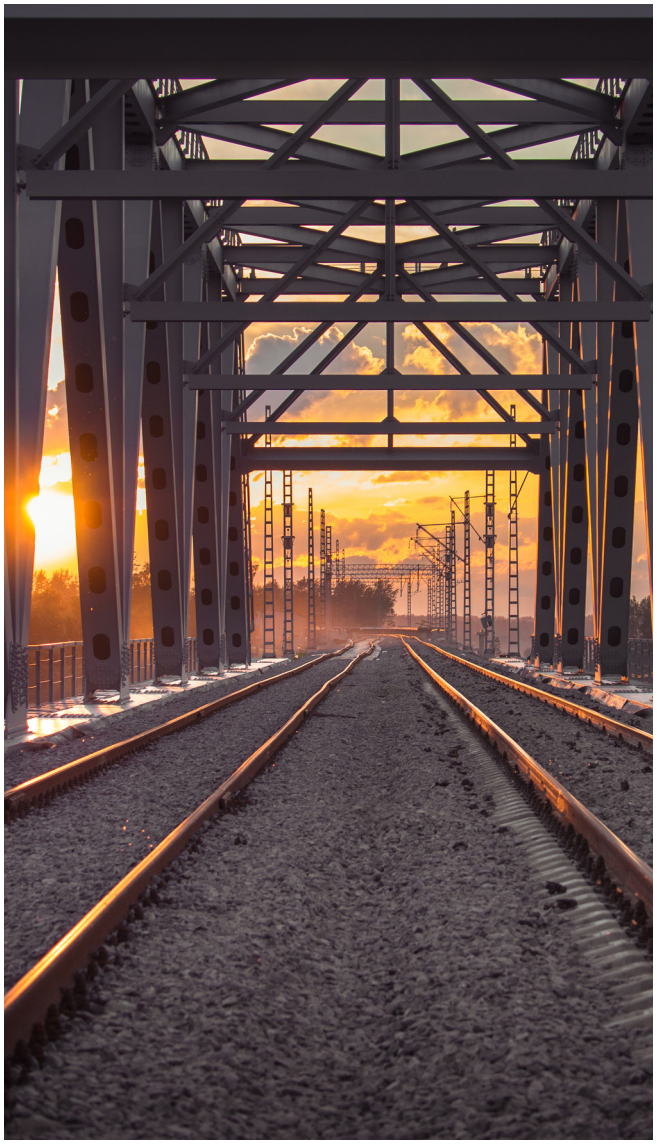
SQUIRE PATTON BOGGS

Local Connections. Global Influence.

frESH Law Horizons

August 2021



UK

Operators of an international rail freight terminal have been fined £6.5 million after the death of an 11-year-old boy. The Office of Rail and Road (ORR) press release reports that ORR prosecuted the operators after the boy and his friends gained access to a depot to retrieve a football. After climbing on top of a stationary freight wagon, the boy received a fatal electric shock from the overhead cables. The company was found guilty of two offences under the Health and Safety at Work etc. Act 1974 (HSAW Act) and at trial, the court heard how the company had failed to assess the risk of unauthorised access to the terminal and failed to implement appropriate measures to prevent unauthorised access to parts of the site where frequent freight movements took place and overhead line equipment could be found. The Chief Inspector of Railways concluded that "the railway industry has done some excellent work in preventing trespass and educating children about the risks, but this case serves as a reminder that should access to the railway not be properly controlled, serious events like this occur."

In *R v Jones*, the Court of Appeal held that a settlement agreement was not an unequivocal statement against private prosecution. The Court of Appeal dismissed an appeal against conviction, finding that the judge had been correct in rejecting the defendant's submission that the private prosecution was in breach of an undertaking contained in a settlement agreement and held that material that was obtained in a type of disclosure order (a Norwich Pharmacal order) could be used against the defendant. While it was recognised that it was an abuse of process to prosecute a defendant for conduct in respect of which they had been given assurances that no prosecution would be brought, it would still depend on all the circumstances of the case and the question would be whether the circumstances are such as to "render the proposed prosecution an affront to justice". Further, the settlement agreement in question only concerned civil proceedings and did not promise immunity from criminal prosecution.

