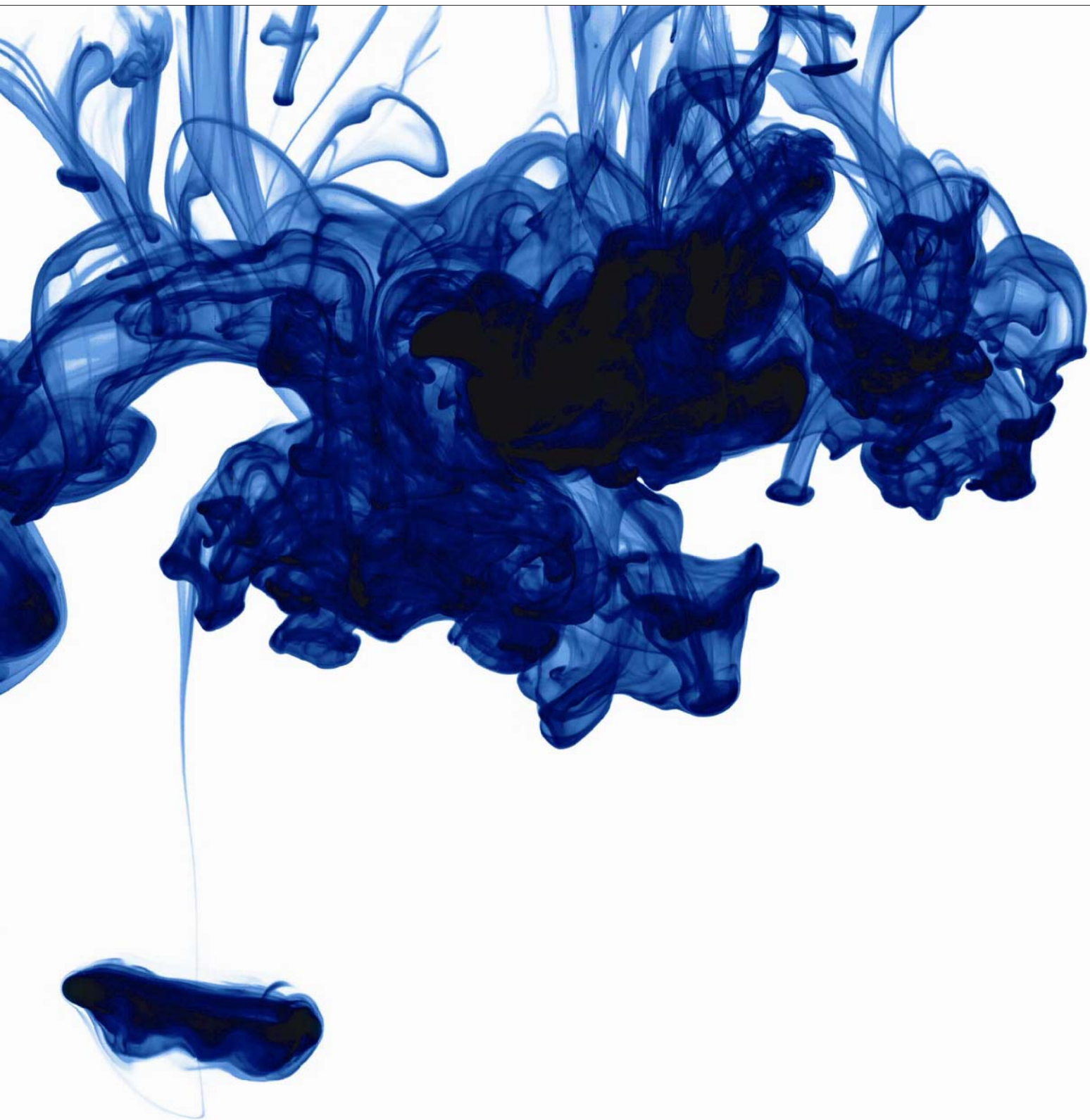


Strategy and guidance for enforcement of REACH in the UK

Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

April 2010



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Introduction

1. REACH (**R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals) is an EC Regulation that has direct effect in the UK. It came into force on 1 June 2007 and replaced a patchwork of European Directives and Regulations with a single system. REACH introduced a scheme for registering, evaluating, authorising and restricting chemicals, and created a fundamentally new approach to chemicals control by moving the responsibility for risk assessment from the regulator to manufacturers and importers. It also placed duties on suppliers and users of chemicals, primarily to ensure that the information gained through registration and evaluation is passed down the supply chain, and effectively applied to control risks.

