that and engaging with the Cabinet Office and the Department of Health and Social Care in England.

Mr Kearney: Does anybody want to speak from DAERA?

Ms Barry: Just to reiterate, that is the work that the group has been involved in to date. We are also looking at engaging with some other Whitehall Departments on access to trade data, which would be useful to help with ongoing enforcement activity.

Ms Lappin: As well as ourselves in DH and DAERA, part of the membership of that group is looking at the education and training needs of the profession, should the law come in. There will be some element of additional training because we will be handling things slightly differently, particularly under health service arrangements, and ensuring that our university in Northern Ireland that trains our dental students is fully versed and on board with it and the implications for the curriculum and its development of students.

Mr Kearney: You have anticipated my next question. There is a certain amount of horizon scanning going on with regard to implementation or non-implementation, but, respectively, there were different forecasts or outcomes in your presentations. What work is the joint departmental working group doing to close those gaps? Is there a landing zone? Have you discussed the landing zone? Is that possible, or does the vires of your respective Departments simply mean that you cannot bridge whatever gaps there may be between you?

Mr O'Neill: DAERA has focused on the environmental side of it and the lamps and the crematoria impacts. It is a very different feel. There is not really a need to come to a settled position in respect of the other overall regulations. Basically, part of the regulations on the health side have a significant impact, and, on the lamps and crematoria side, DAERA's view is that they do not have a significant impact.

Mr Kearney: Other than to say that, if the amendments are implemented, you will continue to work together to ensure that we get optimal outcomes and minimum disruption from that change. Is that fair to ask?

Mr O'Neill: Yes, and that working group will be a fixture and will work together on the regulations.

Ms Barry: We work closely anyway. This has been a long-term engagement, but it is just that this group has now more formalised that.

Mr Kearney: Thank you.

Ms Bunting: Everybody, thank you very much for your evidence. It strikes me that the main problem here is that the EU has brought forward the time frame for a total ban as opposed to considering a phase-down. The evidence that you gave us previously was that you were on that trajectory and had taken steps but it was going to require time. Also previously, you said that this would have the greatest impact on the poorest. We already have the worst record for tooth decay, and it was likely that, with spiralling costs, we would see further evidence of people choosing not to go to the dentist because they simply could not afford it, and that would be a choice. Also, we are conscious of the impact that oral health has on general health and the impact that plaque and so on can have with regard to heart disease.

We heard previously too — you mentioned it again today — about the divergence that this would create from the rest of the UK with regard to qualifications and training. Previously, we heard quite dramatic evidence from the BDA that all of this — a move to a total ban and that ban being brought forward as opposed to a phasing down — could result in practices being tipped over the edge, and you have referred to that today. Thus, there would be exacerbated issues in dental practices and in availability and capacity in dental services in Northern Ireland, so it strikes me that a lot of this is kind of a no-brainer. Since the last time that we heard from you and the work that has been done as you progress this, has anything happened or been discovered that indicates that things are not as disastrous as they initially appeared? Has anything changed, or will we still face a massive and significant impact that will hit the poorest hardest?

Mr O'Neill: There has not been a big change in the input that we provided to the Committee most recently and in April. The only thing that has maybe changed — it is one of the significant things, and, Joanne, you touched on it — is the timescale. Practices are operating at the minute with a lot of uncertainty. They are booking in patients for January and February of next year and there is a

question mark over what the law will be on mercury. That is maybe an added uncertainty, but, no, there has not been any change, really, in our assessment of the impacts.

Ms Lappin: The one thing to make clear on qualifications and training is that it would be a bit of a stretch to say that the training of undergraduate dental students in Northern Ireland will be markedly different from that across the rest of the UK or even dental students in universities in the Republic of Ireland. Discussions with our school of dentistry lead say that, under the current curriculum, students are taught restoration and cavity preparation for all materials. The difference here would be that they would not be in a position to place the amalgam. They would still be taught cavity preparation for that, so that, wherever they worked, they would know the science and the cavity preparation techniques but would not have the experience, if the regulation comes in, of actually placing the amalgam. That would be the biggest difference.