The Law Society has published a revised practice note to clarify the status of legal professional privilege (LPP). On 12 August 2021, the Law Society published the revised note, which, as well as clarifying the status of LPP, looks to explain the main principles of LPP and explores particular contexts in which the rights conferred by LPP are asserted. The practice note confirms that where a claim to privilege is justified, solicitors and their clients should not, in any way, be criticised or penalised for asserting LPP, nor should they be regarded as being uncooperative. The note also contains guidance on communications between foreign in-house lawyers and their clients, waiver and the crime-fraud or iniquity exception to privilege.

The UK government announced an extension to the grace period for the mandatory use of the UKCA mark. Previously, the grace period ran up to 1 January 2022, at which point it became mandatory to include the UKCA mark on a label or accompanying document. However, the extension means that businesses will now have until 1 January 2023 before the UKCA mark becomes mandatory.

The Office for Product Safety and Standards (OPSS) has published a revised version of product safety and non-compliance notification guidance. On 9 August 2021, the OPSS issued the guidance on how local authorities should notify products that pose a risk to the health and safety of consumers or are non-compliant. The revised guidance, among other things, outlines the notification requirements for Great Britain and Northern Ireland under the applicable Regulations on Accreditation and Market Surveillance, along with the relevant product-specific legislation and the General Product Safety Regulations. Typically, UK market surveillance authorities that regulate product safety will continue to use the RAPEX risk assessment methodology to assess the risk posed by an unsafe product. However, since the end of the Brexit transition period, requirements and procedures for reporting unsafe and non-compliant products, as well as market surveillance outcomes, have changed. Notifications should be made to the Product Safety Database (PSD). OPSS will fulfil obligations to report information, where required, to other countries (EU and non-EU) through ongoing monitoring of new PSD cases.

The Chartered Trading Standards Institute (CTSI) has published a guide for businesses on identifying and dealing with vulnerable customers. The guide is designed to help businesses identify and assist customers who are vulnerable so that they can give the appropriate level of support. The guide also offers best practice guidance for businesses to consider, including, among other things, (i) implementing a vulnerable consumer policy, (ii) offering as wide a range of communication methods as possible, (iii) training all staff to understand the nature and scale of vulnerability that may exist and providing them with the right skills to respond and deal with a range of vulnerabilities, and (iv) considering vulnerable consumers at all stages of the product or service design process. Although this guidance will not have the force of law, it will likely be persuasive to enforcement authorities and, therefore, taken into account by such authorities when determining whether commercial practices are unfair. It may also be relevant to considerations of whether a product is unsafe, where the categories of consumers at risk when using the product, in particular children and the elderly, is one of the matters taken into account.

A consultation on the surveillance camera code of practice will run until 8 September 2021. The current surveillance code of practice was issued under section 30 of the Protection of Freedoms Act 2021 and provides guidance on the appropriate use of surveillance cameras by local authorities and police. The proposed revisions make reference to subsequent legislation such as the Data Protection Act 2018 and the judgment in *Bridges v South Wales Police*. A grid of amendments has been produced, which includes the particular amendment/deletion/addition along with the rationale for the change.

A waste management company was fined £150,000 and the managing director was sentenced to six months' imprisonment (suspended) after a worker was hit by a 21-tonne loading shovel. An employee of the company was waiting for his lorry to be re-loaded when he was struck by the shovel. According to its press release, the Health and Safety Executive (HSE) found the company and its managing director had failed to take reasonable steps to make sure that there was adequate pedestrian segregation. Due to previous workplace transport incidents, the directors were considered to be aware of the risks, to have failed to respond appropriately and to have continued to ignore the advice of their health and safety consultant and the HSE. The company pleaded guilty to breaching provisions requiring every workplace to be organised in such a way that pedestrians and vehicles can circulate in a safe manner (regulation 17(1) of the Workplace (Health, Safety and Welfare) Regulations 1992). The managing director pleaded guilty under the provisions of the HSAW Act determining that when an offence has been committed by a body corporate, which is proven to have been committed with consent or can be attributed to any neglect on the part of a director, he, as well as the body corporate, shall be guilty of that offence. The press release is a reminder that courts do sentence company directors, as well as corporate entities, in appropriate cases, and it is also a reminder that they will take into account expert advice received, but not followed.

