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Lab Tech

L@b Brief | June 2021

How well is the government serving exporters?

While it's good to see a renewed commitment to UK science from the Prime Minister, the follow-through in terms of support for UK exports does not seem to be all it should be. This month we have finally heard from DIT about the future of the Trade Access Partnership, and the news isn't good and worse still, members are getting in touch to say that even the basic administration of key services is falling below expectations.

You tell me that the Export Control Joint Unit is failing to meet it's commitments to turn-around times for export licences and as new member Oxford Instrument's MD, Dr Ian Wilcox points out, they are increasingly turning down applications, particularly for export to China.

Are we being more risk averse than other countries? We are supposed to be all working from the same guidelines. Or is the real problem that DIT staff from all walks are being re-directed to work on new trade agreements, and the bread and butter work on which we all depend is going into the round filing cabinet under the desk?

Toodle pip

Jacqueline

INSIDE THIS MONTH

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UK News

Making scientific breakthroughs work for the UK

PRIME MINISTER Boris Johnson has made a personal commitment to drive forward a new initiative to capitalise on scientific and technological breakthroughs made in Britain with a programme to direct research into areas that will benefit the public good.

A new National Science and Technology Council will be established and chaired by the Prime Minister with Chief Scientific Adviser Sir Patrick Vallance to head up a new Office for Science and Technology Strategy, based in the Cabinet Office. Sir Patrick will take up the role of the new National Technology Advisor in addition to his current role as the Chief Scientific Adviser and head of the Government Office for Science.

The Office will aid the government's insight into cutting-edge research and technologies as well as work across government to put science and technology at the centre of policy and public services. It will also identify what is needed to secure and protect the capability in science and technology required in the UK to deliver these ambitions.

Seeking strategic gains for post-Brexit Britain, the plan looks to build on the success of the country's coronavirus vaccine programme and identify other areas where the research and development sector can benefit from government funding.

"With the right direction, pace and backing, we can breathe life into many more scientific and technological breakthroughs that transform the lives of people across the UK and the world."

The government's Chief Scientific Adviser, Patrick Vallance, will head a new public body whose role will be to implement the strategy. The aim is to use the UK's research capability to secure some of the economic benefits of a shift toward greener technology, although competition from other nations is intense.

The majority of research and development spending in Britain is funded by the private sector, and overall investment in 2018 was 1.731% of GDP according to Organization for Economic Co-operation and Development data - below the 2.419% OECD average.

Since leaving the European Union, the government has announced plans to increase its spending on R&D. It plans to invest 14.9 billion pounds ($20.58 billion) in 2021/22, rising to 22 billion by 2024/25, and has committed to raise total R&D investment to 2.4% of economic output by 2027. It is not clear whether any new spending has been committed to the work of the new group, nor how many meetings Mr Johnson himself will attend.

Customs declarations deadline approaches

IF YOU'VE chosen to delay making customs declarations on non-controlled goods you've imported from the EU this year, you may need to start thinking about making a supplementary declaration. These are due within 175 days of your shipment arriving in GB – so if you imported anything in January 2021, your supplementary declaration could be due very soon, HMRC has reminded importers.

Most people use an intermediary such as a customs agent to deal with their declarations. If you have an intermediary, or if you used a service such as a courier or freight forwarder to move your goods, you should have agreed with them who will be making the declaration. If you chose to delay your declarations, you should have kept detailed records on your imported goods at the time of import – an intermediary will need this information to make a declaration on your behalf.

There is still time to ask an agent to make the supplementary declaration for you, even if you have made your own entry in 'declarant's records'. You can search the register of customs agents and fast parcel operators here. Even if you are using an intermediary and are delaying your declarations, you will need a duty deferment account if your intermediary requires you to have your own account. A duty deferment account allows you to make one payment each month for any imports rather than paying every time you import goods. This can be helpful in managing your cash flow.

You can find out how to apply for a duty deferment account for use in GB or NI here. If you choose not to use an intermediary, and you have imported any goods which are not controlled (e.g., not alcohol or tobacco etc.) into

GB, you will need to complete the supplementary declaration yourself. A full list of controlled goods is available here.

If you need to make a supplementary declaration yourself you will require authorisation from HMRC including access to their systems, and software that is compatible with them. You can find more information about making your supplementary declarations here.

Pharma supply chain leaders launch sustainability initiative

EIGHT PHARMACEUTICAL companies have joined together to form *Alliance to Zero*, a not-for-profit group that aims to help bring the sector closer to complying with net-zero emissions in line with goal of the Paris Climate Agreement.

The founders include Ypsomed, Sharp, Health Beacon, Harro Höfliger, Datwyler, Dividella, SCHOTT, and Schreiner Medipharm. Alliance to Zero will work with pharma and biotech supply chain companies to develop ways to encourage and promote sustainable practices. The founders of the alliance recognise the need for collaboration across the pharmaceutical supply chain and believe that whilst discussions are happening about sustainability and climate impact, not enough is being done to reduce emissions.

Alliance to Zero intends to involve, connect and coordinate suppliers, pharmaceutical companies, manufacturers and service providers along the supply chain and engage with academia and non-profit organisations with similar aims.

The organisation has already begun working on a roadmap describing what a net-zero emission concept for pharmaceutical manufacturing and supply chain looks like and the steps necessary to achieve it. This foundational work also includes agreement on harmonised language and principles for the assessment and control of the total emission footprint for the final pharmaceutical products, as well as the company-specific responsibilities.

“The formation of this Alliance is the first step in a challenging but urgent journey that our member organisations have committed themselves to,” said Sebastian Gerner, president of the Alliance to Zero. “Enabling the launch of net-zero pharmaceutical products in regulated markets will require companies like ours to transform our operations, products, services, logistics, innovations and investments. Our combined effort and our shared responsibility to ensure a real and lasting change is at the heart of the Alliance’s mission.”

For more information click here.

BIVDA, alerts GAMBICA members to likely delay to EU IVD Regulations

GAMBICA and the influential British In Vitro Diagnostic Association (BIVDA) have recently announced they will be working collaboratively to provide even better services to members. In this article, which is to be the first of an occasional series in L@b Brief, ***Doris-Ann Williams****, MBE, chief executive of BIVDA offers her insights on the IVD Regulations and explains BIVDA’s current areas of work and priorities so that you can identify any areas where collaboration might be of value to you.*

“WITH THE UK departure from the EU the regulatory environment for medical devices and in vitro diagnostic equipment has become considerably more complex.

