BIVDA
British In Vitro Diagnostics Association

1. What is your name?

Ashleigh Batchen

2. What is your email address?

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3. What is your organisation?

BIVDA

4. Do you agree or disagree that the gov should introduce a fee, charged on a cost recovery basis, for processing applications for an exemption to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

BIVDA, representing over 200 organisations in the in vitro diagnostics (IVD) sector in healthcare, do not agree that this fee should be introduced.

RoHS exemptions have been in place in the EU for a number of years with no associated fee for applying for an exemption. There are 19 active exemption packs in place for IVD devices placed on the market in the EU, with a further 46 now beyond their renewal period (these remain in use but will expire shortly unless new applications were made to reinstate the exemption).

MHRA are in the process of developing a new regulatory framework for medical devices and IVDs in Great Britain, which is already causing concern about additional regulatory burden and associated costs across industry. The risk is that this new regulatory framework could be too onerous for organisations, meaning they simply do not continue to place on the GB market. This would not only affect the economy, but significantly, it would have a catastrophic effect on the availability of products for British patients and stifle innovation.

UK industry has continually been told that regulation in post-Brexit Great Britain is intended to be 'light touch' to ensure products remain on the market. These continual additions to the regulatory structure appear to be resulting in a much higher scrutiny system with adding cost of complying as well as any associated fees.

Additionally, the fee proposed is unproportional to usage and does not take into account any other relevant factors. Although it may be considered a 'low' fee for multi-national organisations (although they would still disagree with it being implemented), this sum could hugely affect SMEs. There is no

incentive to be the first to submit the application as the first organisation will incur the full fee, with other organisations being able to utilise it afterward. This may create a situation where no organisation wants to submit the application, and again, could result in a lack of product on the market.

5. Do you agree or disagree that the proposed fee of £39,721 appears to be reflective of the costs likely to arise in appraising and processing applications?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

This cannot be answered as BIVDA is unaware of the cost currently being incurred by the European Commission for review of exemption packs.

Please note that these exemption packs will have likely already undergone review by the EU Commission. Therefore, requiring separate applications across the UK and EU would be a duplicative process, and could be streamlined by accepting exemption packs in the UK which have already been approved in the EU. This would save DEFRA time and resource, and that of the organisation who would be submitting the application.

6. Do you agree or disagree that, should an application be withdrawn, the fee should be refunded on a pro-rata basis, to reflect costs incurred until that point?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

BIVDA do not support the fee being introduced at all. It is unclear how transparent the 'pro-rata' calculations will be and what would define the milestones throughout.

7. Do you agree or disagree that, in circumstances where we are able to process an application more quickly or cheaply than expected, we should refund the difference back to the applicant?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

BIVDA do not support the fee being introduced at all. It is unclear how transparent the process will be for determining what the difference is.

8. Do you agree or disagree that a commencement date of 6th April 2023 for the charging is sufficient time for business to adjust to the introduction of an application fee?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

This date would be unrealistic for industry. Although BIVDA do not support the fee being introduced at all, this time period would not give sufficient time for budget planning and for progressing this through internal approval processes. It is also unclear the level of additional cost that will be passed onto industry on top of this proposed fee (i.e. hiring of extra staff to manage applications).

We believe that managing exemption pack applications in the EU is co-ordinated throughout the wider industry by a coalition of organisations known as the Umbrella Project. This encompasses all aspects of products covered by RoHS from consumer through to healthcare. We believe to be a good model which should be replicated in this country, but it would take time to co-ordinate and come into effect. Therefore, 6 April 2023 would be unrealistic given all the other regulations industry is having to deal after leaving the EU and the disruptions caused by the pandemic over the last two years.

9. Do you agree or disagree with our assessment of the impact that the application fee will have on business?

Agree

Disagree

Don't know

Please provide evidence in support of your answer

We have assumed that the stated fee has been based on the current situation in the EU in relation to impact on industry. Due to divergence with the EU because of Brexit, this cannot be extrapolated to be reflective of UK organisations. Although the UK has trade associations (such as BIVDA), we do not have the same nor the expertise to collate such technical documents. In Europe, these applications are submitted by the Umbrella Project and are coordinated by MedTech Europe on behalf of the sector.

Although the impact assessment makes mention of this cost being spread over a 7-year period, this would still have a significant impact on cashflow for smaller organisations paying up-front, which may prohibit them from applying for an exemption.

10. Please provide any further comments on the proposal to introduce a fee for processing applications for exemptions to the RoHS Regulations

Please add your comments to this box

We would strongly like to advocate that this fee is not introduced for all the reasons already discussed. The main risk is that products will no longer be placed on the Great Britain market, resulting in a reduction in products available for patient care. This may result in patient safety concerns.

In-vitro diagnostic devices have the potential to reduce healthcare costs through early screening and disease monitoring. The potential loss of these products from the UK market could negatively impact healthcare budgets as well as the impact to patient care discussed above.

Alternatively, this fee would be added to the cost of products and be passed onto the NHS.