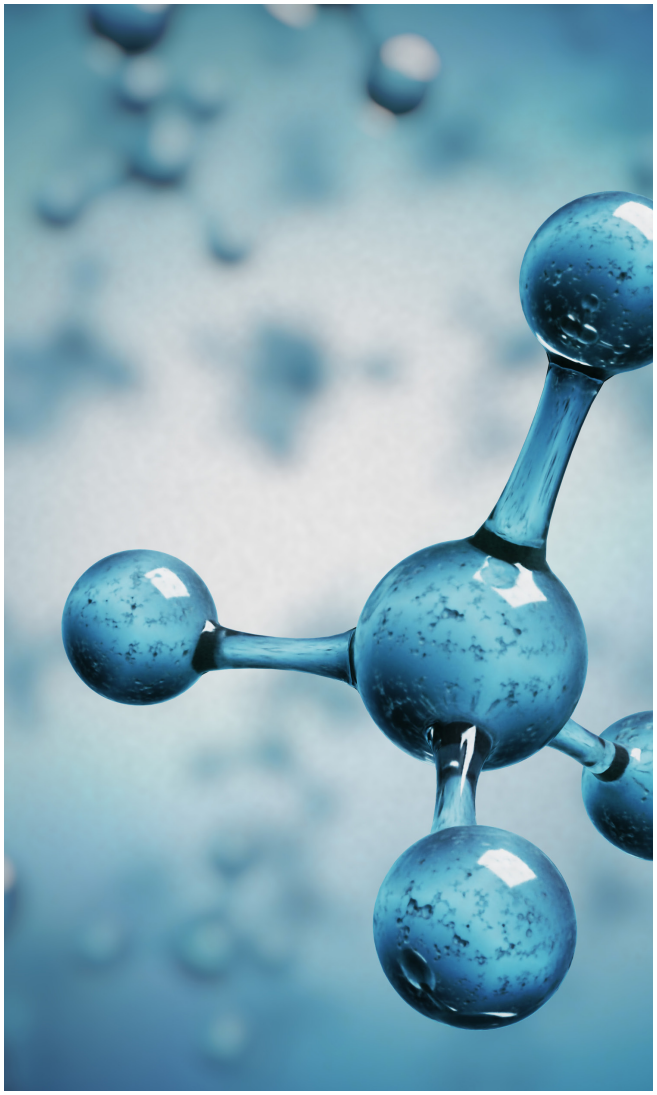
The Advertising Standards Agency (ASA) requests advertisers make better use of audience and media targeting tools for advertising age-restricted products. The ASA published its Monitoring and Enforcement report at the end of July. In that report, it assessed the distribution of advertisements for products such as alcohol, gambling and high fat, salt and sugar (HFSS) products on websites where adults comprise more than 75% of the overall audience. Even though the majority of those using these websites were adults, the ASA called on marketers to make better use of audience and media targeting tools to minimise children's exposure to age-restricted advertisements. In undertaking their research, the ASA used age-categorised avatar technology to act as laboratory proxies for their respective online audiences. A key finding of the report was that gambling and HFSS advertisements were served in broadly similar numbers to the child and adult avatars.

A confectioner issued a product recall after an ingredient was found to contain a genetically modified organism (GMO). Trade press reports indicate that the GMO is not authorised for the ingredient in question in the UK, prompting the decision to recall the relevant product range. Recalls for unauthorised GMOs are relatively rare, but any food that is marketed for consumption by humans and animals and contains a GMO must be authorised under a (retained) EU Regulation on genetically modified food and feed, with such authorisation being valid for a maximum of 10 years. Following Brexit, there is now a list of authorised GMOs for Great Britain specifically, and applications for approvals of GMOs in Great Britain are through the Food Standards Agency's (FSA) regulated products application service. The approach to the application process is based on the EU process for authorisation. For GMOs authorised by the European Commission before 1 January 2021, the authorisation will remain valid in Great Britain as part of the Brexit arrangements.

The FSA published its research into international approaches to the regulation of genetically modified (GM) and novel foods. The report aimed to capture the different regulatory approaches to GM and novel foods. It concludes that countries such as Japan and the US have no equivalent regulatory concept for novel foods, unlike Australia and Canada, which have a regulatory regime more closely aligned to the EU. With regard to GM foods, the report concluded that only the EU and Australia place emphasis on how a product is produced, whereas countries such as Argentina, Canada and the US may not define a product as a GM food if it is substantially equivalent to a product developed through conventional methods. The report also considered the different approaches to labelling food with its GM content, noting that Argentina and Canada have no mandatory requirements unlike the EU, Australia, Brazil and now the US (for bioengineered food).

