REACH E-NEWSLETTER



SGS

WELCOME

Dear Reader,

The UK REACH e-bulletin brings you key issues relating to the EU REACH (Registration Evaluation and Restriction of Chemicals) regulation.

We bring information on proposed changes, confirmed changes and the possible effects of these changes from a manufacturing, retail and consumer perspective. Opinions from all concerned parties are reported so a full picture of the workings and effects of the regulation are shared.

The information in the following pages is sourced from European Chemicals Agency (ECHA). Each of our articles are linked back to source for further reading.

CONTENTS

REGISTRATION NUMBERS GRANTED TO 32,515 REACH 2018 REGISTRATIONS

The REACH deadline for registering existing substances manufactured or imported in quantities from 1 to 100 tonnes per year was on 31 May 2018. By that date, 5,435 companies submitted 33,363 registration dossiers to ECHA.

By 31 August, the deadline set out in the REACH Regulation, ECHA finalised the completeness checks for all registration dossiers submitted ahead of the May deadline. The aim of the completeness check is to verify that all the required information has been included in the registration dossier. Following the completeness checks, registration numbers have been granted to 32,515 submissions made by 5,314 companies. These completed registrations cover 10,708 substances, 7,462 of which have been registered for the first time for the 2018 deadline (for substances in the 1–100 tonnes per year band).

The vast majority of companies were able to submit complete dossiers. For those dossiers that have not been completed, ECHA is waiting to receive further information from companies. These include 477 cases where companies faced exceptional circumstances as defined by the Directors' Contact Group (DCG). They submitted their dossier with a DCG solution and were granted an extension for submitting the missing information. The Agency expects to conclude on all pending cases by May 2019. Around 1% of REACH 2018 dossiers have been rejected so far.

Sixteen per cent of successfully completed registrations were submitted by micro, small or medium-sized companies (SMEs), 84% by large companies. Twenty-eight per cent of the registrations were made by only representatives on behalf of a non-EU company, while 48% were made by importers (some of which may also be manufacturers); the other registrations were submitted by EU/EEA manufacturers.

Registrations were received from 28 EU Member States and three European Economic Area (EEA) countries, with the largest share coming from Germany (26%).

SUMMARY FOR THE 2018 DEADLINE (ALL FIGURES ON 31 AUGUST 2018)	
Completed registrations (1 to 100 tonnes)	32,515
Substances (in completed registrations)	10,708

REGISTRANT TYPE	NUMBER OF REGISTRATIONS	NUMBER OF SUBSTANCES
Importer	14,028	5,059
Only representative	9,167	3,761
Manufacturer	7,630	4,979
Manufacturer and importer	1,689	1,364
Downstream user taking the registrant's role	1	1
TOTAL	**32,515**	**10,708**

MOST FREQUENTLY REGISTERED SUBSTANCES, 1 TO 100 TONNES – SUBSTANCE NAME	NUMBER OF REGISTRATIONS
Ethanol	214
Propane-1,2-diol	168
Silicon dioxide	137
Titanium dioxide	130
Lavender, Lavandula hybrida, ext.	120
Propan-2-ol	106
Aluminium	105
Sodium hydroxide	103
Styrene	101
Ethane-1,2-diol	100
Calcium dihydroxide	92
Lavender, Lavandula angustifolia, ext.	90
Methanol	90
Ethylene	88
Aluminium oxide	84
Diiron trioxide	77
Methyl methacrylate	77
Butyl acrylate	75
Sodium sulphate	74
Iron	71

Article source: ECHA

(UN)LOADING LEAD – SAVING WILDLIFE AND NATURE IN WETLANDS

Lead shot has been widely used for decades in hunting and sports shooting. Yet, we know that lead has toxic effects on ecosystems and wildlife. This is why the EU is looking into restricting its use in wetlands in the near future. The article from ECHA below explains the background.

WHAT IS THE ISSUE?

European wetlands are a habitat for numerous species of waterbirds, including wildfowl like ducks and geese. Hunting them on wetlands with lead gunshot is associated with lead poisoning in wildlife.

This poisoning arises after waterbirds ingest spent lead gunshot that they find on the ground or in water after mistaking it either for food or for small stones (called grit) that they swallow to help them digest their food.