Even before Brexit, there were rumblings about the EU’s move from the IVD Directive to the IVD Regulations. The corresponding move from the Medical Device Directive to the Medical Device Regulations had to be delayed for a year because of COVID, but the situation with the IVDR is a little more complex says Doris-Ann. “The Commission has recognised that they won’t finish the transition by the proposed date in 2022 and those pushing for a postponement say that a year’s delay like the one we had for MDR may not be sufficient. Part of the problem is

that the requirements to be a notified body under the IVDR are considerably more onerous than those for the IVDD which means that some of the current notified bodies are dropping out of the market and there may not be sufficient capacity at the date we were due to go live."

The IVD Directive, being a directive, required UK implementing regulations. In contrast, as Regulations, the IVD Regulations do not require national implementation, but must simply be adopted by EU member states.

The EU MDR and EU IVDR will fully apply in EU Member States from 26 May 2021 and 26 May 2022 respectively. But as the Regulations did not come in during the transition period, they were not automatically retained by the EU Withdrawal Agreement Act and will therefore not automatically apply in Great Britain. This means that the provisions contained within the EU MDR and EU IVDR will not be transposed into law in Great Britain and will not be implemented in Great Britain.

Instead, the UK has announced that it will write its own IVD Regulations and will bring them in by the end of June 2023, so that in the UK, IVDs compliant with the IVDD can continue to be sold until that date. Now, with the potential delay to the EU IVDR, it is possible that the UK Regulations will be out first, making the situation even more complicated.

Like GAMBICA members, BIVDA and its members are of the view that divergence between the EU and the UK Regulations is not in the best interests of UK manufacturers. Unfortunately, not all the UK associations currently lobbying about the IVDR take the same view and rumour has it that those drafting the regulations may seize the opportunity to make 'game changing improvements' to the regulations.

To add to the uncertainty, customers in Northern Ireland, will have to continue to adhere to the EU IVDR.

The government has promised to launch a consultation on the regulations in July, which implies that they are intending to publish the regulations shortly, however, it is now being trailed by the Medicines and Healthcare Regulatory Authority (MHRA) that there may be a delay in the release of the consultation. BIVDA are lobbying hard to make sure that the consultation period is not squeezed by any delay as these regulations will be critical for UK companies.

As part of our partnership, BIVDA has agreed that GAMBICA members can input to their consultation response. As soon as it is released, the consultation will be circulated to GAMBICA members.

Procurement – the other big issue

The other large issue facing IVD companies is how to get the best of the labyrinthine procurement processes of the NHS. For the last 15 years, the path labs of the NHS have largely been run by a very few big companies who operate them as 'managed services' on behalf of the NHS. Three of the biggest are Roche, Abbott and Siemens. The big advantage for the NHS ~~as~~ is it can reclaim the VAT on a Managed Equipment Service.

These large service providers manage all the purchasing of equipment and consumables for the labs. While this has potentially made life more straightforward for lab managers, it may well have squeezed out smaller companies, weakened providers' contact with purchasers and to an extent, suffocated innovation. Doris-Ann is very familiar with the journey path labs have been on and gives the example of a particular hospital which wanted to continue to purchase from the range of excellent diagnostic equipment and consumables available from a niche supplier, but who in the end had to make do with what they considered less innovative and possibly less accurate supplies from the organisation which won the overall bid to run their path labs.

Companies supplying such labs have often been charged a premium for doing so and there has been an element of 'gaming' of contracts by the NHS with penalty clauses being introduced for events which do not actually interrupt services. BIVDA has been working with NHS Trusts, MHRA and the service managers to put together a set of KPIs with a view to helping standardise contracts and provide a more level playing field for suppliers.

Getting the ear of decision-makers

One of the other notable issues currently facing IVD companies is the availability of NHS data.

The NHS is able to charge large pharmaceutical companies heavily for access to data, but such access is equally valuable in the development of diagnostic tests, unfortunately, IVD equipment does not generate the same level of income as drugs do but two tier charging is not on the cards says Doris-Ann.

"The entire NHS spend on diagnostic kits, including all the blood glucose measurements used in the management of diabetes is less than the budget for statins alone. This means that IVD companies cannot afford the high charges which can easily be borne by pharmaceutical companies and we really need to change NHS thinking on this. During COVID, access to samples was critical but the way those samples was shared out was very unequal. First dibs went to research, then to pharmaceutical companies and only then to IVD companies, but without diagnostics you can't do anything!"

Luckily, lobbying on such subjects is a key strength for BIVDA which facilitates an all-party parliamentary group for the life sciences industries with ABPI and the BioIndustries Association and it works closely with the Office for Life Sciences. They are also members of MedTech Europe and have close relationships with a number of shadow ministers including health and innovation which helps them get Parliamentary Questions asked rapidly. Doris-Ann herself is vice president of the Parliamentary & Scientific Committee and runs an annual poster competition for STEM students which is put on display at Portcullis House.

Just in case GAMBICA members are unaware of our joint history, BIVDA was set up in 1992 by the chair of one of GAMBICA's pre-decessor organisations, The British Lab Ware Association (BLWA) working with The Association of the British Pharmaceutical Industry (ABPI) who felt that a specialist diagnostic association was needed to be a voice for the industry during regulatory negotiations with the EU. For the first third of its life the association was focussed almost exclusively on Regulations and while it has a wider remit now, it has a wealth of expertise in diagnostics regulations in the UK, EU and worldwide, and has been highly effective at inputting to regulators on behalf of its members."

- **BIVDA has kindly agreed to provide a regular column for L@b Brief to keep GAMBICA members abreast of issues in the world of IVD and as we develop our plans for working together we will explore all opportunities. If you have particular requests do let me know.**

Speaking opportunity at Chem UK

GAMBICA IS running a session at this year's Chem UK which, after postponement from last year, will run in September at the NEC in Birmingham. The session will be titled: Minimising waste in chemical formulation, and we aim to give delegates step-by-step expert instructions on how to reduce the energy, raw materials and waste involved in chemical formulations. If you have a product which helps minimise waste in this market, please get in touch. We have one presenter slot left. Jacqueline.balian@gambica.org.uk

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Scammers hit GAMBICA member's distributor

GAMBICA MEMBERS may wish to re-inforce their warnings about cyber security and scam avoidance to their distributors after a member's European distributor was hit by scammers apparently based in the UK.