Ms Bunting: Thank you very much for all of this. Can I check one other thing? From what you know at this stage, what will the potential criteria be for medical exemptions? A lot of the time, people need this and have to jump through a lot of hoops to get it. Maybe it is straightforward. Do you have any indication what will be required for an exemption? Will it be easy or difficult to get?

Ms Lappin: In all honesty, I am not clear yet where the medical exemptions criteria will be set, whether it is within each member state, which potentially means that each member state of the EU could have different exemptions, or on a much more EU member state-wide level. For instance, in certain medical conditions, it would be clear that the use of alternative materials would not be suitable for a patient or a patient would be unable to sit in a chair for longer or unable to cooperate for a much more technique-sensitive filling placement. However, as of yet, I am not clear as to where that barrier, that level, will be.

Ms Bunting: OK. Thank you very much.

Mr Tennyson: Thank you all for your evidence so far. I wonder what the big, unique factor is that places Northern Ireland in a relatively weaker position than other European health systems. Is it the level of public provision, the level of subsidy that we pay or human resource issues? What is the big factor that gets us placed under so much pressure, relative to other countries?

Ms Lappin: There are several. Are you all OK if I go first on this?

Mr O'Neill: Yes, absolutely. Go ahead.

Ms Lappin: The first factor is that our overall level of oral health in Northern Ireland is not where any of us wants it to be, so our dependency on restoring teeth is higher than that of many other countries across Europe. Secondly, we differ in Northern Ireland in that we are a heavily publicly funded system. Across Europe, a lot of dental services are delivered through insurance-based systems, so it is a different funding model. Thirdly, the big issue at the minute is around the capacity in our system to be challenged by this quick change and the impact of that on a system where capacity is already reduced from where we were four years ago.

Mr O'Neill: Let me add that it is obviously applicable in Northern Ireland from January, but, if the same law were being applied across the UK and other jurisdictions, we would have similar difficulties. Whilst the decay levels are certainly pertinent, I would say that the predominant reason is the model that we have and the difficulty of transitioning to something different.

Mr Tennyson: Were the regulation not to apply and we continued on the phase-down trajectory, would you have any concern about the security of supply of mercury? I know that a number of manufacturers either have closed or intend to close. Are you concerned about the potential cost implications in that scenario?

Mr O'Neill: We are. The EU is obviously a big player in this market. When it withdraws from the market, the supply of mercury will not be as commercially viable for the suppliers. That is why we started our statement by saying that mercury is on its way out. Regardless of this specific law, the Minamata convention could well come in with an end date for the use of mercury. Those larger things at play are likely to keep the subject on the agenda for the coming years.

Mr Tennyson: That is helpful. Thank you, Chair.

Mr Brooks: On the back of that, I understand that updating Minamata and everything else could lead to change in this, but, at the moment, are we seeing any active steps throughout the UK or evidence that it is being driven down significantly? From my conversations with those linked to the UK Government, there seems to be no immediate will to say, "Yes, we are going to go along and align with this. We are going to get rid of mercury", other than to say, "Who knows what will come out of the next Minamata conference?". So, at the moment, is there any evidence that the UK is seeking to follow this route or that we are significantly driving down and actively trying to drive down the use of mercury as it is?

Mr O'Neill: COVID has obviously impacted on the number of amalgam fillings that we treat, but, even pre COVID, we had reduced our usage of amalgam fillings by 30%, so there was a change already. The UK-wide policy is basically to implement Minamata, so the UK as a nation has been adhering to that. As and when Minamata changes, it will be to adhere to that. That is overriding. It is not to go beyond Minamata, and there does not seem to be a change, at the UK level, at this point to do that.

Mr Brooks: Thank you.

The Chairperson (Mr McGuigan): I have no more questions. Once again, I thank the four of you for coming, providing us with evidence and taking our questions.

Ms Lappin: Thank you very much.