Gower Salt Marsh Lamb receives protected status after becoming the first food registered under the independent (post-Brexit) UK Geographical Indication (GI) scheme. The meat produced from lambs born and reared on the Gower Peninsula has gained full protection and recognition as a Protected Designation of Origin (PDO). The protection means that producers will benefit from protection against imitation.

House of Lords Sub-Committee publishes its introductory report on the Northern Ireland Protocol. The report, prepared by the sub-committee, assesses the operation of the protocol, its economic, political and social impact, and possible mitigations and solutions. It concludes that both the UK and the EU need to urgently agree practical steps to ensure the proportionate application of the protocol. It notes that the search for solutions has been hampered by flaws in the UK and the EU's approach, which has led to a mutual lack of trust. In practice, the operation of the protocol has led to reported complications and delays with getting products from Great Britain into Northern Ireland.



An Irish government agency report claims that post-Brexit trade frictions have "significantly altered" the flow of traffic between Great Britain and the Republic of Ireland. The report gives an insight into how Irish businesses have adapted their practices when exporting to the EU and how Irish importers and exporters have reconfigured their supply chains post-Brexit. The report claims that Irish importers and exporters benefited from a significant increase in choice of direct EU services in 2021. The trends listed in the report are said to be underpinned by the new customs and trading arrangements between Ireland and the UK that came into force on 1 January 2021.

Updated guidance is published regarding pre-notification requirements on imports. Under the Official Control Regulations, there is a requirement for traders to pre-notify at least one working day before the expected arrival of a consignment into Great Britain. However, there is now a derogation under the regulations that allows for this requirement to be reduced to not less than four hours before the arrival where logistical constraints would prevent compliance. It is a matter for the competent authority at the Border Control Post (BCP) to apply the derogation and set the necessary pre-notification time. Updated guidance, however, states that from 1 October to 31 December 2021, businesses will be able to self-apply the derogation for pre-notification of consignments into Great Britain. This means that products of animal origin, animal byproducts and high-risk foods not of animal origin imported from the EU to Great Britain can notify no less than four hours in advance of arrival at any point of entry without the requirement to attend a BCP. From 1 January 2022, importers will need to contact the relevant competent authority at the point of entry to be able to determine if, and by what degree, a derogation from 24 hours can be applied.

The government published the first UK hydrogen strategy. As set out in the 10-point plan for a green industrial revolution, the government, working with industry, is aiming for 5GW of low-carbon hydrogen production capacity by 2030 for use across the economy. This could be equivalent to the amount of gas consumed by more than 3 million households in the UK each year. This new strategy outlines how the UK will rapidly and significantly scale up production and lay the foundations for a low-carbon hydrogen economy by 2030 and how government will support innovation and stimulate investment in the 2020s to scale up low-carbon hydrogen. It sets out a twin-track approach to supporting both electrolytic "green" hydrogen (produced from renewable sources) and "blue" hydrogen (derived from fossil fuel but with carbon capture) production, alongside other potential production routes. The strategy includes a comprehensive road map for the development of the wider hydrogen economy over the 2020s to deliver the government's 2030 5GW ambition. Alongside the strategy, a number of associated documents have been published, including a Consultation on a Hydrogen Business Model and a Consultation on a UK Low Carbon Hydrogen Standard. The publication of this document has provoked significant debate and disagreement about the relative merits of blue and green hydrogen, including a peer-reviewed report called How green is blue hydrogen? and this blog from SINTEF Energy, presenting contrasting views on the subject.