A legitimate looking invoice for a live order was sent to one of the firm's distributors for payment, but with altered bank details and company name. The distributor, rather than phoning the known telephone number for the GAMBICA member, simply emailed to check. It appears that the distributor's email had been hacked, so this email went straight to the scammers who 'confirmed' that all the details were correct. The scammer had very subtly altered the GAMBICA member's email domain and were intercepting invoices emailed to the distributor, replicating them with accurate order info, but changing the account and company info. The distributor unfortunately handed over £21K and it is not likely that they will be able to recover this.

As in the recent case where a company purporting to be GAMBICA tried to sell the GAMBICA membership lists, this incident was reported to Action Fraud, but here too no action was taken.

While Action Fraud do provide some useful training materials on how to avoid fraud (see here), their ability to take an active role in combatting fraud appears limited. It would be interesting to hear about Members' experience of Action Fraud, so if you have any experience, good or bad, please do let me know.

Ransomware attacks grow

According to the UK's National Cyber Security Centre (NCSC) ransomware attacks, are becoming alarmingly common but many of the companies affected do not wish to publicly acknowledge their losses. As a result, NCSC has made a number of tools available online to help businesses avoid becoming victims.

1. **NCSC Small Organisation Newsletter** aims to break down cyber-related issues into bitesize pieces which can be read in your coffee break. Sign up to receive a copy here.
2. **Cyber Aware Campaign:** a basic messaging for public and business is available here.
3. **Small Business Guide:** which explains how to improve cyber security; affordable, actionable advice for organisations is available here.
4. **Cyber Security for Small Organisations** is here.
5. **Top Tips for Staff** is here.
6. **And a whole training zip file** which contains the package as a SCORM-compliant file is here. An API version is available as an alternative to help users who have been unable to use SCORM.
7. As previously mentioned, **Exercise in a Box** a free online tool helps organisations to find out how resilient they are to cyber-attacks and practice their response in a safe environment is available here.
8. **Cyber Essentials:** a government backed certification scheme that helps you to guard against the most common cyber threats and demonstrate your commitment to cyber security information is available here.

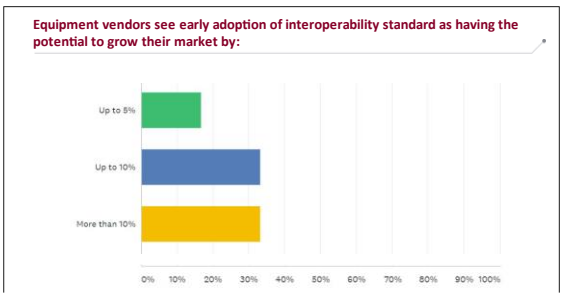
An increasing number of tenders are now specifying Cyber Certification as part of their tender process. There is a newly-launched Cyber Essentials Readiness Toolkit, a free, online resource that guides organisations through a series of questions to help you prepare for certification here.

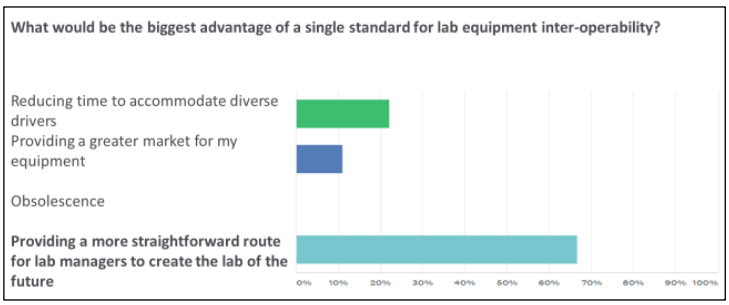
Meanwhile, BEIS and NCSC have asked any firms who have suffered a ransomware attack to give them details. The information would be used in strict confidence to build up intelligence to help combat this crime, and perhaps also used as examples to warn others, with all details that might identify the target firm removed. If you have such examples please do get in touch.

All smiles after lab inter-operability standards debated at Future Labs Live

GAMBICA WAS called in to moderate what could have been a mud slinging match between the various standards being offered for lab equipment inter-operability at the Future Labs Live event in June. Nearly 100 people joined for the debate in which representatives of the different standards carried out a role play, identifying the benefits of using a standardised approach for a research scientist, an equipment vendor, a start-up CEO and a data analyst.

The conclusion was that whatever your role, there is a standard which will make your life easier and cut your costs. This echoed the results of a survey of GAMBICA members' attitudes to the need for a single lab interoperability standard which showed that lab vendors believe that being an early adopter for a single lab standard would increase their market share but that they still see the majority of benefits being for the lab managers rather than themselves. You can access a recording of the debate here.





Security of electricity supply concerns in Ireland

AN IRISH regulator has warned that 'rolling blackouts' could result if steps are not taken to address the rapid rise in demand for electricity from in the country's data centres sector.

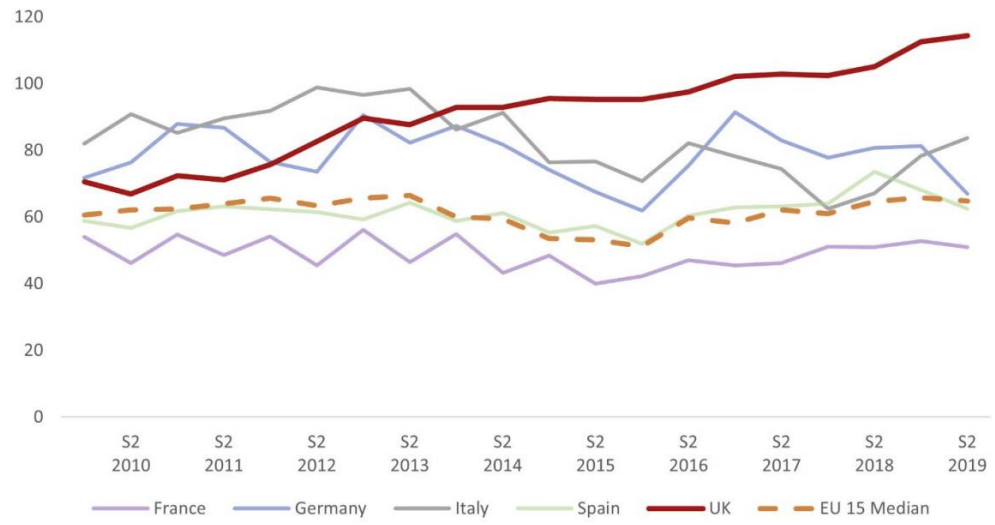
The Commission for Regulation of Utilities (CRU) has highlighted the impact the growth in data centre electricity grid connections is having in comparison to other energy-intensive sectors. One forecasting model suggests that up to a third of all electricity demand in Ireland in 2030 could stem from data centres, however this figure does not account for all of the most recently data centre applications. If those connections were factored in, the electricity demand for data centres in Ireland would account for around 3.8GW. The current demand peak for the whole electricity system in Ireland is 5.5GW.