Scavenging birds that feed on unretrieved waterbirds killed using lead gunshot can also consequently suffer from lead poisoning. After the lead gunshot is ingested, it is ground down into small pieces in the birds' gizzards (a muscular digestive organ unique to birds). These pieces are then absorbed from the gut and into birds' tissues.

As lead is highly toxic, this frequently results in birds dying through lead poisoning. Depending on the quantity of lead ingested, death can occur soon after the shot has been consumed or after a period of two to three weeks. Ingestion of a single lead shot can cause the death of a small duck. Where lead poisoning is not fatal, it can also cause harmful, sub-lethal effects on reproduction and the immune system.

The amount of lead released into EU wetlands due to hunting has been estimated to be around 4,000 tonnes per year. Sports shooting in wetlands contributes an additional amount, although this is difficult to precisely assess.

These uses of lead shot are believed to result in the deaths of up to one million waterbirds each year throughout the EU. There could also be additional impacts on scavenging and predatory birds.

HOW LEAD CAN AFFECT HEALTH

Although there is no quantitative data available on the risks to humans from consuming wildfowl hunted with lead gunshot, lead remains a concern for human health.

Exposure to it is associated with a wide range of negative health effects, including neurodevelopmental impairment, reduced fertility, hypertension and damage to the kidneys. It is considered as a non-threshold toxic substance, meaning that there is no safe level of consumption.

Any reduction of dietary lead exposure will therefore contribute to reducing the human health risks posed by lead, particularly for children and adults who regularly consume game meat. Avoiding the contamination of groundwater from shooting ranges could also reduce human exposure to lead through drinking water.

REGULATING LEAD SHOT ACROSS THE EU

In the EU, all but three Member States – Poland, Romania and Slovenia – have signed up to the African Eurasian Waterbird Agreement (AEWA), which has been in place since 2000 and proposes to phase out the use of lead gunshot in wetlands. Several Member States implemented legislation that completely prohibits the use of lead gunshot, including the Netherlands, Belgium and Denmark. In others, partial bans are in place.

However, four Member States – Ireland and the three AEWA non-signatories: Poland, Romania and Slovenia – have not implemented any restriction on the use of lead gunshot in wetlands. Regulating the risk at EU level will therefore ensure an appropriate and harmonised level of protection for European wetlands and wildlife.

A restriction will harmonise the level of protection across Member States, which as a consequence of the different levels of protection still see millions of birds die each year. Those Member States without current legislation account for 13-15% of these deaths.

WHAT IS BEING PROPOSED?

In December 2015, the European Commission asked ECHA to prepare a restriction proposal for the use of lead in shot in wetlands. ECHA analysed the evidence and submitted its dossier in April 2017.

ECHA's proposal suggests restricting the use of gunshot that contains more than 1% of lead, for shooting with a shotgun over or within wetlands, including at shooting ranges or on shooting grounds in wetlands.

At the same time, the Commission also asked ECHA to start collecting information on the potential risks of using lead in ammunition for hunting in terrestrial environments outside of wetlands. This work is being done separately to the restriction of lead in shot used in wetlands.

ARE THERE ANY VIABLE ALTERNATIVES?

Experience from those countries where a ban is already in place shows that hunters and sports shooters have adapted to using alternatives without any significant problems in relation to ricochet and other safety issues.

Indeed, several scientific studies have shown that the use of steel gunshot cartridges results in similar hunting success to that achieved with lead gunshot cartridges and without causing concerns related to crippling or wounding waterbirds.

The need to replace older shotguns with newer ones so that alternatives to lead gunshot can be used has also been a topic of fierce debate. However, evidence gathered while preparing the restriction indicates that modern shotguns (those manufactured after 1970) are capable of using standard steel shot, and this has been confirmed by major gun manufacturers.

Lead-free gunshot cartridges are suitable for all types of shooting in wetlands and are widely available in the EU. They are also similarly priced to lead gunshot cartridges.

If 'high-performance' steel cartridges are needed, for example, when hunting larger waterfowl, older shotguns may need to be modified or replaced.

Bismuth- or tungsten-based gunshot cartridges can also be used as alternatives to lead cartridges and can be used in any shotgun, including vintage shotguns. However, bismuth- and tungsten-based shot cartridges are about four to five times more expensive than equivalent lead gunshot cartridges.