The Intergovernmental Panel on Climate Change (IPCC) published a significant report on the physical science basis of climate change. The IPCC published its Working Group 1 report, Climate Change 2021: the Physical Science Basis, as the first part (of four) of the IPCC's Sixth Assessment Report. As the name indicates, this report looks at the physical science of climate change, and future parts will focus on climate impacts and adaptation, as well as mitigation, and then a final report to draw it all together in late 2022. The headlines from the report are that "climate change is widespread, rapid and intensifying", this is "code red" for humanity and that it "must sound a death knoll for fossil fuels". The IPCC says it is unequivocal that human activity is responsible for global warming and that limiting warming to close to 1.5 degrees Celsius, or even 2 degrees Celsius, will be beyond reach unless there are immediate, rapid and large-scale reductions in greenhouse gas emissions. This report will be a critically important scientific input into COP 26 in Glasgow later this year, but also puts further pressure on governments to act and legislate in this area, as well as on corporates to take action. It also potentially provides further support for climate litigation.

First UK REACH authorisation decisions are published together with a database. The HSE has published a database containing a full list of applications for authorisation (for the use of substances of very high concern (SVHCs) on the authorisation list to continue temporarily) received by the HSE, including links (where applicable) to the HSE's opinion and the decision made by the secretary of state, and a full list of authorisations that have been carried over ("grandfathered") from EU REACH. It has also published the first decisions granting authorisations under UK REACH to PPG Industries (UK) Ltd, Boeing Distribution (UK) Inc, Wesco Aircraft EMEA, LTD (UK) and Ortho-Clinical Diagnostics.

The HSE has opened a call for evidence on the proposed restriction of lead in ammunition. HSE is working with the Environment Agency (EA) to prepare a UK REACH restriction dossier that will assess the risks of lead in ammunition. HSE will propose restrictions, if these are needed, to manage any significant risks identified. HSE's call for evidence invites interested parties to respond with general information and on some specific topics. The finalised dossier, including any restriction proposal, will be published on HSE's website, expected to be in April 2022. Interested parties will then be able to submit comments on any proposed restriction.

A noise nuisance claim from a new holiday development against an existing MoD aircraft fails. In the case of *Jones and another v Ministry of Defence*, the claimant sought to change the use of land on Anglesey from water treatment/agricultural to a holiday park, and issued a nuisance claim against the MoD regarding the noise of jets regularly flying in the area associated with RAF Valley. While this decision does not remove the possibility of a "newcomer" being able to claim that a pre-existing activity causes a nuisance, in this case the judge found that there was no actionable nuisance, nor any breach of human rights. He concluded that this aircraft noise had been part of the local environment for generations, and he also considered that the claimant's change of use of their land to something more sensitive to this noise was a relevant factor. The judge said that "If an occupier of land has conducted an activity in a reasonable manner for many years, I do not consider it fair that a new neighbour who wishes to start doing something that is sensitive to the occupier's activity can complain that the activity in question will disrupt the sensitive use of his land that the neighbour wishes to introduce."

Natural Resources Wales (NRW) launched a public consultation on the proposed reforms to its Enforcement and Sanctions Policy. The proposed changes are intended to clarify how NRW will engage with individuals and businesses to educate and encourage compliance through good working practices, placing the protection of the environment as the priority. NRW's review of this policy and associated guidance considers legislative changes for its core purpose, its new organisational structures, clarity on the use of civil sanctions (where NRW has those powers) and accessibility requirements, for publishing as a series of webpages. The consultation closes on 27 September 2021.

The EA published a press release and a consultation on the reform to charges for abstraction licences. England is facing increased pressure on its water resources due to population growth and climate change, and the EA says that action is needed to avoid significant water shortages in parts of the country. The new proposed charges, which have not changed for the past 10 years, will be based on volume taken, location and the amount of water returned. Around 45% of abstractors will see their annual charges decrease and 55% will see an increase. Overall, three-quarters (75%) of all abstractors will see either a decrease or an increase of less than £100 in their charges. There will also be a higher initial application fee. The consultation closes on 10 November and companies that are going to be directly affected should also have received a letter from the EA.

The Department for Business, Energy and Industrial Strategy (BEIS) published guidance for ultra-small emitters (USEs) on opting out of the UK Emissions Trading Scheme (UKETS). Operators can opt out of UKETS if their installation emits less than 2,500 tonnes of carbon dioxide equivalent (CO_2eq) in the relevant period. To opt out, a USE will need to register its installation and continue to monitor its emissions and notify the regulator if emissions exceed the agreed threshold. This guidance explains how to register aninstallation as a USE, how to comply with emissions targets as a USE and what to do if an installation no longer qualifies as a USE.