Major energy users to be consulted on industrial electricity costs

THE DEPARTMENT for Business, Energy and Industrial Strategy (BEIS) has published a consultation reviewing schemes to compensate energy-intensive industries such as glass-blowing for indirect emission costs in electricity prices.

The consultation includes striking evidence of the cost of electricity to extra-large industrial consumers. Whereas the UK was bunched with other major EU economies ten years ago, since then costs in £/MWh have risen by half while remaining broadly the same in the other countries. The UK is now clearly the most expensive, as the graph below from the consultation shows:

Figure A: Trends in electricity prices for extra-large industrial consumers in selected EU countries (£/MWh)



The disparity has heightened concern about high energy costs in UK manufacturing, the impact this is having on attracting investment in existing and new facilities and the transition to net zero. Businesses are concerned about carbon leakage (when manufacturing moves to a country with lower carbon costs).

The consultation closes on 9 August. To respond please click here.

Further delay to the reintroduction of in-person right to work checks

UPDATED GUIDANCE from the Home Office says digital right to work checks – introduced as a temporary measure at the start of the pandemic to support businesses to work remotely – will be extended until the end of August.

Employers will now be required to resume in-person checks from 1 September.

In a statement, a Home Office spokesperson said this latest postponement was because of the "benefits the adjusted checks have brought employers", and that the Home Office was "reviewing whether there are changes we can make to the right to work scheme to increase the digital checking aspects, including through the use of specialist technologies".

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Questions and Answers

DECLARATIONS OF Conformities for products that fall under IVD, RoHS, EMC or LVD

Q: **We know EMC is covered by the IVDD/IVDR so we do not have to declare to the EMCD on the IVD DoC however, LVD states we have to declare all applicable regulations and applied harmonised standards so should the IVD declaration include it?**

A: The Radio Equipment Directive (RED) calls up the safety requirements of the LVD and the compatibility requirements of the EMCD. The RED applies and would be cited on the DoC but the LVD and EMCD do not apply and would not appear on the DoC.

In the new IVDR, it states:

> 5. This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

Article 2(3) of the EMC directive states:

> 3. Where, for the equipment referred to in paragraph 1, the essential requirements set out in Annex I are wholly or partly laid down more specifically by other Union legislation, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of that Union legislation.

As the IVDR is union legislation which lays down specific EMC requirements within the regulation in annex I, the EMCD does not apply.

The following EMC standard is cited as a harmonised standard under the IVDR: EN 61326-2-6:2006

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.

The regulation also calls up safety requirements, so the LVD would not apply and the following safety standard is harmonised under the IVDR rather than the LVD: EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

Annex II of the LVD lists the exclusions:

ANNEX II

EQUIPMENT AND PHENOMENA OUTSIDE THE SCOPE OF THIS DIRECTIVE

Electrical equipment for use in an explosive atmosphere

Electrical equipment for radiology and medical purposes

Electrical parts for goods and passenger lifts

Electricity meters

Plugs and socket outlets for domestic use

Electric fence controllers

Radio-electrical interference

Specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.

Custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

Therefore I would just cite the IVDR and RoHS on your DoC.

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Harmonised standards and IVDR

Q: I was wondering if you have any visibility on when the list of harmonised standards for IVDR will be finalised and released. For now we are assuming that the latest revisions of the standards will be harmonised/ applicable. Secondly, do you know if and when the UK will adopt IVDR?

A: The list of harmonised standards is here.

The UK is not planning to adopt the IVDR, there are plans to write a UK specific regulation see here.

The EU MDR fully applied in EU Member States from 26 May 2021 and EU IVDR is intended to do so from 26 May 2022. As these regulations did not take effect during the transition period, they were not EU law automatically retained by the EU Withdrawal Agreement Act and therefore will not automatically apply in Great Britain. This means that the provisions contained within the EU MDR and EU IVDR will not be transposed into law in Great Britain and will not be implemented in Great Britain.

Also see BIVDA partnership with GAMBICA story which predicts major delay to EU IVDR also in this issue of L@b Brief.

Are declarations of Conformity not valid if from the UK?

Q: We are facing an issue with our German distributor who will not clear goods because our declaration of conformity is from the UK not EU entity. They say:

"We are facing customs issues with this order as the CE documents provided are no longer valid since they were not issued by an entity established in the EU. To get cleared we need the documents from such an entity."

A: I have not heard of this being a problem for other GAMBICA exporters to the EU. The manufacturer can draw up the EU Declaration of Conformity wherever they are based in the world. USA, Japan, Germany, etc… manufacturers have been doing it for decades.

If the regulation in question requires a Notified Body then this has to be a Notified Body recognised on the EU NANDO list: EUROPA - European Commission - Growth - Regulatory policy - NANDO. In your attached DoC, you are self-declaring to the LVD [2014/35/EU], EMCD [2014/30/EU] & RoHS [2011/65/EU] which do not require a Notified Body.

The only thing that will change is that from 16th July, an EU address will be required somewhere with the product when the new Market Surveillance regulation comes into effect, but this does not need to be on the DoC.

The only thing I can think of is that maybe they are thinking of another regulation…

EU authorised representatives

Q: We are looking for help/support on exporting our ELISA kits to the EU. Has the GAMBICA information on authorised representation for exporting to the EU post Brexit, been updated and if so, where can I find it on the GAMBICA website?

Also, am I right in believing that this is only required for products that are being placed on the market for the first time i.e. products that are already being sold in the EU are exempt?

A: The importer guidance document can be download here. And further government guidance is here and here. A note that refers to the application of this in Northern Ireland is here.

The requirement to have an EU importer address applied from 1 Jan 2021 and the requirement for an EU representative for online direct sales from 16 July 2021. This applies to individual products or batches as they are placed on the market (ie if you have already placed Product A on the EU market in the past, it doesn't

mean you can continue to place more of Product A on the EU market without following the new requirements). For individual products that have already been placed on the EU market before those dates (eg with a distributor in the EU), then they can continue to circulate in the EU market.