Hunters will need to decide how best to comply with the restriction depending on their individual circumstances and preferences, although it is assumed that most will switch to steel.

WHAT HAPPENS NEXT?

ECHA's scientific Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) finalised their opinions in June 2018.

The opinions supported ECHA's proposal to restrict lead and its compounds in gunshot as well as the conclusions on the number of birds currently being killed by lead gunshot and the costs of the restriction to hunters.

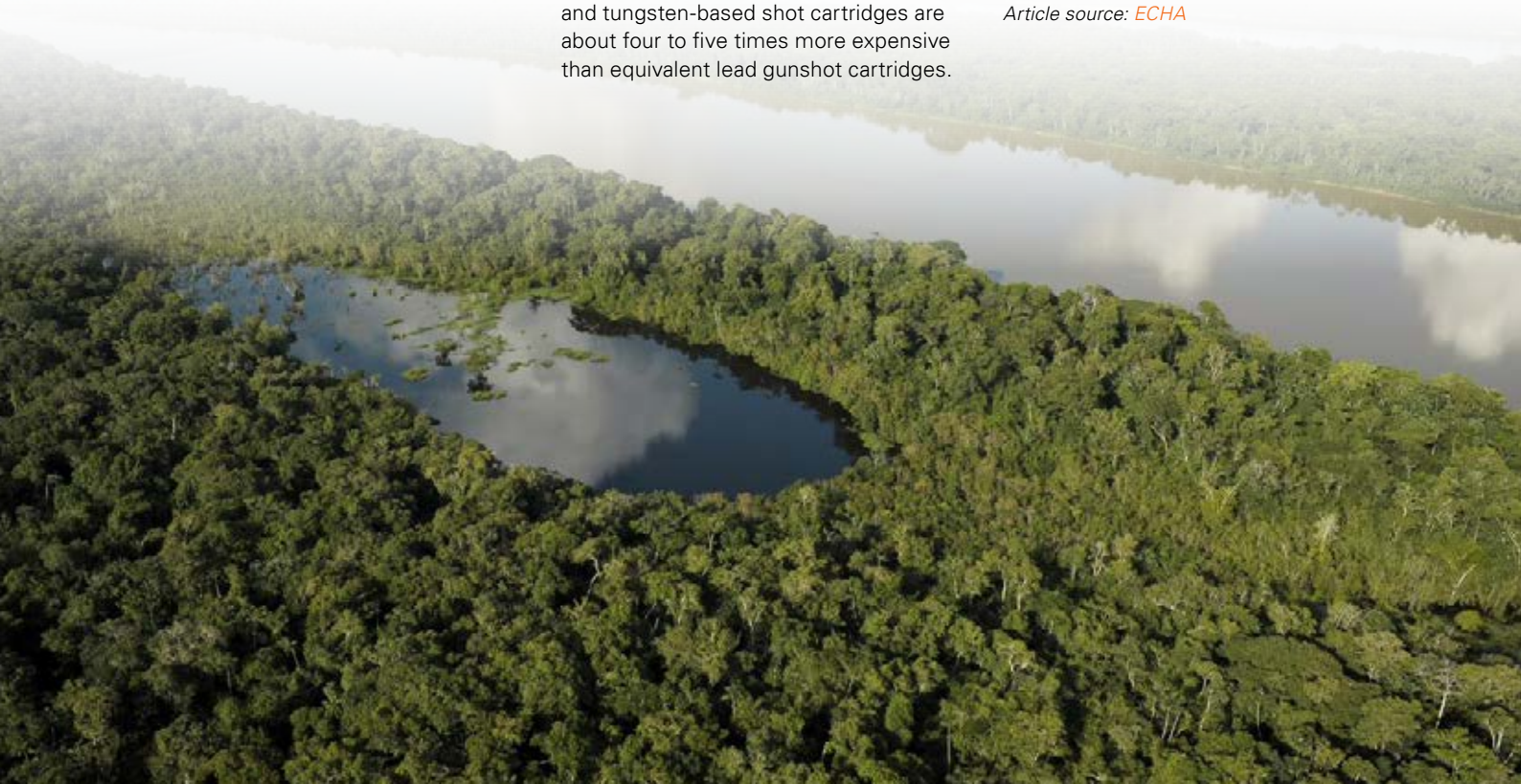
In its final opinion, SEAC concluded that further action on a Europe-wide level is required to address the risks associated with lead gunshot in wetlands.

