L@b Brief | June 2022

Hello again,

The UK's slow drift away from away from the EU is picking up pace and it's in the area of environmental regulations that the changes are beginning to be seen.

Five new substances have been added to the EU REACH list, but not the UK list and there are now 15 substances on the EU list of Substances of Very High Concern (generally carcinogen, mutagens or things which are toxic for reproduction) which are not on the UK list. The UK REACH rolling action plan states the intent to 'compliment rather than replicate evaluation work that has been or will be performed by other regulatory regimes' (such as via the EU REACH). While this sounds like a sensible and cost-saving approach, members will still be facing the additional costs of having to monitor and comply with two separate regimes. Compliance staff are in high demand at the moment so luckily you can reduce your workloads by using the GAMBICA environmental regulatory group to help you with alerts on changes in either jurisdiction.

If you have anything you would like raised with the group, give me a bell or rock up to their next meeting on 26 September.

Toodle pip!

Jacqueline

INSIDE *this* MONTH

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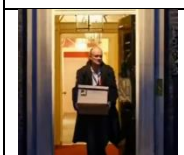
	**Merck invests €440 million in extension to science facilities** Two plants in Southern Ireland are to benefit from biggest site investment in the history of Merck's life science business
Stick to Science Put science collaboration before politics	**Stick to science** Industry invited to support scientists' plea to remain part of Horizon Europe
	**EU life sciences industry raises concerns about IVDR** Risks of insufficient notified body capacity highlighted for IVDS and companion diagnostics
	**Protecting your business from departing employees** Upcoming GAMBICA webinars help you protect against risks and take advantage of opportunities
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UK News

Stick to science if you value Horizon Europe

RESEARCH LEADERS in both the EU and the United Kingdom are fighting a vocal and high-profile campaign urging politicians to keep politics out of science. Stick to science is an online signature campaign set up by the European research community for an open and inclusive European Research Area. The campaign results from Britain's departure from the European Union, when researchers were assured that this did not mean leaving the EU's research programme, Horizon Europe.

Under the terms of the UK's EU exit, the country would keep paying into the €95.5-billion (US$100.6-billion) fund and researchers would continue to be able to access grants (including prestigious European Research Council (ERC) grants).

Unfortunately, since the UK government introduced draft legislation to amend the Northern Ireland Protocol, relations between UK and EU policymakers have nose-dived and the EU is taking legal action against the UK for breaking international law. The legal case will probably take several years to run its course, and Horizon Europe is time-limited: it ends in 2027. In the meantime, researchers awarded ERC and other grants are now expected to lose them. UK recipients of EU grants have now been told they will need to move to an EU institution if they want guaranteed access to the funds. Some are reluctantly preparing to do so.

Signatories to the campaign request that the European Commission, and Member States, and the governments of the UK and Switzerland, recognise that advancement in R&I is best achieved when those in science and innovation work together across geographic boundaries. It urges them rapidly to reach association agreements so that the UK and Switzerland can contribute scientifically and financially to the strength of Horizon Europe and to a truly open, inclusive and excellence-driven European Research Area.

Europe's technology industries institution, Orgalim, has explicitly called for the UK and Switzerland to continue contributing to the European RDI community saying: "Exclusion of non-EU companies or of experts from non-EU countries seems to be more and more a recurring theme. It has been a problem in the Industrial Alliance for Semiconductors, where the Commission was initially resisting participation of non-EU companies like Samsung. There is now a new approach to exclude non-EEA experts in the Commission's expert groups (such as for example on the Radio Equipment Directive), or to reduce the opportunities for non-EU companies to contribute to EU standardisation."

You can follow Stick-to-science on twitter @Stick2Science or email at info@stick-to-science.eu

Help to optimise your supply chain

A NEW assistance and information hub has been created to help SME manufacturers to leverage digital technologies to develop smarter digital supply chains, target bottlenecks and pinpoint unnecessary waste.

The Made Smarter Innovation Digital Supply Chain Hub aims to empower individuals and organisations to work together to make supply chains smarter. Developed by Digital Catapult and funded by the Made Smarter Innovation challenge at UKRI, it is claimed the Hub will transform UK manufacturing by accelerating digital innovation – making supply chains more efficient, resilient and sustainable.

A flagship programme called 'The Future of Supply Chain Labs' is being led by Deloitte and EDGE Digital Manufacturing and funded by the Hub to help SME manufacturers to explore and realise the potential of digital technologies to increase productivity and competitiveness by digitising supply chains.

Through structured workshops and one-to-one support, Future of Supply Chain Labs will help SMEs to develop smarter supply chains, and access the wider support and funding available for digital technology innovation and adoption. The Labs will provide a creative space to explore and learn new ideas and digital technologies which can directly improve companies' supply chains; and to design, test and experiment with new approaches; outside of their day-to-day environment.

Future of Supply Chain Labs will provide ideas and approaches to:

- Improve forecasting and demand management
- Improve visibility of real-time data, tracking and traceability
- Manage disruption and the impact on lead times
- Measure carbon footprint, emissions and reduce energy use.
- Improve stock control, reduce waste and manage materials price volatility
- Improve after sales service and customer satisfaction

Four hour long labs will run regularly from July 2022, starting at 9.30 but places are limited. Proposed dates are:

- Friday 15 July
- Tuesday 19 July
- Wednesday 20 July
- Tuesday 26 July

Participation in a Future of Supply Chain Lab is fully funded for UK-registered SME Manufacturers. If you would like to take part you are advised to register as quickly as possible (and certainly before 8 July) here.

Also - new guidance available on supply chain resilience from DIT

THE DEPARTMENT for International Trade has developed some new guidance and a toolkit for business, with the help of the Centre for the Protection of National Infrastructure (CPNI). The guidance suggests businesses:

1. Understand and map their supply chains
2. Put together a plan of action to tackle identified risks

3. Set up a review process and process owner to maintain oversight

There is no 'one size fits all' method of building supply chain resilience and the toolkit helps businesses to think about the specifics of their own supply chains and the most appropriate plan of action. Additional resources for business are available through the Export Academy. Businesses are also encouraged to contact their local International Trade Advisor through their local trade office for more tailored support on building their business.

The guidance is available here.