The prosecution of an electrical recycling company includes a charity donation. The company (Environcom) was prosecuted for breach of its environmental permit, and pleaded guilty. It was only fined £100, and agreed to donate £20,000 to the Lincolnshire Rivers Trust, but was ordered to pay £35,000 in costs to the EA. This is a very unusual outcome, as donations of this nature are usually associated with enforcement undertakings (EU), rather than with prosecutions. Based on subsequent reports about the case, it appears that an EU may have originally been offered but rejected, although it is not clear why this donation was brought back into the prosecution proceedings. The company's view was that the case should never have been brought: "This took place five years ago and resulted in no environmental impact, this should never have come to court. Such was the judge's view on this matter that he awarded a nominal fine. The company only pleaded guilty to a technical breach of permit." It was also reported that four other offences to which the company had pleaded not guilty had been withdrawn by the EA before the court hearing.

Government proposes a biodiversity amendment to the Environment Bill. The government has tabled new amendments, including strengthening the duty to set a legally binding target to halt species decline by 2030. The government says that this new amendment reflects the prime minister's pledges during the UK's leadership of this year's G7 summit and will enable the UK to meet its ambition to make this "world-leading target" the nature equivalent to the net-zero target. Other amendments proposed include a new requirement for water companies to monitor the water quality impacts of their sewage discharges and publish this information, and to publish near real-time information on when their storm overflows operate. These measures are intended to drive action by water companies to reduce sewage discharges that do the most harm, to better protect the environment and public health. A further safeguard for the independence of the new Office for Environmental Protection (OEP) is also proposed, by requiring greater parliamentary scrutiny of any guidance issued to the OEP.

Government announces it will consult on banning a range of single-use plastic in England. This autumn, a consultation will be launched regarding a potential ban on a range of single-use plastics, including plates, cutlery and polystyrene cups (the announcement refers to these items as being "among a raft of items that could be banned" – it seems we will need to wait for the consultation to see the full list). The EU's single-use plastics directive (SUPD), which came into effect in July 2021 with a number of product bans and labelling requirements, does not apply in Great Britain, although it will be implemented in Northern Ireland with a slight delay, in January 2021. Wales and Scotland have already proposed their own single-use plastic bans, which cover similar ground to the SUPD. England's plans are, therefore, long-awaited, and it will be interesting to see how closely, or not, they mirror the SUPD.

EU

The European Commission discusses implementation of the SUPD with member states. The commission made available the summary record of the most recent meeting of its Waste Technical Adaption Committee in June. The commission replied to multiple questions from the member states' representatives in that comitology committee with regard to the implementation of the Single-use Plastics Directive 2019/904 (SUPD), the commission's guidelines on the scope of the SUPD and Implementing Regulation 2020/2151 on marking specifications. The commission also stated that it distributed the first draft on the implementing act on reporting and quality checks of post-consumer waste from tobacco filters to the member states for written comments. Regarding the calculation and reporting of the consumption reduction target for single-use plastic food containers and beverage cups, the commission said that it would propose an approach based on the weight of plastic (including coatings) contained in those products in order to ensure consistency with the reporting under Packaging and Packaging Waste Directive 94/62. Reporting additionally on item count will be optional. This will likely motivate member states to focus on reducing the weight of plastic in these products. In addition, the commission made available the draft of an explanatory document concerning the concept of "placing on the market" in the SUPD in view of its Blue Guide on the implementation of EU product rules.

Member states vote on rules on the separate collection of single-use plastic beverage bottles. The member states' representatives in the Commission Committee on Waste delivered a positive opinion on the draft implementing act, laying down rules on the calculation, verification and reporting of data on the separate collection of waste single-use plastic beverage bottles. Twenty-six member states voted in favour and one against. The commission implementing act under the SUPD is addressed to member states to ensure the comparability of this data across the EU. The SUPD provides that member states must collect 77% of single-use plastic beverage bottles by 2025 and 90% by 2029, and report data on this to the commission each year. The draft the committee voted on does not differ from the version on which the commission publicly consulted. The annexes to the implementing act provide the calculation formulas, as well as the reporting and quality check formats. The commission is expected to adopt the implementing act in the near future.