Furthermore, SEAC concluded that the effective implementation of the AEWA requires a consistent minimum level of protection of waterbirds across the EU, which would be achieved by the proposed restriction.

The compiled RAC and SEAC opinion was submitted to the European Commission on 17 August 2018 for decision making. The Commission now has three months to produce its draft decision.

If adopted, a transitional period of 36 months after entry into force is proposed, to allow a smooth transition to the use of alternatives.

Article source: ECHA



MEMBER REGISTRANTS WILL START RECEIVING DOSSIER EVALUATION DECISIONS IN 2019

As of 1 January 2019, ECHA will start checking the compliance of all relevant dossiers for a given substance and will address its decisions to all registrants with non-compliant dossiers. This is a change from the current practice of addressing mainly the lead registrants. Similarly, the Agency will address its decisions on testing proposals to all those registrants intending to rely on the proposed tests to fulfil their information requirement.

At the same time, the content of ECHA's decisions will be streamlined to provide more focused justifications for the information requested and clear information to registrants about their legal obligations.

The change aims to support the collaboration and communication between registrants regarding their joint submissions after the substance information exchange forums (SIEFs) ceased to exist as of 1 June 2018. After that date, the registrants of the same substance are nonetheless still bound by the obligation to submit the information on their substance jointly.

In addition, in line with the expectation that registrants are keeping their dossiers up to date, as required by the REACH Regulation, the Agency will no longer consider changes related to the tonnage band, uses or the intermediate status of a registration after a draft decision is notified to the concerned registrants.

HOW YOU CAN PREPARE AS A REGISTRANT

Be sure to review and update your registration dossiers before 2019. Pay special attention to the following:

- Changes in production or import volumes (increase or decrease)
- New or obsolete uses
- New or changed measures to ensure the safe use of your substance
- Your transported or on-site isolated intermediate status
- New data on the intrinsic properties of your substance
- Your justification for relying on waivers for the required information, or on adaptations such as category or read-across approaches

This is particularly important for substances registered in the highest tonnage bands, with wide dispersive uses but also if you rely on opt-outs or adaptations for endpoints needed at the highest tonnages. These are ECHA's criteria for prioritising evaluation activities.

In addition, make sure that your contact details are up to date both in REACH-IT and in your joint submission, so that you can always be reached regarding your registration. As of 1 January 2019, if you and other registrants within the joint submission receive an ECHA decision because of missing information or a testing proposal evaluation, you should coordinate your reply to ECHA, and speak with one voice during the entire process.

Article source: ECHA

REACH 2018 – KEEP YOUR REGISTRATION UP TO DATE

The seventh and last step to successfully register your chemicals is to maintain your registration data. REACH registration is not a one-off exercise, but rather the start for managing your substance portfolio responsibly under the EU chemicals legislation.

The registration dossier is meant to reflect the current knowledge on how your substance can be used safely at production sites and through the supply chain all the way down to the end user. This means that although you have successfully submitted a registration and gotten your registration number, you still have work to do.

It is up to you to review your registration on a regular basis and update it when new information becomes available – even if ECHA does not request you for an update. Being proactive is not only good practice, but also a legal requirement.

WHAT TO UPDATE?

You need to update your registration dossier, for example, when you learn something new about the composition of your substance, its properties, how it is used by your clients, or the specific risk management measures needed to ensure safe use.

Significant changes in the production or import volumes and the company information must also be reported.

In addition, new information may become available when new companies that want to register the same substance join the joint submission – this must also be reflected in the joint registration.

WHY UPDATE?

ECHA and Member State authorities use the registration dossiers as a basis for further regulatory work. The information needs to be up to date, so that authorities – and also you – do not waste time on clarifying potential concerns that are, in fact, no longer relevant.

ECHA's task is to examine the registrations to verify if the information in them is compliant with the legal requirements. ECHA checks at least 5% of the registrations per tonnage band during compliance checks, for which dossiers are selected either randomly or by targeting certain endpoints of concern.