Will July deadline really happen?

Q: Do we really have to have our EU representative set up by 16 July 2021 in order to keep exporting into EU? This is going to be another EU deadline that SME exporters won't be ready for. Is there any likelihood of the date being postponed?

A: In a word, yes, you do need to have an EU importer address that can be contacted for market surveillance reasons. This could be your own EU office, an importer or a 3rd party acting on your behalf. There is little to no chance of this being delayed. It has been long planned by the EU and supported by industry (as a way to make Amazon and other fulfilment centres responsible for products they place on the market).

There's a link here Placing manufactured goods on the EU market - GOV.UK (www.gov.uk) which covers some of this.

The Lighting Industry Association has passed on details of a company that can assist with EU Authorised Representation. While we at GAMBICA have no experience of them and can't give an opinion on their services, it could be worth contacting if you need further help in this area.

Eurolink (eurolink-europe.com)
Charles Green | ***Commercial Director***
EUROLINK
DDI: +44 1793 279 241 | Mob: +44 7957 641 460 | E: charles@eurolink-europe.co.uk

Heat rise in transformers

Q: We are testing three-phase current transformers for heat rise.
Clause 7.2.2.201 of BS EN 61869-2 states; For Current transformers in three-phase gas-insulated metal enclosed switchgear all three phases have to be tested at the same time.
The implies that if the three-phase CT is mounted in a cabinet that is air cooled, the tests can be carried out on each phase one at a time. Can you please confirm this assessment is correct?

A: A GAMBICA expert member comments:

1. In BS 61869-1 & 61869-2 section 7.2.2 it states that the test shall be performed with 'the current transformer… mounted in a manner representative of the mounting in service and the secondary windings shall be loaded with the burdens according to 6.4.1.'
2. 61869-1 section 6.4 states – 'If the instrument transformers are used within enclosures, attention shall be paid to the temperature reached by the surrounding cooling media within the enclosure.'

Where the three current transformers are in an enclosure, and as of point 1 and 2 above, they should be mounted as done so in service, and those carrying out the tests need to use their judgement whether:

- They could affect each other by raising localised air temperature if all are operating at once
- They could obstruct the air cooling in the enclosure so one of the CTs may not be being cooled with the same efficiency

At the end of the day, the point of the test is to ensure that no part of the windings or the magnetic circuit exceed the temperature limits as of Table 5 in the standard such that the winding wire insulation softens or melts and makes the product defective. If I was testing I would perform the worst case scenario, which is probably all three CTS measuring fully rated currents. But as it does not specifically say all three should be operated all at once so they can be tested individually.

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Upcoming GAMBICA webinars

Export Group meeting | 6th July

THIS WILL be a business meeting of the Export Group. If you haven't been to an Export Group meeting you are very welcome to join. This time the group chair, Hazel Hall, has agreed to share SPECAC's wellbeing at work guidance on managing employee mental health responsibilities in the light of COVID. The rest of the agenda will cover current exhibition satus and will include a state of trade round-table and discussion of the agenda for future meetings. To reserve your place click here.

Test and measurement sector steering group meeting | 12 July 2021

WE HAVE three speakers for this second meeting of the test and measurement steering group covering the future for electric vehicles and their charging systems.

Sebastian Von Dort will provide a short introduction to relevant energy standardisation work and BSI's wider role in energy transition.

Dr Nina Klein – an Energy Engineer in the BEIS Science and Innovation for Climate and Energy (SICE) team, has kindly agreed to provide an overview of the Energy Smart Appliances work (focusing on PAS 1878 PAS 1878 Energy smart appliances – System functionality and architecture and explain the wider policy and regulatory context. Isaac Haigh, policy advisor in the consumer experience team at the Office for Low Emissions Vehicles will then explain the roll out timetable and offer some insights on how things are progressing.

The meeting will also provide an opportunity for members to set the direction of future meetings.

To reserve your place, please click here.

Benefits of digital initiatives for lab, test & measurement companies | 13 July 2021

AS MAJOR customers, particularly in the pharmaceutical industry begin to look seriously at digitalisation, and two of the big four business consulting firms have set up divisions specifically to advise clients on laboratory digitalisation, GAMBICA is providing an in-depth, two hour webinar explaining how lab and test and measurement companies can benefit from digitalising and how to do it.

Designed specifically for the senior management of SMEs in GAMBICA's lab and test and measurement sectors, it not only give an overview of the benefits, it will explain how you can identify suitable projects which will yield a real return on investment and will offer case studies which are not only inspirational, but are fully costed, giving you the chance to evaluate those that might be applicable to your own operations.

AGENDA:

- **Welcome - Ken MacLachlan, Thermo Fisher**
- **Digitalisation without the fluff:** Steve Brambley, CE of GAMBICA, sets out why digitalisation is important, what it can yield for your company and will look at some of the macro factors which make engaging with these new technologies essential.
- **Shortcuts to inspiration:** Jan Hemper and Pat Nash of InControl Systems will explain how you can identify any sub-optimal aspects of your operations by use of simple monitoring. It will set out the costs of these initial inquiries and how they can be achieved without impacting on your day-to-day operations. Examples will be provided to illustrate how to understand what your new data is telling you.
- **One sensor – 15% savings:** David Taper, Motortronics**:** The first case study of the morning will show delegates how a sensor/soft starter installed at New Form Tools/ Blanchard Grinders not only

prevented unplanned downtime, it reduced energy consumption by up to 15%. This case study demonstrates how low-cost interventions can save time and money.

- **Digitalisation for your products**: Andrew Norcliffe, B&R Automation will provide a case study featuring machine monitoring which allows you to remotely commission, monitor and maintain your equipment. The value of such systems has been amply proven during lockdown. This case study will not only set out how such systems can be incorporated in your products and give you an idea of the likely costs of installing them, but will explain how you can handle the data you get back without needing additional staff or a data analysis services.
- **Automation to reduce chemical use:** Tony Deane of Phoenix Contact**,** will show how automation projects have been instrumental in reducing use of energy, water, raw materials and plastic and can form an important part of your journey to net zero. This case study will explain how certain sensors, integrated using the right PLC, allowed a train track to be kept free of weeds while eliminating the use of glyphosate.