The European Commission registers a citizen initiative on a plastic bottle deposit system. The European Citizen Initiative (ECI) "ReturnthePlastics" aims to implement an EU-wide deposit-return system (DRS) to recycle plastic bottles. According to its organisers, the system would be based on a €0.15 deposit for every plastic bottle purchased in the EU, which the consumer would receive back after returning the used plastic bottle to a reverse vending machine in a supermarket. In addition, they propose that plastic bottle manufacturers would bear the costs of putting this system in place. Some member states already have a DRS to collect beverage bottles (not only plastic bottles). The SUPD encourages this measure to achieve the collection of 77% of single-use plastic beverage bottles by 2025 and 90% by 2029. However, introducing DRS is not mandatory. If the ECI receives at least 1 million signatures of citizens from at least seven member states within 12 months from a date chosen by the organisers, which must be not later than six months from its registration, the organisers may present it at a public hearing of the European Parliament and meet with the commission, which must set out its legal and political conclusions on the ECI in a communication. However, the commission is not obligated to take any further action.

The European Commission consults on pollutants in surface and ground waters. The commission has launched an open public consultation on its upcoming legislative proposal on the lists of pollutants affecting surface and ground waters and corresponding regulatory standards. In 2019, its Fitness Check of EU Water Law concluded that water legislation is generally fit for purpose, but there is room for improvement in many key areas, such as chemical pollution, where legislation did not sufficiently address pollutants of emerging concern, such as pharmaceuticals, (micro-) plastics and per- and polyfluoroalkyl substances (PFAS). In October 2020, the commission issued an inception impact assessment (IIA), laying out the road map for a revision of various pieces of EU water legislation. The public consultation will be open until 1 November. In parallel, an expert questionnaire will be available until 5 October. The commission plans to issue its legislative proposal in Q3 2022. The EU co-legislators (Council and European Parliament) would then negotiate and adopt it following the ordinary legislative procedure.

The European Commission grants an exemption for the use of phthalates in medical devices. The commission adopted a delegated directive allowing the use of four phthalates (plasticisers) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, for the purposes of adapting to scientific and technical progress. The permitted substances are bis (2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). The commission also granted exemptions for (1) the use of DEHP in ion selective electrodes for analysing human body fluids and/or dialysate fluids and (2) in plastic components in magnetic resonance imaging detector coils. The commission explained that the total negative environmental and health impacts of substitution were likely to outweigh the total benefits. In 2015, the European Commission added these phthalates to the list of restricted substances in the Annex of the RoHS Directive 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, setting a maximum concentration value by weight in homogeneous materials of 0.1%. The restriction regarding these substances in medical devices and spare parts for their repair, reuse and updating of functionalities has applied since July 2021. The exemptions provided by the recently adopted delegated directives would apply retroactively from one day before these restrictions, and for seven years. The delegated directives are expected to enter into force after a period of scrutiny by the Council and European Parliament of, in principle, two months.

The European Commission seeks views on endocrine disruptors. The commission launched a targeted consultation on information requirements on endocrine disrupting chemicals (EDCs). The input provided will be used by the commission to evaluate the potential impacts of two proposed options for introducing standard information requirements in REACH Annexes VII-X. In the consultation survey, the commission recalls that it has been investigating the regulation of endocrine disruptors for a number of years, leading to the adoption of the Community Strategy for Endocrine Disruptors and to the 2020 Fitness Check on Endocrine Disruptors. The survey asks for views on the impact of endocrine disruptors, the measures to manage these, existing legislation and the appropriate ambition level, as well as the revision of the REACH Annexes. It also asks about alternative test methods that could reduce animal testing, as well as the impact on research, development and innovation, competitiveness and employment (in laboratories and the chemicals industry). Interested stakeholders can reply to the survey until 8 October 2021.

The European Commission launches a consultation on the revision of classification and labelling rules for chemicals. The consultation seeks views on the revision of the Classification, Labelling and Packaging of Chemicals (CLP) Regulation 1272/2008. The commission had announced the revision of the Chemicals Strategy for Sustainability (CSS) in October 2020 (please also see frESH Law Horizons March 2021). The survey asks about introducing three new hazard classes: endocrine disruptors (EDCs); persistent, bio-accumulative and toxic (PBT); and persistent, mobile and toxic chemicals (PMT). Questions cover using the World Health Organisation (WHO) criteria for endocrine disruptors as a basis for CLP criteria, specific rules for online sales, the use of an only representative type-system for poison centre notifications, and changes to labelling rules. The survey also asks about the harmonisation of toxicological and ecotoxicological as part of the "One substance, one assessment" concept. The survey will be open until 15 November 2021. The commission plans to make the legislative proposal in Q2 2022. The EU co-legislators (Council and European Parliament) will then negotiate and adopt it.