UK consultation on MDR – government response published

THE GOVERNMENT has published the results of a consultation on the UK's medical regulations and their enforcement. One of the key issues was the application of the UKCA mark to medical and in vitro devices which had originally been scheduled for 1st July 2023. The government document now suggests that products that are CE marked under MDR regulations can continue to be placed on the market until either the certificate expires or for five years after the new regulations take effect, whichever is the sooner. This will apply even if the certification/declaration of conformity is dated after the new regulations take effect. Products certified to this standard will be permitted to be placed on the Great Britain market for up to five years from the date on which the new regulatory framework takes effect, with a view to reviewing this provision at the end of the five-year period.

The Medicines and Healthcare products Regulatory Agency (MHRA) will proceed with preparing regulations reclassifying products such as certain implantable devices, extending the scope of regulations to capture certain non-medical products with similar risk profiles to medical devices (e.g., dermal fillers, coloured contact lenses) and to strengthen and increase post-market surveillance requirements to ensure better incident monitoring reporting and surveillance.

Strong support was also heard for improved traceability of medical devices, including the use of Unique Device Identification (UDI).

The consultation also outlined changes with potential to improve support for innovation in medical devices, and access to medical devices. These included improving regulation of novel and growing areas such as software (including artificial intelligence (AI)) as a medical device to offer alternative and safe routes to market for game changing innovation.

The government will also be introducing alternative routes to market, including domestic assurance, to enhance the supply of devices while retaining appropriate levels of scrutiny to ensure patient safety remains a priority. The changes the MHRA will be taking forward will also ensure the UK aligns with international best practice where those standards are superior than current standards and they will introduce greater transparency of regulatory decision making through updating the requirements that apply to Approved Bodies and increasing the consistency of conformity.

In the light of responses the government has stated its intention to 'improve' regulation of Medical and in vitro devices by:

- Strengthening MHRA power to act to keep patients safe;

- Making the UK a focus for innovation, the best place to develop and introduce innovative medical devices;
- Addressing health inequalities and mitigate biases throughout medical device product lifecycles;
- Developing proportionate regulation which supports businesses through access routes that build on synergies with both EU and wider global standards; and
- Setting world leading standards – Building the UKCA mark as a global exemplar.

"A considered implementation plan for such an ambitious programme of reform is critical to its success", says Secretary of State for Health and Social Care, Sajid Javid.

"Our plan balances prioritisation and pace with the need to ensure there is time for the sector to adapt. It seeks to ensure patients and the healthcare system can continue to access the essential medical devices they need through the transition to the UK Conformity Assessed (UKCA) marking."

You can read the report in full here.

Hike in producer price inflation reducing but growth momentum in the OECD slows

PRODUCER INPUT prices rose by 22.1% in the year to May 2022, up from 20.9% in the year to April 2022, according to the June Office for National Statistics' figures. Although this is the highest the annual rate has been since records began in January 1985, the monthly producer input and output prices improved slightly in May. May rises on input prices were 2.1% and output prices increased by 1.6% in May 2022, down from April's 2.7% and 2.8%, respectively.

Food products, and metals and non-metallic minerals provided the largest upward contributions to the annual rates of output and input inflation, respectively.

Meanwhile, the Bank of England revised upwards its prediction for inflation, which it now says will peak in October at just above 11%, one percentage point higher than its previous forecast.

Unsurprisingly, the latest set of Composite Leading Indicators (CLIs) from the OECD indicate that growth may lose momentum in the OECD area as a whole over the next six to nine months.

The CLIs are now either at or below long-term trend levels in most major OECD economies. Pushed down by high inflation and very low consumers' confidence, the CLIs point to a loss in growth momentum in the euro area as a whole, including in Germany, France and Italy, and also in the United Kingdom and Canada. In contrast, the CLIs continue to point to stable growth in the United States and Japan.

Among major emerging economies, the CLIs now point to growth losing momentum in China (for the industrial sector) and slowing growth in Brazil, but stable growth in India.

Table 1: Composite Leading Indicators*

	Ratio to trend, amplitude adjusted (long term average =100)					Month on Month change (%)					Growth cycle outlook
	2022					2022					
	Jan	Feb	Mar	Apr	May	Jan	Feb	Mar	Apr	May	
OECD Area	100.4	100.2	100.1	100	99.9	-0.12	-0.13	-0.14	-0.12	-0.11	Growth losing momentum
Euro Area	100.5	100.3	100.1	99.9	99.7	-0.21	-0.23	-0.24	-0.21	-0.18	Growth losing momentum
Major Five Asia**	99.5	99.4	99.4	99.3	99.2	-0.08	-0.08	-0.07	-0.07	-0.07	Stable growth
Major Seven	100.3	100.1	100	99.9	99.8	-0.12	-0.13	-0.13	-0.1	-0.08	Stable growth
Canada	100.2	100.1	100	99.9	99.7	-0.16	-0.13	-0.12	-0.12	-0.12	Growth losing momentum
France	99.7	99.5	99.2	99	98.7	-0.21	-0.26	-0.28	-0.25	-0.21	Growth losing momentum
Germany	100.8	100.6	100.4	100.2	100	-0.16	-0.18	-0.21	-0.19	-0.17	Growth losing momentum
Italy	100.8	100.4	100	99.7	99.4	-0.4	-0.42	-0.4	-0.33	-0.27	Growth losing momentum
Japan	100.5	100.6	100.6	100.7	100.7	0.03	0.03	0.04	0.04	0.04	Stable growth
United Kingdom	100.9	100.6	100.2	99.9	99.6	-0.27	-0.33	-0.37	-0.34	-0.31	Growth losing momentum
United States	100	99.9	99.9	99.8	99.8	-0.08	-0.08	-0.06	-0.03	-0.02	Stable growth
Brazil	99.4	98.9	98.6	98.5	98.4	-0.62	-0.44	-0.28	-0.15	-0.07	Slowing growth
China***	99.2	99.1	99	98.9	98.8	-0.12	-0.11	-0.09	-0.09	-0.09	Growth losing momentum
India	100.4	100.3	100.3	100.3	100.3	-0.03	-0.03	-0.03	-0.02	-0.02	Stable growth

* CLI data for 33 OECD member countries and 6 OECD non-member economies are available at:
http://stats.oecd.org/wbos/default.aspx?datasetcode=MEI_CLI
Please note that CLI for New Zealand is currently under revision and could not be updated this month.
** China, India, Indonesia, Japan and Korea.
*** The reference series for China is the value added of industry.