ECHA studies the most common shortcomings from the compliance checks and publishes their recommendations online.

Check these recommendations to avoid having the same problems in your own registration. In addition, it is your responsibility to check whether a harmonised classification and labelling applies for your substance.

Member States, on the other hand, scrutinise substances, which might be a concern for human health or the environment.

To clarify whether or not a concern exists, they may ask you to generate information beyond the registration requirements laid down under REACH.

It is good to keep in mind that although the lead registrant updates the joint part of the registration dossier, all affected registrants are responsible – and must share costs – to fix the situation if a non-compliance is found or further information needs to be generated.

Article source: ECHA

ARE THE NEW REACH INFORMATION REQUIREMENTS FOR NANOS RELEVANT FOR YOU?

Despite increasing amounts of nanomaterials in products on the EU market, not enough is known about their hazards to adequately assess and control their risks. To bridge this knowledge gap, the REACH annexes that specify what information is required from companies placing chemicals on the market have been revised, legally obliging industry to also provide data for substances in nanoform. The new changes enter into force in January 2020.

WHAT DO THE REVISED ANNEXES CHANGE?

The implementation of REACH for nanomaterials has been challenging. This is because there is a general lack of information on the hazards of most nanomaterials as well as uncertainties on the applicability of test methods currently used to assess their properties.

There have also been differing opinions relating to the legal aspects of how information requirements should be fulfilled by industry and what exactly should be considered when carrying out a hazard assessment. These have related to, for example, how nanomaterials or nanoforms should be characterised under REACH.

The revised REACH annexes clarify the existing information requirements and introduce some new ones for companies registering nanoforms of their substances. By making the requirements explicit, implementing REACH will be easier and more efficient. Over time, these changes will also contribute to increasing knowledge on the hazards and risks of nanoforms of substances on the EU market.

A better understanding of the safety of nanomaterials will benefit consumers and workers, but will also help regulators identify whether further risk management measures are needed for specific uses or substances.

WHO DO THE CHANGES IMPACT?

The changes are relevant for companies manufacturing or importing nanoforms of substances that fall within the scope of REACH. Nanoforms of substances are those covered by the European Commission's recommendation for a definition of a nanomaterial.

It is important to point out that each nanomaterial can also exist in multiple forms depending on, for example, deliberate changes made to the surface of the particle.

Due to the various ways in which particles can be manipulated and thereby also characterised, it is recommended that if you manufacture or import small particles, familiarise yourself, at the earliest opportunity, with the introduced changes to assess whether they are relevant for your substances.

WHEN WILL THE NEW ANNEXES COME INTO FORCE?

Industry needs to comply with the new requirements by January 2020. This might seem far away but this transitional period is needed for companies to not only assess if the changes apply to their substance, but also to conduct any necessary testing and further assessment.

Article source: ECHA

ECHA PROPOSES 18 SUBSTANCES FOR REACH ANNEX XIV

ECHA has opened a consultation on its ninth recommendation to add 18 priority substances to REACH Annex XIV – the Authorisation List.

ECHA regularly assesses the substances from the Candidate List to decide which ones should be included in the Authorisation List as a priority. This prioritisation is primarily based on the information in the registration dossiers on uses and volumes of the substance in the scope of authorisation. Therefore, registrants are encouraged to keep their registration dossiers up to date.

Downstream users of substances are encouraged to communicate relevant information regarding their uses and conditions of use up the supply chain to ensure that registrants have sufficient information to update their registration dossiers.

The chemicals with reprotoxic properties, and examples of their uses, that ECHA has recommended can be found in the public consultations area of their website. The 18 substances listed include 8 lead compounds that are primarily used as stabilisers in PVC: https://echa.europa.eu/recommendation-for-inclusion-in-the-authorisation-list