ECHA updates guidance on REACH registrations. The European Chemicals Agency (ECHA) published updated guidance on registration requirements under REACH. It aligns the guidance with two implementing regulations that the commission adopted recently on the registration and data sharing of phase-in substances after the final registration deadline and on updates of registration dossiers, respectively (please see frESH Law Horizons October 2019 and October 2020). ECHA removed all the references to the now obsolete pre-registration process and guides companies on how to calculate the tonnage band in which they have to register. For each tonnage band, REACH defines the minimum information that the registrant must provide on the intrinsic properties of their substance. ECHA also provides guidance to companies on determining when they need to update their REACH registrations. Additionally, the updated document includes a section on joint submission of data that updated and adds to a section that was previously in the guidance on data sharing.

The European Commission reports on nanomaterials in cosmetic products. The report to the European Parliament and Council covers the use of nanomaterials in cosmetics in the context of a review of Cosmetics Regulation 1223/2009 as regards nanomaterials. The Cosmetics Regulation establishes that, if the commission has concerns regarding the safety of a nanomaterial, it shall request its Scientific Committee on Consumer Safety (SCCS) to give an opinion on the safety of its use and on the foreseeable exposure conditions. The report found that most of these SCCS opinions are inconclusive, due to a lack of or insufficient data. Therefore, there is a need for the responsible economic operators to provide information as accurate as possible when making notifications to the Cosmetic Products Notification Portal (CPNP). However, the report addresses shortcomings of the notification procedure. For instance, whereas the safety assessment is carried out at ingredient level, notifications are made at product level. In general, the effectiveness of the current notification process via the CPNP merits specific attention, and the scientific safety assessment of nanomaterials could be strengthened, according to the commission. It sees an urgent need for aligning the horizontal definition of nanomaterial throughout different pieces of EU legislation, as it announced for 2021 in its CSS (please also see frESH Law Horizons March 2021).

The European Food Safety Authority (EFSA) publishes guidance on nanoparticles and nanomaterials in food products. The EFSA published two guidance documents, one on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles and another on risk assessment of nanomaterials to be applied in the food and feed chain for human and animal health. In the first document, EFSA, following a mandate from the commission, sets out criteria for assessments, as well as information requirements for applications in the regulated food and feed product areas (e.g. novel food, food/feed additives, food contact materials (FCM) and pesticides). The second document updates previous guidance and, together with the first one, elaborates on physico-chemical characterisation, as well as methods and techniques that can be used for the characterisation of nanomaterials and their determination in complex matrices.

EFSA deems silver nanoparticles used as FCM additive safe. The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) issued an assessment on the safety of the silver nanoparticle additives used in plastics. These additives are used as a surface biocide in food contact plastic materials. The experts panel considered information on theory, specific migration and abrasion tests. The data showed that, under the intended and tested conditions of use, silver nanoparticles stay embedded in the polymer, do not migrate and resist release by abrasion. Thus, they do not give rise to exposure via food and to toxicological concern. Therefore, they do not raise safety concerns for the consumer if used as an additive at up to 0.025% w/w in polymers.

Contacts

Rob Elvin
Partner, Manchester
T +44 161 830 5257
E rob.elvin@squirepb.com

David Gordon
Partner, Birmingham
T +44 121 222 3204
E dave.gordon@squirepb.com

Ken Huestebeck
Senior Associate, Brussels
T +322 627 11 02
E ken.huestebeck@squirepb.com

Nicola A. Smith
Director, Birmingham
T +44 121 222 3230
E nicola.smith@squirepb.com

Anita Lloyd
Director, Birmingham
T +44 121 222 3504
E anita.lloyd@squirepb.com

Gary Lewis
Director, Manchester
T +44 161 830 5373
E gary.lewis@squirepb.com

SQUIRE PATTON BOGGS

squirepattonboggs.com

42165/09/21