Chinese investment in UK up by 50% from ten year low

THE LATEST MERICS* report on Chinese Foreign Direct Investment (FDI) into Europe shows that inflows into the UK recovered from a ten year low of €1.4 billion (£1.2 billion) in 2020 to €2.1 billion (£1.8 billion) in 2021, an increase of 50%. The overall UK share of Chinese investment in Europe rose to 20% last year up from 18% in 2020.

In the other direction, FDI into China also remained strong. Official statistics published by China's Ministry of Commerce for May showed that foreign investment rose 17.3% year-on-year in Chinese currency Ren Min Bi (RMB) terms. While the latest releases didn't provide a national breakdown, according to public data for 2021, British investment into China last year rose by 22% compared to the previous year.

Meanwhile, China's economic data remains fragile. Consumption in May continued to drop by 6.7 per cent year-on-year, but the country's massive export sector surpassed analysts' expectations, surging by 16.9 per cent last month compared to May 2021. With inflation still weak, the biggest victim of China's zero-Covid policy appears to be less the Chinese economy and rather Beijing's intended rebalancing towards a more domestic consumption-driven growth model.

*** The Mercator Institute for China Studies (MERICS) report is not available except by subscription.**

Do you have an interest in pipettes, lab robotics, plastics or glassware?

BSI IS desperate for new members to join its LBI/001/02 committee which is responsible for the preparation and maintenance of British Standards for laboratory equipment (including glass and plastic laboratory ware) and laboratory robotics. By volunteering for this BSI committee you can:

- Review past standards in this area and bring them up-to-date;
- Initiate new standards where they could be of value;
- Network with leading technical experts in your field; and
- Be nominated for involvement with European or ISO standards bodies whose standards are used worldwide.

Quite a lot goes on in ISO committees, in recent times there has been a long-running debate about which calibration methods should be used for robotic liquid handlers and pipettes.

Participation on committees can have market-building effects too. Those who developed the new British Standard on laboratory autoclaves found that there was no European equivalent of the standard they produced and that European customers were specifying the UK standard for all their autoclave purchases. The UK firms who had worked together on the standard, most of whom were GAMBICA members, were already compliant with the standard, but their European counterparts found they had work to do.

If you would like to volunteer for the committee, please get in touch. Jacqueline.balian@gambica.org.uk.

Time to support workers' physical activity as 'couch potato' effects of lockdown become clear

PRIVATE HEALTH firm Bupa has identified sedentary lifestyles and missed medical appointments as contributing to physical health effects of the pandemic, which it says, may take years to overcome.

- One in five (19% of those working from home exercised less often and just under a third (31%) are still eating more.
- 15% admitted to drinking more.
- Nearly half (48%) haven't visited their GP in the past year.
- 60% have not had a dental appointment in that time.

The Bupa Wellbeing Index (which can be accessed here) surveyed 8000 UK adults and found that the removal of the daily commute had resulted in 19% exercising less frequently and that physical (29%) and mental (34%) health of UK adults declined during the pandemic. 31% of adults say their fitness is now 'poor' with the 35-44 age group most likely to say that they are unfit. Bupa's data indicates that in 2021, 41% of people were overweight and 28% were obese, 81% had some kind of musculoskeletal disorder and about a quarter reported anxiety or depression.

The inactivity of a sedentary lifestyle can be as harmful as smoking and spending more time sitting is associated with an increased risk of diabetes, cardiovascular disease and blood clots and with depression, anxiety and chronic stress according to Bupa.

Dr Robin Clark, medical director for Bupa Global and UK says: “Lockdowns, gym closures and general uncertainty made it difficult for many people to prioritise their health during the pandemic. And despite restrictions ending, it looks like as a nation we’re still struggling to stay active and eat well. With the unfortunate consequence that it may take years for our health to return to pre-pandemic levels.

Tracey Devonport, professor of applied sport and exercise sciences at the University of Wolverhampton concurred: “An international survey we delivered examining the impact of the pandemic on health behaviours revealed UK participants reported the lowest levels of perceived physical health and greatest weight gain during the pandemic. It also indicated that irrespective of country of residence or age, participants reporting reduced physical activity typically experienced poorer physical and mental health.

UK Active has called for a radical re-think of health incentivisation in the workplace including expanding the Cycle to Work scheme to cover gym memberships and equipment as more people work from home.

No-one wants to be a couch potato

A study conducted by the UKactive Research Institute, informed by Sport England and business organisations including the Federation for Small Businesses (FSB), examined the state of physical activity in the workplace for small to medium enterprises (SMEs) following the Covid-19 pandemic.

While SMEs account for 99.9% of UK businesses, they have less access to, or means to provide, opportunities for physical activity, and the majority of research around workplace physical activity centres on solutions for large corporate-based organisations.

The Active Workforce, which is the first report of its kind, focuses on the role that businesses, the fitness and leisure sector, business umbrella groups, the Government and the health sector can play in supporting employees of SMEs to be more active during work hours.

The Active Workforce report shows:

- The most popular physical activity opportunities among SMEs include the Cycle to Work scheme (39.7%), and physical activity challenges and competitions (22.1%).
- Measures offered by fewer businesses are those that involve more cost, such as providing access to private leisure facilities through membership (7.4%) or providing fitness equipment for employees (10.3%).

The report recommends that organisations in the fitness and leisure sector improve awareness among SMEs of existing services through targeted marketing, working with UKactive to showcase the sector's offer. It encourages fitness providers to integrate physical activity into 'holistic wellbeing packages' for businesses, as well as offering hybrid models of delivery.

Recommendations for employers:

- Give employees time to be active at work – for example, through flexible working or scheduled breaks between meetings to allow for movement.
- Role-model workplace physical activity from senior leaders alongside providing verbal and/or policy permission for employees to be active.
- Keep workplace physical activity simple and social, and implement ideas that are co-created with employees and that allow them to connect and socialise.

Huw Edwards, CEO of UKactive, commented: "If the Government is serious about doing more to look after the workforce, drive productivity, and reduce health inequalities, it must make radical changes to how we support and incentivise physical activity.

"By simply extending the Cycle to Work scheme to include other health-related products such as gym memberships and fitness equipment we could turbocharge our nation's workforce." To read or download The Active Workforce report click here.

UK audit framework to be strengthened

ACTING IN response to a series of large corporate failures that have led to job losses and uncertainty over the last few years, the Government set out plans to strengthen the UK's audit and corporate governance framework.