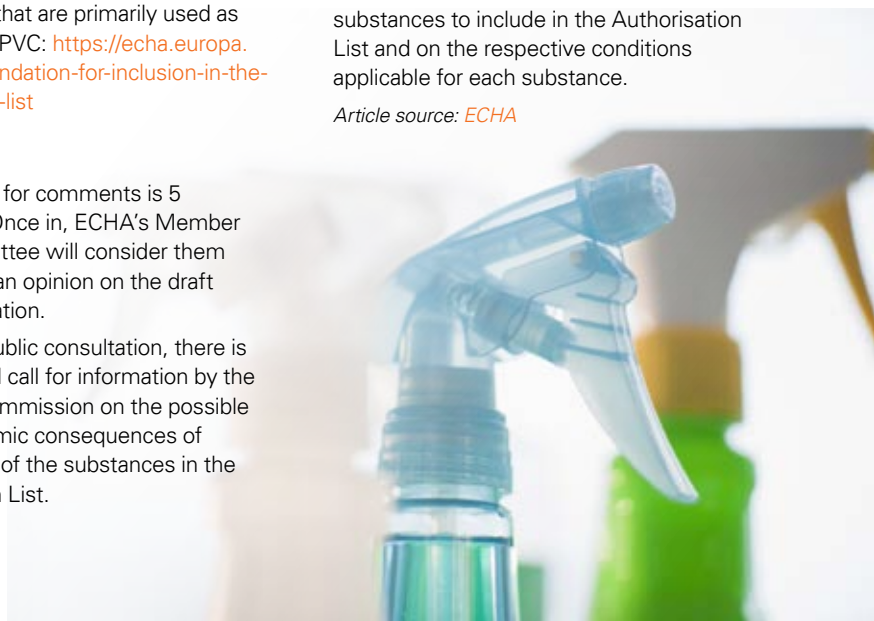
DEADLINE

The deadline for comments is 5 December. Once in, ECHA's Member State Committee will consider them and prepare an opinion on the draft recommendation.

During the public consultation, there is also a parallel call for information by the European Commission on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List.

ECHA will then provide its final recommendation, based on the opinion of the Committee and the public consultation, to the Commission. The EU Executive will decide on which of the substances to include in the Authorisation List and on the respective conditions applicable for each substance.

Article source: ECHA



SIX PROPOSALS TO IDENTIFY NEW SUBSTANCES OF VERY HIGH CONCERN (SVHCs)

On 4 September 2018, European Chemical Agency (ECHA) opened its second public consultation of 2018 on six potential Substances of Very High Concern (SVHCs) [1]. The Candidate List will expand to 197 if these proposals are accepted.

The substances and examples of their uses are:

1. Undecafluorohexanoic acid (PFHxA) (EC 206-196-6; CAS 307-24-4) and its ammonium salt (APFHx) (EC 244-479-6; CAS 21615-47-4). No direct uses of PFHxA as such are known. PFHxA precursors can be used as surfactants or as monomers for the production of side-chain fluorinated polymers. Ammonium undecafluorohexanoate (APFHx), the ammonium salt of PFHxA is used in industrial settings mainly in connection with the manufacture and processing of polymers
2. 2,2-bis(4'-hydroxyphenyl)-4-methylpentane (EC 401-720-1; CAS 6807-17-6). There are no active registrations under REACH. Potentially used in the manufacture of polymers, or in thermal paper, surface coatings, inks and adhesives
3. Fluoranthene (EC 205-912-4; CAS 206-44-0). Not registered under REACH. Normally not produced intentionally but rather occurs with other PAH's as a constituent or impurity in other substances
4. Benzo[k]fluoranthene (EC 205-916-6; CAS 207-08-9). Not registered under REACH. Normally not produced intentionally but rather occurs with other PAH's as a constituent or impurity in other substances
5. Pyrene (EC 204-927-3; CAS 129-00-0). Used as a transported Intermediate for the manufacture of fine chemicals. Normally not produced intentionally but rather occurs with other PAH's as a constituent or impurity in other substances
6. Phenanthrene (EC 201-581-5; CAS 85-01-8). Not registered under REACH. Normally not produced intentionally but rather occurs with other PAH's as a constituent or impurity in other substances

Article source: ECHA

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your services and value chain by increasing performance, managing risks, better meeting stakeholder requirements and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language and understand the culture of the local market and operate in a consistent, reliable and effective manner.

TO LEARN HOW SGS CAN HELP YOU EXCEED CUSTOMER EXPECTATIONS, VISIT WWW.SGS.CO.UK OR CONTACT GB.REACH@SGS.COM FOR MORE INFORMATION.

WWW.SGS.COM
WWW.SGS.CO.UK

WHEN YOU NEED TO BE SURE