2. REACH aims to ensure a high level of protection of both human health and the environment. At the same time, it aims to enhance the competitiveness of the EU chemicals industry by fostering innovation and ensuring high safety standards for its products. This is set against a background of a lack of information about the hazardous properties of chemicals already on the market. The European Commission stated at the time REACH entered into force that there was insufficient information on hazards, uses and risk management measures for 99% of chemicals available.

3. Under REACH, each EU manufacturer or importer of chemicals in quantities of one or more tonnes per year – around 30,000 substances – will have to register them with the new European Chemicals Agency (ECHA), submitting information on properties, uses and safe ways of handling them. Safety information must be passed down the supply chain to 'downstream users' so that they know how to use the substances without creating risks for workers, consumers and the environment. REACH will restrict the use of the most dangerous substances, and for other substances of very high concern, use-specific authorisation will be required. This will only be granted to companies that can show that the risks are adequately controlled or if social and economic benefits outweigh the risks where there are no suitable alternative substances or technologies. This will encourage substitution for safer alternatives.

REACH requirements as regards enforcement

4. REACH (Titles XIII and XIV) requires Member States to appoint a Competent Authority and maintain an appropriate control system with respect to enforcement. Member States had to have an enforcement regime in place by 1 December 2008, which provides for 'effective, proportionate and dissuasive' penalties for non-compliance. Results of inspections, monitoring and penalties must be reported to the European Commission by 1 June 2010, and after that every five years.

5. REACH also recognises the need for high levels of co-operation, co-ordination and exchange of information between Member States, ECHA and the European Commission regarding enforcement, to make the system operate effectively. A 'Forum for Exchange of Information on Enforcement' will coordinate harmonised enforcement projects and joint inspections, as well as develop working methods and tools for inspectors, identify enforcement strategies and develop an electronic information exchange procedure.

Allocation of enforcing authorities for REACH enforcement

6. The Health and Safety Executive (HSE) acts as the UK Competent Authority (CA) for REACH. Legally, the designated CAs are the Secretary of State in England, and the relevant Ministers or departments in Scotland, Wales and Northern Ireland – as set out in the REACH (Appointment of Competent Authorities) Regulations 2007. However, under Agency Agreements, together they have delegated the functions of the CA to HSE while maintaining overall ministerial responsibility.

7. The Department for the Environment, Food and Rural Affairs (Defra) is the lead UK Government department for REACH, and acts in this capacity on behalf of the devolved administrations. This role is distinct from that of the CA; Defra is responsible for the implementation of REACH in the UK, which includes developing and implementing the UK enforcement regime. This is reflected in the REACH Enforcement Regulations 2008, a statutory instrument introduced under the European Communities Act 1972, which entered into force on 1st December 2008.

8. There have been two public consultations on REACH enforcement, led by Defra in association with the Devolved Administrations. The first was during Spring 2007, and this sought to establish the principles upon which an enforcement regime would be developed. This considered, amongst other things, whether enforcement of REACH should be carried out by a new regulator, but concluded with the proposition that enforcement should be undertaken by existing enforcing authorities, using the powers generally provided to inspectors of those authorities, alongside their current regulatory activities. The second consultation was undertaken in Summer 2008, this time focussed on the details of the draft Regulations, as well as the administrative arrangements for the proposed UK enforcement regime for REACH.





9. The authorities given enforcement responsibility by the REACH Enforcement Regulations 2008 (the 'Enforcement Regulations') are those with existing remits to protect human health, consumer safety, and the environment:

- the Health and Safety Executive (HSE);
- the Health and Safety Executive for Northern Ireland (HSENI);
- the Environment Agency (EA);
- the Scottish Environment Protection Agency (SEPA);
- the Northern Ireland Environment Agency (NIEA);
- the Department of Energy and Climate Change (DECC); and
- local authorities (LAs), as regards occupational health and safety and consumer protection (trading standards).

10. The Enforcement Regulations set out which enforcing authority is responsible for enforcing the various provisions of REACH, though broadly speaking:

- HSE, in its capacity as UK REACH CA, will enforce those duties in REACH concerning **registration**;
- HSE in Great Britain and HSENI in Northern Ireland will enforce **supply** related duties up to the point of retail sale, with local authority trading standards departments then responsible for consumer protection issues;

- A wide range of enforcing authorities will enforce **use** related duties, as per existing arrangements for enforcing health, safety and environmental legislation. The diagram below sets out which enforcing authorities are involved.