There will be ample time for questions and discussion. To reserve your place, please click here

What you need to know about the plastics tax | 10 August, 10.30

£200 PER tonne is the rate of tax you will soon have to pay on plastic packaging which is not at least 30% recycled. In this webinar, Louisa Goodfellow, policy advisor at Ecosurety will explain what we currently know about this tax which is planned to come into effect on 1 April 2022.

Much remains unclear about the detail of how the tax will work. The Government has undertaken to give more complete guidance before it comes into effect, but has not said how long before. Some information is already available however, including the exemptions and the broad rules about how the tax will work and who will be liable. Louisa will give a short overview of what we know now, and will provide advice on how to prepare if you feel you may fall within the scope of the new regulations.

Ecosurety is a sister organisation to our own B2B Compliance and is the leading producer responsibility compliance scheme for packaging, WEEE and batteries. To reserve your place, click here.

Masterclass in market selection, prioritisation and research | 24 August, 13.30

THE NEXT of GAMBICA's shared cost training opportunities is an intensive and interactive masterclass which will remind exporters about the range of techniques which can be used to select and prioritise potential export markets and plan and conduct export market research projects.

The masterclass covers research strategies, desk and field research and offers practical and cost-effective solutions for conducting research in-house and using Government support and external agencies. The half day workshop is designed to help delegates to plan their international marketing research so that they can collect, interpret and report on the information they have gathered. Each workshop session builds on the last to ensure that delegates leave with a clear action plan.

On completion, delegates will be able to:

- understand the key criteria for selecting and prioritising overseas markets;
- plan, undertake or commission, and report on a market research project;
- make effective use of the internet and other sources of desk research;
- plan and undertake field research activities in their target export markets;
- use market research to gain an in-depth understanding of potential customers and partners; and
- have an awareness and appreciation of government and other regional services open to them.

The workshop will be delivered by John Harrison MIEx CMRS

John is a trainer, facilitator and consultant whose focus is entirely on international trade. He has developed a portfolio of export workshops and training courses and established a high-quality client list of government

departments, Chambers of Commerce, trade associations and similar organisations in the UK and Ireland. He is regularly invited to facilitate seminars and conferences and also works closely with companies on a one-to-one basis to advise and assist them in their export activities. His experience of delivering export training extends over 20 years and he has in-depth knowledge of Department for International Trade and Chamber of Commerce networks and the schemes and services available to SMEs.

The masterclass costs £280 plus VAT for GAMBICA members and £350 plus VAT for non-members

To book your place please click here

Assertive Communication Training Workshop | 14 September

AS ABOVE, Members have asked GAMBICA to arrange training courses centrally to give you access to industry focussed training, at a reasonable cost even for small numbers of trainees. The first date for this Assertive Communication Training sold out immediately so we are offering a second date in September.

The virtual workshop will increase the knowledge and skills of all individuals, assisting them in becoming more assertive, professional and confident and will help them improve relationships with employees, managers, stakeholders, and customers both when communicating virtually, over the telephone and face-to-face.

The workshop starts by defining assertiveness and learning how to distinguish between the different behaviours. Delegates will then learn the essential skills of assertiveness which will assist in both work and personal situations. Ahead of the workshop, participants will complete an online Assertiveness Profile for use during the workshop.

To book a place, please click here.

If you have any other subjects you would like me to arrange training on, please let me know which topics are of interest. I am currently planning a session on Finance for non-financial managers. Email me on Jacqueline.balian@gambica.org.uk

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EVENTS

Webinar on med tech regulations in Canada | 8 July | 10-11.30am

MEDTECH CANADA are hosting a webinar on the regulatory and innovation landscape in Canada Click here to register. Details are here.

HSE course on the Machinery Directive |12 to 13 July 2021

THIS COURSE costs £525 and delegates attending it will gain a thorough understanding of the UK Supply of Machinery Regulations and the European and International safety standards. To register or find out more, please click here.

20th International Metrology Conference | 7-9 September | Lyons, France

THE INTERNATIONAL Metrology Congress is a showcase for industrial applications, advances in R&D and prospects dedicated to measurements, analysis and testing processes. An impressively packed programme includes 200 presentations and six round table sessions. To register click here.

Protein Degradation Europe | 21-23 September 2021 |Virtual

THE PROTEIN degradation field has expanded beyond just PROTACs; with developments in rational molecular glue design and the emergence of TAC variants, including abTACs and oligoTACs, this conference will consider how proximity-based drugs can be used for therapeutic benefit using cellular activity beyond the ubiquitin-

proteosome. It purports to be a high end science led conference and delegate passes cost a minimum of £1,000. They claim to be able to put you in front of lead scientists from big pharma or the heads of research and development from the biotech industry. It may be possible to arrange discounts for GAMBICA members either as exibitors or as delegates so if this is of interest, please let me know, Jacqueline.balian@gambica.org. For information on the event email ryan.sanderson@kisacoresearch.com

Chem UK |15th & 16th September | NEC Birmingham

VISITOR REGISTRATION has opened for the UK Chemical Industries EXPO, CHEMUK 2021.

GAMBICA will be hosting two conference sessions at the face to face event, including one on minimising waste in chemical formulation. The event will feature 320 chemical industry supply chain exhibitors,and 140 plus expert speakers.

You can register for your free 2-day visitor badge to the exhibition floor and all presentations by visiting the CHEMUK 2021 website at www.chemicalukexpo.com. For information contact: Duncan Harrison, duncan.harrison@ukindustryevents.com

Electric Vehicles exhibition | 7-9 December

THE ONLINE London EV Show 2021 aims to provide three days of networking, an exhibition and a conference. The show seems to be at an early stage of development but the website is here.

The Pharmacy Show | 17-18 October | NEC Birmingham

EXHIBITION FOR pharmacy owners and senior buyers. For information click here.

Big Science Business Forum | Granada, Spain | 4-7 October 2022

GIVEN THE continued uncertainty due to COVID-19, the BSBF International Organising Committee has postponed the event to 4 - 7 October 2022. BSBF2022 will be held in Granada (Spain), at the Granada Congress Centre. All registered attendees, sponsors, exhibitors, and participants of the BSBF2021 edition have been automatically transferred to 2022 and do not need to follow any special procedure regarding registration or participation. If you would like a refund, this can be requested until 31 December 2021. Further information about the postponement to 2022, the updated programme, and the new calendar is available here.

South East Health Technologies Alliance event | Hilton, Tower Bridge, London | face-to-face event | 8 October | virtual event July to November 2021

A HYBRID conference and exhibition for NHS suppliers aims to help delegates make sense of the complexities of health and social care delivery, and the challenges of accessing the NHS.