One aim of the changes is to ensure that all of the main parties who play a role in financial reporting can be, and are, held to account if they fail to fulfil their responsibilities. It proposes to establish a strong independent regulator, the Audit, Reporting and Governance Authority (ARGA) and to make directors accountable for significant failures in their corporate reporting and audit-related duties. Auditors will be held to high standards under the new regulator, and professional bodies will be subject to better oversight by ARGA.

Large companies will have to report in a more comprehensible way on their resilience and on how far their reporting is independently assured and for the first time large private companies' corporate reporting and audit will be subject to the same scrutiny as that of listed companies.

The government has announced it will put measures in place to provide reliable corporate reporting and greater resilience and choice in the audit market, but will reduce regulation for smaller entities caught by requirements of retained EU law.

The government says it will 'set market participants the challenge of shaping their own future through the assurance they commission, the skills and opportunities made available to audit professionals, and the relationships forged with the new regulator'.

Summary of key proposals:

- Extending the definition of "Public Interest Entity" to increase scrutiny of large unlisted companies;
- The introduction of a stronger internal control framework for companies;
- Improving transparency around dividends and capital maintenance;
- New corporate reporting, particularly a Resilience Statement and an Audit and Assurance Policy;
- Making directors of PIEs accountable to the regulator for failures in carrying out their duties;
- Measures to ensure companies' audit committees properly safeguard shareholders' interests;
- Improving the supervision of audit quality;
- Creating, funding and governing a new independent regulator, ARGA, to replace the FRC;
- More effective arrangements for the supervision of accountants and their professional bodies;
- Powers of the regulator for use in cases of serious concern; and
- Transfer of responsibility for arranging oversight of the statutory audit work performed by Auditors General from government to appropriate parliamentary bodies.

Federation of Small Businesses (FSB) National Chair Martin McTague said: "It's good to see BEIS grasping the nettle on audit reform. In order for the measures to work, there must be inclusion of payment practices within Audit Committees' remits. This reform would ensure a whole board awareness of payment practices. Without it, there will be more Carillions.

For more information click here.

Regulators, including HSE, are struggling post-Brexit, says NAO

EU EXIT has had a major impact on many UK regulators, says a new report from the National Audit Office. Many have taken on functions previously carried out by the EU and "they need to overcome many challenges if they are to manage the transition successfully.

"It is essential that regulators and policy-makers develop their future strategies as soon as possible to avoid wasting effort on short-term work and to ensure the decisions they make now meet their longer-term goals," the NAO says.

The report focuses on three regulators: the Health and Safety Executive, in its new role as the main regulator for chemicals in

the UK; the Food Standards Agency (FSA); and the Competition and Markets Authority (CMA).

All three regulators are finding it challenging to recruit the specialist skills they need. They have also lost access to data and information sharing arrangements with EU regulators, which they say has negatively impacted their ability to assess risks and carry out their work, the NAO says.

The Commons' Public Accounts Committee is holding a rapid inquiry following the NAO report.

Eligibility widened for Help to Grow scheme

COMPANIES CAN now send two senior managers onto the Help to Grow management programme which offers business leaders 50 hours of leadership and management training across 12 weeks, and includes mentoring from the likes of Santander, Google and award-winning mentor Herman Stewart.

Companies with ten or more employees can now have up to two participants join the scheme, and previous participants on the Small Business Leadership Programme will also now be eligible to join the scheme.

More information about the schemes and how to apply is available on the dedicated website and in the press notice on GOV.UK

Upcoming GAMBICA Webinars

The product innovation journey; minimising the risk of the great leap forward | 4 July 10.30am

A WEBINAR to help you identify developments which would improve your product's competition-beating qualities, while minimising risks. This complete run-through of how-to develop new products which meet customer needs and secure real market growth will be provided for GAMBICA's Business Growth Community by Cormac O'Prey of Kestrel Consulting. Cormac has many years' experience in engineering product design and now works mainly with the medical technology industry on developing innovative products in that highly regulated field.

Cormac will cover:

- How to generate ideas for product innovation;
- How to validate your ideas and produce and test initial designs; and
- How to move from design to production using an agile, flexible product development strategy.

He will also talk about how short, sharp, product re-design initiatives can help to combat supply chain issues and what risk assessments you should be doing now so that early action is targeted where it is most needed. To reserve your place click here.

Export licence applications – the dos and don'ts | 11 July | 10.30am

ADRIAN BOND of the Export Control Joint Unit will present a webinar for GAMBICA members to help them expedite export licence applications. Adrian will provide guidance on how to avoid the common pitfalls in licence applications, covering:

- What does and does not require a licence
- Common errors in licence applications
- How to ensure that your licence can be transferred speedily to other government departments if necessary
- How to make your application clear and unambiguous

We have also asked Adrian to run through the product description systems to help members identify where their equipment falls. To reserve your place click here.

Protecting your business from departing employees – Restrictive Covenants and Confidential Information | 12 July | 10.30 am

IN A world where employees 'jump ship' to join competitors or to set up competing businesses themselves, it is vital that employers know how to protect themselves from breaches (or potential breaches) of confidentiality or restrictive covenants.

Generally, the best way to protect organisations is to include confidentiality clauses and restrictive covenants at the time of employment. However, if an employee threatens the business by breaching post-termination restrictions, then while court action may be a last resort, injunctions can be a very powerful tool for limiting the damage. As speed can be key in these circumstances it's important to be prepared.

In this webinar Nick McQueen and Rebecca Jackson of legal firm Walker Morris will cover:

- Restrictive covenants and confidentiality provisions – what are they?
- What are the risks? Are your employment contracts robust enough?
- What can employers do in the event of a breach?
- In what situations is it appropriate to consider using an injunction?

The Walker Morris team of specialist lawyers are experienced in successfully advising clients throughout the entire process of business protection from drafting restrictive covenants,

obtaining interim injunctions through to enforcing injunctions and trial. To reserve your place, click here.

Events

Contamination and Geotech Expo | NEC, Birmingham | 14-15 Sept 2022

THE EXPO is set to welcome 3000+ visitors and 150+ exhibitors from across relevant sectors and runs alongside the Flood Expo and RWM & Letsrecycle Live, which together form the UK's largest event for the environmental sector with more than 12,000 visitors.