| Enforcement of <i>use</i> related duties | Environmental protection | Health and safety |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| England & Wales |  Environment Agency |  & Local Authorities |
| Scotland |  SEPA |  & Local Authorities |
| Northern Ireland |  NIEA <small>www.ni-environment.gov.uk</small> |  & District Councils <small>CONTROLLING RISK TOGETHER</small> |
| Offshore |  DEPARTMENT OF ENERGY & CLIMATE CHANGE |  |

Role of other enforcing authorities / organisations in REACH enforcement

11. Though not identified in the Enforcement Regulations as named REACH enforcers, there are a number of other authorities and organisations that have important roles to play:

- *the UK Border Agency (UKBA)* is responsible for delivering risk based anti-smuggling controls at UK points of entry to detect illegal imports of prohibited and restricted goods. UKBA may provide assistance to the named REACH enforcing authorities by detaining goods at import for a maximum of two working days, either when requested to do so or in the event that UKBA have reasonable grounds to suspect that goods may be being imported which are in breach of REACH.
- *HM Revenue & Customs (HMRC)* is responsible for delivering the customs clearance function for imports from non EU countries and for operating the import customs declaration system. HMRC may disclose information obtained or held in the exercise of its functions relating to imports, to facilitate the exercise of a duty of an enforcing authority under the Enforcement Regulations.
- *the Home Office & the Department of Health, Social Services and Public Safety:* A key theme of REACH is the need to minimise the use of animals in testing and where possible to use suitable non-animal methods. In the UK, the Animals (Scientific Procedures) Act 1986 regulates any experimental or other scientific procedures that may have the effect of causing animals pain, suffering, distress or lasting harm. This Act is administered in Great Britain by the Home Office and in Northern Ireland by the Department of Health, Social Services and Public Safety. Licences will, if necessary, be amended to ensure REACH compliance is taken into account when projects are agreed for the conduct of animal tests, and appropriate conditions added to licences so that meaningful and informative records of these tests are maintained and made available for inspection.

- *ECHA*: While not an enforcing authority itself, ECHA's work will have a significant bearing on enforcement. It can reject registrations of substances, with the consequence for enforcing authorities that the continued manufacture, importation or supply of those substances will become illegal. It may also request enforcing authorities to undertake enforcement action on its behalf, for example, should ECHA be unsuccessful in obtaining further information it requires from a dutyholder during evaluation.
- *Industry*: One of the benefits of pre-registration is that those who pre-registered became part of a group of companies who also pre-registered the same chemical. This group, called a Substance Information Exchange Forum (SIEF) must share information on hazards so that only one set of technical information has to be submitted to ECHA. The SIEF must also work collectively on other aspects of the registration package. REACH places requirements on SIEF participants to work together and make every effort to reach agreement about the sharing of studies or the cost of studies. Such requirements are excluded from the Enforcement Regulations as being enforceable by the named enforcing authorities, as it is impractical and inappropriate to enforce such provisions using criminal sanctions. The rights and obligations which are created by these provisions are instead matters for civil law processes to resolve as and when appropriate.

Co-operation and co-ordination between enforcing authorities

Co-operation and co-ordination within the UK

12. Close co-operation and co-ordination between enforcing authorities will be crucial to the effective enforcement of REACH in the UK. The Enforcement Regulations require enforcing authorities to co-operate with each other, equivalent enforcing authorities in other Member States, Competent Authorities in the UK or other Member States, and ECHA. Where reasonable, enforcing authorities must also exchange information with each other in relation to REACH enforcement activities.

13. The Enforcement Regulations also give enforcing authorities the power to agree arrangements with each other to allow the carrying out of an enforcement duty by another authority. This means that there is flexibility for the most suitable enforcing authority to carry out enforcement in any particular case.

14. The Enforcement Regulations are accompanied by a Memorandum of Understanding (MoU) on REACH enforcement. This details the administrative procedures and working arrangements between enforcing authorities, and contains provisions as to:

- joint working arrangements, including joint visits, where enforcement responsibility overlaps (e.g. where the use of a substance raises both health and safety and environmental concerns);
- the sharing of information between enforcers;
- notification of matters of concern regarding dutyholders;
- supporting each other with enforcement, and in particular the provision of specialist advice; and
- the establishment of an Enforcement Liaison Group (see below).

15. To further strengthen co-operation and co-ordination, and to ensure the effective operation of any MoU on enforcement, a UK Enforcement Liaison Group has been

established. This brings together representatives from all UK REACH enforcing authorities at periodic intervals, and its functions include:

- carrying out the functions of the MoU (above), such as sharing information, arranging joint visits, notifying matters of concern, supporting enforcement action etc;
- discussing emerging enforcement issues, grey areas, the interpretation of REACH and so on;
- proposing amendments to guidance, based on practical experience;
- advising on arrangements for informing industry on REACH developments; and
- determining priority substances and/or issues, and proposing and co-ordinating enforcement activity on these where possible.