All Exhibitors and Sponsors will be able to showcase their 3 min video on the event's Digital Hub which will be open until November 2021. The event's one-to-one Partnering Portal will also be open for all attendees from July to November 2021 to enable you to connect with each other, prior, during and after the event. GAMBICA members can book exhibition space at the early bird rate of £500 plus VAT right up to the week of the exhibition. For more information about the event click here.

Genomics Live and Bio Data World | November 2-4 | Basel

RUN IN tandem, these congresses cover precision medicine, multi-omics and diagnostics. This three day conference costs over 650 euros for face-to-face participation but if it has to be run virtually, the conference delegate fees will be refunded in full - according to the website. To book click here.

GAMBICA
Lab Tech

Export News

Minister announces end to TAP scheme

AFTER MONTHS of prevarication, Minister for Exports at the Department for International Trade, Graham Stuart MP has finally announced the end of the Trade Access Programme Scheme which has, over many years, supported UK companies exhibiting their products overseas.

Despite extensive lobbying to increase support, given that the UK support for exporters lags hugely behind that of our competitors, notably Germany, the Government has decided that its support for exporters will come in the form of the Internationalisation fund (which is paid for by a European fund) and other yet-to-be-decided Treasury support for trade shows.

In a letter to the UK Export Partners, of which GAMBICA is a member, the Minister said:

"The Internationalisation Fund will invest £38m in SME Grants over a 3-year period to 7,600 SMEs across 37 LEP areas (all of England, excluding Cornwall & Isles of Scilly, which has its own, similar scheme), providing £1k-£9k of co-investment funding to SMEs. The scheme will run between November 2020 until early 2023. As our strategy refresh continues, other changes will follow. One of those changes will be changes to aspects of DIT's delivery of trade show support.

"As part of the changes mentioned above, we are no longer offering TAP grants. We are working with HM Treasury on future arrangements for supporting businesses so they can make the most of key tradeshows as part of our ambitious plan for supporting exports to help drive growth around the whole of the UK. Whilst the details of those changes are still being finalised, in general, you should be aware that in delivering its future export promotion plans, DIT's focus will be on a number of key tradeshows, aimed to expand the impact that is generated from those events.

"We are currently developing our plans for those export campaigns and officials in my department will update you as soon as more information is available."

UK Export Partners fears that the 'alternative plans for tradeshows' may simply be some mechanism for the aggrandisement of Ministers and the government and based on short term hits rather than longer term wins or alternatively may go to a large consultancy firm rather than being something which will actively support exporters. It is intending to step up its efforts to fight for the interests of exporters. We will keep you informed on progress.

Trade credit re-insurance scheme ends

THE GOVERNMENT has confirmed that it will end its trade credit re-insurance scheme at the end of June.

The decision has been criticised by the Confederation of British Metalworking (CBM), which says its members have been warning that their cover will be withdrawn when the scheme comes to an end. Insurers will no longer have short-term government guarantees.

The government says that the scheme has been a huge success, providing £210 billion in cover to more than half a million firms; but that the economy is now recovering and the vast majority of firms will see their cover maintained or increased after the scheme end. It is right that this is now done by the insurance industry, it says.

Express export licence applications 'only in exceptional circumstances' says government

AS CRITICISM mounts of the increasingly lengthy delays with issuing export licences, a new form has been launched by the government by which companies can apply for express applications. Requests to the Ministry of Defence (MOD) for express clearance of MOD Form 680 applications increased in the first four months of 2021 but can only be made in exceptional circumstances and compelling reasons must be given for consideration on an express basis.

Cases when swift assessment of an application is necessary include:

- humanitarian purposes such as search and rescue/recovery;
- aiding the global effort to combat coronavirus (COVID-19);
- life threatening scenarios; and
- when routine processing would impact UK defence interests such as HMG-led export campaigns that may arise at short notice.

In order to be eligible, companies will have to provide evidence from the relevant HMG department in support of such requests.

Compelling reasons do not include:

- short-notice requests for routine renewals of approvals; or
- requests led by overseas customers' demands.

Normal turnaround time for F680 applications is 30 days says the MOD.

For more information email exportcontrol.help@trade.gov.uk

DIT life sciences sector putting together diagnostics offer

THE DEPARTMENT for International Trade is putting together a Diagnostics Offer which is likely to include information on labware and equipment. The offer is likely to be included on a new microsite being launched by DIT aimed at overseas buyers/Governments. The aim is to allow for a more detailed profile to be offered on key subsectors and drum up some export opps for UK companies.

If you would like to be included, please get in touch; Jacqueline.balian@gambica.org.uk

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Fiscal Representation is a way out of the Brexit VAT Trap

In the first of an occasional series from Chamber International for GAMBICA members, Customs specialist, Ioanna Orfanidi, a qualified customs broker, looks at the alternatives on export VAT.

SIX MONTHS on and UK companies now have a better understanding of the UK-EU Free Trade Agreement (FTA). The firefighting is almost over and, as the dust continues to settle, they're beginning to review approaches to global trade and Brexit processes.

Many are moving away from high-risk Incoterms© such as ExWorks and DDP (Delivered Duty Paid) and switching to FCA (Free Carrier) and DAP (Delivered at Place) to address new supply chain rules and responsibilities. DDP has created by far the biggest headache for companies selling to the EU 27 because it puts the seller in the position of importer in the buyer's country making them responsible for customs clearance, import duty and VAT.

If the UK business does not have an EU presence it needs to appoint a fiscal agent to meet these responsibilities. This can be complex and time consuming but it is more cost effective than setting up an EU office. In some EU countries, including Belgium, Netherlands, Germany, a set arrangement, known as limited fiscal representation or general fiscal representation, is available. However, in other countries, such as The Republic of Ireland, this option is not available and businesses are usually required to register for VAT in the country where they wish to handle the import formalities so they can recover import VAT.

Limited, or general fiscal representation, is an agreement between an overseas business and a fiscal agent in another country under which the exporting company gives the fiscal agent authority to act on its behalf for VAT

reporting and reclaims. Under the terms of such an arrangement, businesses can also explore the potential for using their fiscal agent's duty deferment too.

The main difference between these two options is that limited fiscal representation does not require a UK business to register for VAT in the import country, as the fiscal agent will submit the VAT reclaims using their own VAT number. However, general fiscal representation does require VAT registration.