It will also offer free networking events, with an on-site pub, street food market and live music. Topics covered will include land remediation, brownfield regeneration, air quality, waste and contaminated water and hazardous materials. Conference level panel debates from independent experts on the latest innovations, thought leadership, legislation, and best practice will be complemented by:

- industry tailored, expert-led speaker content programme;
- using 5 new halls, completely refreshed and a bigger layout;
- expanded relationships with key industry partners; and
- increased data capture for exhibitors and opportunities for ROI.

To find out more and register your interest visit the website here.

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

BSBF2022 WILL be held at the Granada Congress Centre, the second edition of the single one-stop-shop for European companies and other stakeholders to discover more about Europe's Big Science organisations' future investments and procurements, worth €37million. Big Science organisations featured will include CERN, EMBL, ESA, ESO, ESRF, ESS, European XFEL, FAIR, F4E, ILL and SKAO.

During the event, a variety of parallel sessions and meetings will be held on areas such as electronics, ICT, instrumentation, mechanical components, cryogenics, magnets, remote handling and many more. For information click here.

Global Health Exhibition and Congress, Riyadh | 9-11 October 2022

UNDER THE patronage of the Saudi Ministry of Health, Global Health Exhibition claims to be the largest annual gathering of healthcare professionals in the Kingdom of Saudi Arabia. This year Global Health Exhibition and Congress will return as a live, in-person, event at the Riyadh International Convention and Exhibition Centre (RICEC).

To book exhibition space contact: sales@gloablhealthsaudi.com

BioTechX, Basel | 8-10 November 2022

THE BIOTECHX event runs across three days and features 400 speakers in 17 'tracks'. The event is free to attend for the first 400 pharma, academic and healthcare staff. Panel discussions include enabling access to healthcare data while protecting privacy.

For information click here, to visit click here.

Orphan Drug Congress | Sitges Near Barcelona | 14-17 November 2022

THIS CONGRESS offers three days of knowledge exchange and networking. Confirmed speakers include:

- **Magali Taiel,** Chief Medical Officer, Gensight BiologicsKeir Fitch
- **Thomas Bols,** Head of Government Affairs and Public Policy, EMEA & APAC**,** PTC Therapeutics
- **Fleur Chandler,** Head of Market Access UK and Ireland, Sanofi
- **Diego Ardigò,** Head of R&D, Global Rare Diseases, Chiesi group

For information click here.

Maximising Returns from Life Science Innovation, London | 4-8 December 2022

LIFE SCIENCE body, One Nucleus, is running its annual conference, genesis 2022 on 7 December with fringe events taking place from 5-8 December.

The programme includes:

- A keynote programme covering winners and losers 2022, innovative deal making, technology-driven diversity in life sciences, a house debate and anatomy of a life science leader.
- Innovation workshops scheduled online around the in-person day.
- Online 1-2-1 partnering.
- An exhibition reserved for sponsors of the event.

For more information click here.

Export News

Analytica pleases exhibitors but showcases unappealing stats

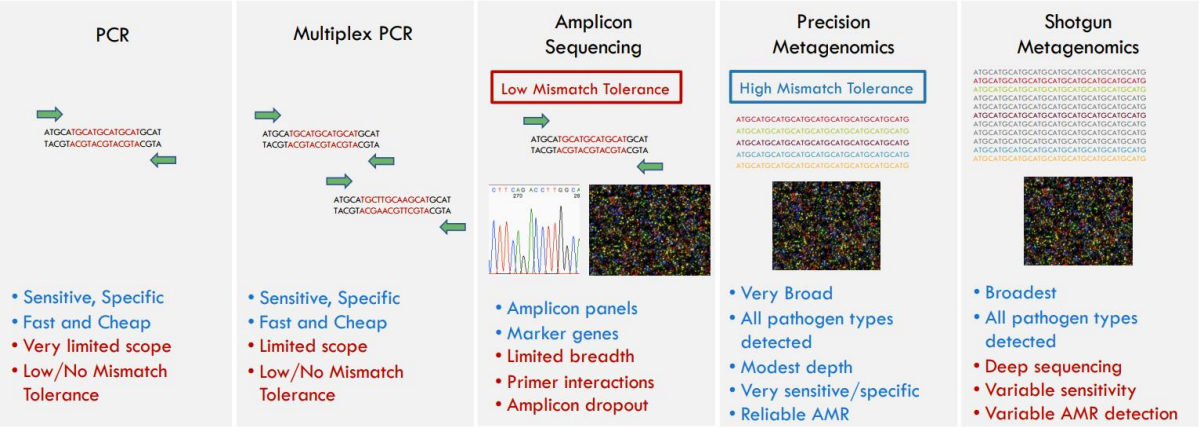
THE FIRST Analytica for four years took place in Munich in June and GAMBICA members attended in force, with ten companies in the GAMBICA pavilion and a further 12 on stands elsewhere in the six halls. The Chinese were, of course, notable by their absence with only those with staff already in Europe able to exhibit. There was only one single Chinese exibitor in Hall B1 where the infamous 'Great Wall of China' had been in previous years. Overall, exhibitors were down in numbers and visitor footfall was also 30% lower according to organiser, Messe Meunchen. Despite that, those who participated in the GAMBICA pavilion were generally happy with the event with most rating the event 7 or 8 out of 10 and all unanimous in their willingness

to re-book for the next one. Most felt they had seen end users or OEMs with serious intentions to buy and were looking forward to a real boost in sales from the event.

Three special areas were set aside on the exhibition floor for health and safety, digital innovation and a biotech theatre, as well as the more traditional – in depth conference sessions. The conference sessions did not seem overly well attended and certainly the subject matter seemed to cater for those in some of the smaller niches of research. A session on arsenic in mushrooms and truffles (it turns out there isn't much) was the very most appealing of the afternoon slots.

The future of biotech is – testing everything and testing quickly

Industry events running alongside the exhibition offered some interesting insights. At the meeting of the Analytical Life Science and Diagnostic Association (ALDA), Professor of personalised microbiology, Dr. John W. A. Rossen, a medical molecular microbiologist with seats at two Dutch and one American universities, talked about 'setting the standard for identifying and understanding microorganisms and their role in human disease and public health'. Having successfully implemented the use of next-generation sequencing for routine clinical microbiology and infection prevention Dr Rossen is now concentrating on applying metagenomics into clinical microbiology and public health. Metagenomics, the comprehensive analysis of microbial and host genetic material (DNA and RNA) in samples from patients, is rapidly moving from research to clinical laboratories. Although often considered too expensive, one study has shown that metagenomics saved a hospital with an MRSA outbreak £200,000 even though each test cost €202.49, because it allowed them to have better surveillance and identification of cases and avoid preventive isolation. Professor Rossen offered this snapshot analysis of the alternatives for testing.



