- 1. What is your name? *Ashleigh Batchen*
- 2. What is your email address? ashleigh@bivda.org.uk

## 3. What is your organisation?

BIVDA is the National Trade Association representing over 200 In Vitro Diagnostics suppliers in the United Kingdom. Our members are producers of electrical and/or electronic equipment, waste management companies, distributors (retailer or distance seller), and in some cases end users of electrical and/or electronic equipment.

4. Should the Secretary of State set a compliance fee for the 2022 compliance period (1 January - 31 December 2022)? Please provide some comments and any supporting evidence you have available.

Yes, a compliance fee is an accepted and familiar system for financing the cost of collection, treatment, recovery and recycling of WEEE arising from private households. The WEEE Regulations establish a system of annual collection targets that are imposed on producer compliance schemes (PCSs) and the system has been in place for many years and forms part of business-as-usual operations. Companies are familiar with this mechanism, and would not expect significant change, although would expect the current climate to be considered appropriately by the Secretary of State.

5. Please score each of the two proposals received on how well they meet the published evaluation criteria. Please refer to Question 2 of the consultation document for more details as to how to respond to this question and the evaluation criteria.

Criteria	JTA Proposal	Valpak Proposal
Methodology for calculation of fee (5)	20	10
Administration of fee (3)	9	9
Methodology for dispersal of funds (4)	8	8

Timetable for implementation of operation (3)	9	9
Experience of proposer and operator (2)	6	8
Proposed IT systems (1)	6	8
TOTAL	58	52

6. Please provide comments and any available evidence to support your scores against the published evaluation criteria.

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. Additionally, DEFRA has indicated that they will be introducing fees associated with RoHS exemption applications from April 2023. The risk is that any fee not considering the economic and regulatory landscape 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.

In addition, the ongoing cost of living increase across the UK is making manufacturing and supply of IVDs and medical devices even more expensive. Again, this would risk products being removed from the UK market.

From our sector, the JTA proposal has accommodated the specification and consideration of the economic pressures yet has not detracted from the benefits and methodologies that this scheme has worked within for many years. This in contrast to Valpak who seem to have disregarded the specific challenges facing the UK and GB with regard to cost of living, and the regulatory challenges to ensure that the UK can remain attractive and a place to do business.

BIVDA supports the promotion of recovery of WEEE overall as a way of supporting the circular economy, and therefore considers the JTA proposal most able to do this.