Fiscal representation is the most popular approach requested by our customers operating door-to-door deliveries and those encountering other supply chain issues, such as 'VAT triangulation'. This is where three separate businesses are involved: the UK exporter, which invoices its EU customer; an EU supplier, which ships the goods within the EU and the EU end-customer which receives the goods and pays the UK exporter.

In technical export terms, such shipments fall between an intra-EU shipment and an export, which causes similar VAT implications.

The set-up cost for fiscal representation varies depending on the country and averages £1,500. This can be offset by the government's SME Brexit Support Fund. Ongoing VAT reporting charges also apply and are payable directly to the agent by the client.

Businesses with any supply chain concerns following EU Exit can contact Ioanna on +44 07827 318684 or email ioannao@chamber-international.com

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Company News

New GAMBICA member hits out at poor performance by UK Export Control Organisation

WHEN IT was formed in by Sir Martin Woods in 1959, specialist instruments firm Oxford Instruments, was the first commercial spin out from Oxford University. The company has recently joined GAMBICA to support its wider activities, particularly to help its compliance teams keep abreast of the changing compliance landscape worldwide and to expand its lobbying activities, especially those aimed at overcoming barriers to export.

Dr Ian Wilcock, who runs Oxford Instruments' Materials Analysis Group (which focuses on electron microscopy, NMR and Raman and atomic force microscopy) joined the company five years ago having previously been with Danaher. Oxford Instruments has seven business units based in the UK and the US and has recently acquired an eighth, WITec, in Germany.

The company has supported notable scientific successes over many years, having been involved in at least three Nobel prizewinning projects, for example with the Manchester team who developed Graphene. This success has been mirrored by its financial performance. Shares have been at a record high since the announcement that its annual turnover had reached £318m at its March 21 year end. Oxford Instruments employs over 1700 people worldwide, a little over half of whom are in the UK.

Since over 90% of the company's products are exported, it is no surprise that Ian pays close attention to export strategy and the global investment climate. "We match our growth plans to global investments in R&D. So China is our biggest market both in academia and industry, followed by US, Japan, Germany, Korea, France and the UK in that order. We monitor R&D spend carefully because our mission is to provide the equipment and services scientists need for cutting edge research.

"We also match our product development to the key areas of research receiving funding. At present we are concentrating on where the big challenges are: energy, the environmental agenda, batteries, solar panels and hydrogen fuels etc. In the medical arena we are heavily involved in facilitating disease research particularly cancer and our aim is to work alongside the first movers in the quantum technology space. Now quantum computing can provide orders of magnitude faster processing and unbreakable codes and new semiconductor materials for drones, phones and mobility are developing so fast, we want to be at the forefront of these areas as well.

"We work closely with the UK's Department for International Trade's Export Control Joint Unit, especially related to our trade with China. Unfortunately, we are seeing increasing delays in the granting of export licenses, I believe due to resource constraints in the department and elsewhere in Whitehall. Worse still, we are seeing an increase in refusals to grant export licenses, particularly to China. We calculate that this has cost Oxford Instruments many millions of pounds in the last year in direct or consequential loss of business. I don't think we are alone in this, I'm sure that other tech companies are being similarly affected.

"Such refusals can cause our customers to look elsewhere, and we don't always see the same reluctance to grant licenses in the US, Germany or Japan, even though we are all working from the same rule book, so particularly German and US firms are picking up business which could have been ours. There is also the likelihood that if China finds it difficult to access equipment from existing expert suppliers, it will look to develop local sources of equipment. The effect on UK companies and UK jobs is already significant and will become more so, unless this key UK administrative unit is sufficiently resourced, and we see more clarity in Government policy."

Oxford Instruments has partnerships with microscope manufacturers and other OEMs and is always looking to expand its portfolio, so sees the development of positive relationships with its partners as a priority.

Ian Wilcock would like to develop joint action with other GAMBICA members to encourage customers to see the value of connecting their equipment to the internet to facilitate a whole new range of products. "Progress on this front would have benefits for both suppliers and customers, suppliers can improve their services to customers by offering remote diagnostics, remote servicing and support and customers will get significantly improved downtime and more efficient running of equipment. But I have noticed a reluctance among customers to have equipment connected to the web. It would be good to work together to get a better understanding of the causative issues and how we can overcome them."

Hopefully, you will meet Ian and other members of the Oxford Economics team at an event shortly, but if you would like to know more about the company their website is here.

HORIBA joins tech development consortium for cell and gene therapy

A NEW consortium for the development of technology for the manufacture of cell and gene therapy headed by the Cell and Gene Therapy Catapult, has attracted GAMBICA member Horiba to join what is said to be the first organisation of its kind within the cell and gene therapy space. Comprising technology providers, pharmaceutical companies, therapy developers and charities, it will evaluate the application and combination of new and existing technologies from multiple industries to develop technologies specifically for cell and gene therapy (CGT) manufacturing.

HORIBA will contribute its new A-TEEM Molecular Fingerprinting technology, which powers HORIBA's Aqualog Industrial QC/QA Analyser which can shed light on biochemical changes within bio-reactors. This provides valuable insight into cell health and ensures the most efficient cell growth processes. Working within the consortium will allow analysts to couple data from the HORIBA system with information from many other sensors to obtain a broad scientific overview of the process.

The new consortium will act as a catalyst in fast-tracking knowledge and understanding at reduced cost and investment risk to each organisation. Access to this key information will allow technology providers and manufacturers to develop lower cost and more robust manufacturing processes, accelerating development of advanced therapeutics.

Legal and Regulation News

The implications of the new employment watchdog

THE GOVERNMENT has announced the creation of a new workers' watchdog to take responsibility for enforcing rights in relation to anti-slavery, National Minimum Wage, and protection of agency workers. The body will combine the three separate existing bodies of Gangmasters and Labour Abuse Authority, HMRC's National

Minimum Wage Enforcement and the Employment Agency Standards Inspectorate with an expanded remit from those three.

The hope is that the new body will bring greater consistency across all areas of enforcement, a more comprehensive intelligence picture, more effective use of resources, and clear independence and accountability. Against this are concerns that the body will be under-resourced, and suffer from a loss of specialisation and expertise, as well as a potential for increased bureaucracy.

The government states the new single body will support employers to comply with the law, by building on the compliance activity of the existing bodies as well as providing detailed technical guidance and potentially introducing a compliance notice system for lower harm breaches. It is, for example, intended to complement the work done by Acas rather than overlapping with it.