Professor Rossen is also a consultant for IDbyDNA which has developed a wide panel PCR which detects over 40 pathogens and resistance genes. He described next generation sequencing as a first diagnostic one-stop-shop in clinical microbiology saying, "It can identify new variances and strains, type for source tracing, predict resistance, detect mutations and offer precise, culture free identification, quantification and characterisation of pathogens and AMR markers."

Every number tells a story

At the meeting of European Lab trade associations' umbrella group, Eurom II, the interest was all on sales figures and they told an alarming story.

German analysis, biotechnology and laboratory technology continues to recover and expects significant growth after a double-digit increase in sales in 2021. The German industry generated sales of 10.9 billion euros in the 2021 financial year, which corresponds to an increase of 12.5 per cent compared to the previous year. Foreign sales increased by 12.9 per cent and reached a value of 6.1 billion euros. Exports to the five most important target countries China, USA, Great Britain, France and Italy rose significantly, each with double-digit growth rates. The growth of exports to Great Britain was far higher than any other market however, **with exports to the UK having grown by over 30% in 2021**.

The German growth forecast was also positive with sales expected to increase by around seven per cent for the 2022 financial year, which would then correspond to total sales of 11.6 billion euros. "As expected, the German industry for analysis, biotechnology and laboratory technology was able to continue on its successful course this year. However, the Ukraine war, supply chain disruptions and rising material, energy and logistics costs are increasingly burdening the business and will leave their mark. In addition, internal work organisation and technical adjustments weigh on the margins," reported Mathis Kuchejda, Chairman of Analysis, Biotechnology and Laboratory Technology at SPECTARIS.

"Despite the many challenges, companies continue to look to the future with confidence. Many megatrends in the areas of health, nutrition, the environment and energy and, last but not least, digitisation are real growth drivers for our industry. However, in order for companies' expectations to be met, the export engine in particular must continue to run even in these difficult times. Tendencies towards national isolation must be resolutely counteracted," stresses Kuchejda.

The Analytica event was not all work…

It is clear that any trend towards reshoring or near shoring is seen as a huge threat by German industry which relies heavily on its ability to export.

Another threat which the industry is grappling with is rapidly rising costs of components and materials. MD of one mid-sized German company commented: "We are trying not to raise our prices even as our costs are going up, because we see that the prices of our Chinese competitors are not going up."

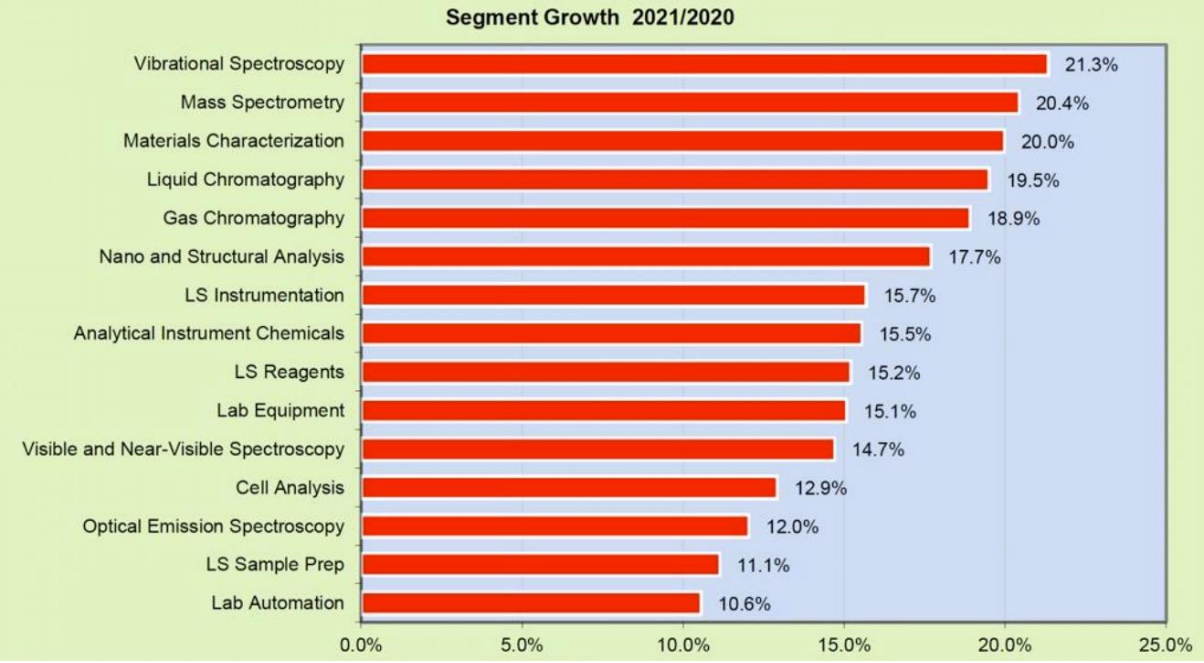
As well as doing a bit of sightseeing in Munich, GAMBICA members enjoyed the opportunity to visit a traditional beerkeller and sample German food and music.

The report on US sales indicated that demand in the fourth quarter of 2021 exceeded $16 billion, a growth of 8.6% on the previous period with spectroscopy and materials analysis having achieved double digit growth. Key graphs are included below from the US and Japanese association reports and their full powerpoints are available here.

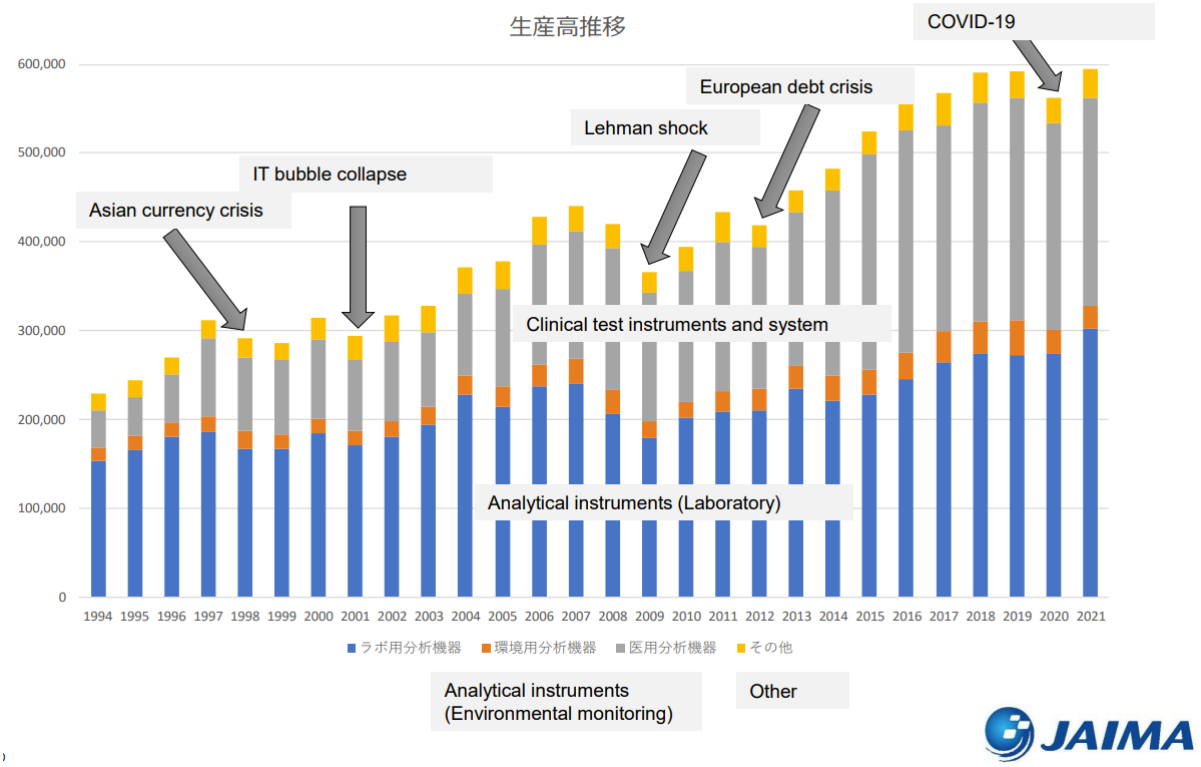
US twelve months revenue by product

$Mil	2021	2020	Growth
Spectroscopy and Materials Analysis	**16,959**	**14,490**	**17.0%**
Laboratory Equipment	3,466	3,012	15.1%
Materials Characterization	2,343	1,953	20.0%
Nano and Structural Analysis	5,882	4,997	17.7%
Optical Emission Spectroscopy	1,369	1,222	12.0%
Vibrational Spectroscopy	1,957	1,612	21.3%
Visible and Near-Visible Spectroscopy	1,943	1,694	14.7%
Chrom, Mass Spec & Automation	**17,799**	**15,147**	**17.5%**
Gas Chromatography	2,887	2,428	18.9%
Laboratory Automation	4,026	3,642	10.6%
Liquid Chromatography	6,138	5,135	19.5%
Mass Spectrometry	4,748	3,943	20.4%
Life Science	**21,546**	**18,873**	**14.2%**
Cell Analysis	1,608	1,424	12.9%
Life Science Instrumentation	4,897	4,233	15.7%
Life Science Reagents	9,982	8,664	15.2%
Life Science Sample Prep	5,059	4,552	11.1%
Analytical Chemicals	**2,563**	**2,218**	**15.5%**
Total	**58,868**	**50,728**	**16.0%**

US report on segment growth



Japanese analytical instruments production trends



Merck to build €440m facility in Ireland

LIFE SCIENCE company Merck is to expand its existing premises in Cork at a cost of €440 million. A €290m expansion to the company's plant at Carrigtwohill which will add a module for the immersion casting of membranes to support gene therapies, virus sterilisation etc, follows a €36m investment at the same site in 2021, which was used to produce rapid diagnostic testing for tropical diseases such as dengue fever, malaria and ebola.

At Cork's Blarney Business Park, Merck will also build a €150m filtration manufacturing facility. Work on the two projects is due to be completed by 2027 and will create 370 permanent jobs.

Matthias Heinzel, chief executive of Merck Life Science division, said: "The investment in Cork is the biggest site investment in the history of our life science business and will accelerate the delivery of the critical products, technologies and services our customers need to fight the world's toughest health challenges, including Covid-19."

AI raises 'challenges' with existing product liability law, study finds

UK PRODUCT liability laws need to be updated to address the use of artificial intelligence (AI), according to an expert at law firm Pinsent Masons. Katie Hancock says the UK risks being left behind unless reforms are implemented soon, with the European Commission expected to put forward proposals for new EU legislation on AI liability.

Hancock was commenting after a study commissioned by the Office for Product Safety and Standards (OPSS) found that the use of AI in consumer products can "challenge the regulatory framework for both product safety and liability".

Hancock said: "The publication by the OPSS of this report serves to highlight the fact that legislation is struggling to keep pace with technological development. The General Product Safety Regulations are now 17 years old, and the Product Liability Act is 35 years old. Neither was developed with modern smart or digital products in mind."

"The European Commission recognises the unsuitability of product liability and safety legislation for the digital age and is currently considering an overhaul. The UK has launched its own call for evidence seeking views on possible changes to its product safety regime, including in relation to artificial intelligence, but it risks being left behind if it does not move quickly," she said.

Researchers at the Centre for Strategy and Evaluation Services (CSES), commented:

"More complex AI systems, as well as general technological and market changes, challenge many of the definitions detailed in laws. More specifically, it is not clear to what extent these developments fall within the existing definitions of product, producer and placing on the market, as well as the related concepts of safety, harm, damages, and defects."

"Furthermore, the characteristics of AI systems, the general trends highlighted, and the lack of clarity around the applicability of existing legal definitions and concepts, bring additional impacts. These include a lack of legal certainty for economic operators involved in the manufacture of AI driven consumer products, as well as a need to improve the skills and knowledge of regulatory bodies, such as MSAs and conformity assessment bodies, on AI systems."

EU legislators are currently scrutinising proposals for a risk-based approach to the regulation of AI systems on a cross-sector basis. The EU AI Act is separate to potential reforms to EU product liability laws to account for the use of AI that are also under consideration.

EU life sciences industry raises concerns raised about full application of IVDR

THE NEW EU In Vitro Diagnostic Regulations (IVDR) came into force in May 2022 requiring assessment of about 70% of IVDs placed on the market for the first time, a new risk classification system, updated clinical evidence requirements, a new post-market system, a new database enabling more transparency (EUDAMED), and a unique device identification system facilitating supply chain traceability.

The IVD Regulation was amended in January 2022 and granted most IVDs – depending on their risk class – three to five more years to transition to the new Regulation if they comply with certain conditions, but some key pillars of the regulations are still not fully operational or even in place according to Med Tech Europe the European Association for the med tech sector.

"The amendment has not addressed all challenges", says Serge Bernasconi, CEO of MedTech Europe, "and the incomplete IVDR infrastructure poses critical ongoing risks that need urgent resolution to make the regulatory systems fully operational to certify the highest risk IVDs and companion diagnostics (including those needed to manage infectious diseases and diagnostics to support personalised medicines)."

In addition, concerns have been raised that there is insufficient Notified Body capacity to support certification of all IVDs and reduce the long and unpredictable certification timelines currently being experienced.

"Until these challenges are resolved, the IVD Regulation will not constitute a sufficiently predictable and reliable pathway to certification of needed medical tests. Such challenges need ongoing attention and work by the EU Commission and Medical Devices Coordination Group, if Europe is to ensure a workable system both today and over the longer term.

The EU Medical Devices Regulation (MDR) has been in full application for 12 months but here too, concerns have been raised. According to Jörg Mayer, Managing Director of the German industry association SPECTARIS: "The system for implementing the MDR is still not fully operational. A joint survey by SPECTARIS with the Association of German Chambers of Commerce and Industry (DIHK), of 378 German manufacturers of medical devices, after the MDR came into force, shows that the regulation is not practical in many places and that the first negative effects are already appearing. Medical products from numerous fields of application, such as orthopedics or classic surgical instruments, are being taken off the market. Corporate innovation is suffering. Practicable solutions are required as soon as possible in order to continue to ensure access to innovative medical products that have been tried and tested over many years.

You can access the joint survey on the MDR in German here.

Free trade areas targeted by organised crime

GOODS PASSING through free trade zones are a growing risk in terms of organised criminal activity, including the trafficking of banned goods, money laundering and sanctions evasion, according to a report by the International Coalition Against Illicit Economies (ICAIE), a non-government organisation headquartered in Washington, DC.

The development of free trade zones has accelerated rapidly, of the 3,500 areas in operation today, including free ports and special economic zones, nearly a third were established in the last five years. Their direct trade-related value has been estimated at over US$500bn by the International Chamber of Commerce.

However, the regulation and supervision of free trade zones has “not kept pace with the rapidly changing global supply chains and ‘just-in-time’ delivery strategies” according to the ICAIE. As a result, the report says, criminals are able to exploit them as a means of abusing containerised shipping to move illicit goods or funds across international borders.

“Kleptocrats, criminal organisations, terrorist groups, and their enablers exploit networked hubs of illicit trade centred on free trade zones, ports, and other logistical channels of transportation, communications, and trade,” says ICAIE executive director David Luna.

“This allows illicit networks – such as the Chinese triads, Mexican cartels, Primeiro Comando da Capital and Hezbollah – to profit from an array of criminal activities and corrupt institutions, drain resources for economic development, and compromise the integrity of supply chains.”

One issue is that goods passing through free trade zones are often subject to “mutations”, such as assembly, manufacturing, processing, warehousing, repackaging and re-labelling. Those goods can then be imported into the free trade zone’s host country, or re-exported elsewhere.

Groups involved in counterfeit and pirated goods use this process to “conceal the illicit provenance of their products”, ICAIE says. It adds that as much as 3.3% of international trade involves such goods.

“Through illicit commerce and the abuse of maritime containerised shipping, counterfeits, illicit goods and contraband are flooding markets across the region through free trade zones,” the report says and criminal groups increasingly control “critical strategic infrastructure” at ports and free trade zones.

“Ports across the Americas continue to be exploited or remain vulnerable to transnational criminal organisations that corrupt officials and strategically use maritime shipping as logistical platforms to move tens of billions of dollars worth of narcotics, precursor chemicals, opioids, counterfeits… illegally-poached wildlife, illicitly-harvested timber and other goods,” it says.

For example, ICAIE says cocaine cartels wield influence over several seaports in Mexico, such as Lázaro Cárdenas, Manzanillo and Veracruz, enabling the movement of drugs and precursor chemicals into the US and beyond.

At the same time, the report warns China’s Belt and Road Initiative has created opportunities for Chinese criminal organisations to carry out trade-based money laundering through free trade zones in the Americas.

Chinese entities controlled all or some of 37 ports across Latin America in 2019, including nine in Mexico, four in Brazil and three in Argentina, according to an investigation by IBI Consultants, an investigative consultancy focusing on the Americas.

“In many cases, local law enforcement is not authorised to inspect anything in the Chinese-controlled port areas, and in multiple cases from Puerto Cortes, Honduras to Iquique, Chile ship manifests have been found to contain false declarations of items imported,” ICAIE says.

“For example, one manifest declared that a ship was carrying four tons of tomatoes from China to Honduras in an unrefrigerated hold, something both impossible and economically irrational. In that case the ship actually carried barrels of unidentified chemicals that were offloaded without passing through customs.”

Goodbye CHIEF

HMRC HAS written to traders imploring them to act now to move to the Customs Declaration Service, warning they may not be able to continue trading if they do not move to the Customs Declaration Service in time. After 30 September 2022 the Customs Handling of Import and Export Freight (CHIEF) system will close for import declarations, and these will need to be made on the Customs Declaration Service. The ability to make export declarations will end and the CHIEF service will close on 31 March 2023.

Businesses which use more than one customs agent or fast parcels operator will need to contact everyone who makes import and export declarations on your behalf because new instructions/authorisations will be needed.

A free **Trader Dress Rehearsal service** is available so businesses can practise making declarations on the Customs Declaration Service.

For more information visit the **Customs Declaration Service** on **GOV.UK**, which offers a **Customs Declaration Service toolkit and checklists**.