Co-operation and co-ordination across the European Union

16. The Forum for Exchange of Information on Enforcement ('the Forum') is the principal mechanism for ensuring co-operation and co-ordination across the European Union. It is composed of representatives from all EU Member States and also the EEA-EFTA States (Iceland, Liechtenstein and Norway).

17. The Forum's aim is to contribute to more effective and harmonised enforcement in Member States. REACH states that the Forum shall coordinate the "network of Member State authorities responsible for enforcement" of REACH, and allocates to the Forum the following specific tasks:

- spreading good practice and highlighting problems at Community level;
- proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;
- co-ordinating exchange of inspectors;
- identifying enforcement strategies, as well as best practice in enforcement;
- developing working methods and tools of use to local inspectors;
- developing an electronic information exchange procedure;
- liaising with industry and other stakeholders, including relevant international organisations; and
- examining proposed chemical restrictions to advise on enforceability.

Powers, offences and penalties

18. The Enforcement Regulations give each enforcing authority the suite of powers they need to enable them to carry out their responsibilities. While the powers are all described in the Regulations themselves, in most cases the powers merely reflect those already used in an enforcing authority's other enforcement activities.

19. The REACH Enforcement Regulations 2008 provide that it is an offence for a person to contravene a 'listed REACH provision' (this refers to the REACH requirements listed in the table in Schedule 1 of the Regulations) or to cause or permit another person to do so.

20. The Enforcement Regulations allow for a breach of a listed REACH provision to be tried summarily (e.g. in Magistrates Courts) or on indictment (e.g. in Crown Courts), and provide that the same potential maximum penalty will apply for each provision, namely up to the maxima permitted under the European Communities Act 1972. These are currently:

- up to £5,000 fine and/or up to three months imprisonment following summary conviction; and
- an unlimited fine and/or up to two years imprisonment following conviction on indictment.

21. The Enforcement Regulations also provide for a number of supplementary criminal offences. These include obstruction of inspectors, providing false statements, failing to comply with enforcement notices, and so on. These supplementary offences are also the subject of criminal penalties which are consistent with those above.

Enforcement strategy

22. It is envisaged that REACH will become central to the assessment and control of risks to human health and to the environment from chemicals. The objective of this strategy is to ensure that high standards of compliance with REACH are achieved and maintained, but in ways which minimise the burden of verifying compliance for both businesses and for public authorities.

23. In 2005, Philip Hampton's report, *"Reducing administrative burdens: effective inspection and enforcement"*, was published by the Treasury. The report set out a number of ways in which Government should aim to reduce the administrative burden imposed by regulation. This included a number of principles to be considered when developing a regulatory framework:

- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most.
- Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.
- All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all interested parties should be consulted when they are being drafted.
- No inspection should take place without a reason.
- Businesses should not have to give unnecessary information, nor give the same piece of information twice.
- The few businesses that persistently break regulations should be identified quickly, and face proportionate and meaningful sanctions.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.
- Regulators should be of the right size and scope, and no new regulator should be created where an existing one can do the work.
- Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.

24. The overall strategy is to create and operate enforcement processes that make best use of the skills of enforcing authorities' staff to secure compliance, using two principal approaches:

- (i) the provision of education, advice and help to dutyholders, and the promotion of REACH, as increased awareness and understanding will lead to increased levels of compliance; and

- (ii) the use of a range of interventions (both proactive and reactive), backed up by formal enforcement where necessary. The principal focus of interventions should be on those provisions which are most important to enforce in order to make REACH work effectively.

25. The term “enforcement” is used in a broad sense and encompasses a number of different interventions aimed at securing compliance.

REACH duties: priorities for enforcement

26. The basic components of the REACH process are set out below:

- **Registration** with ECHA of all substances which are manufactured or imported into the EU in quantities of one or more tonnes per year per manufacturer/importer. Central to registration is Article 5 of REACH, which prohibits the manufacture, import and/or supply of substances (on their own, in preparations or intentionally released from articles) that have not been registered or pre-registered. The registration of existing substances currently manufactured or on the market takes place in three phases, based on tonnage and hazardous properties. However, to take advantage of these phase-in periods, manufacturers or suppliers had to pre-register their substances between 1 June 2008 and 1 December 2008. Pre-registration is not a requirement, but if a manufacturer or importer did not pre-register, they had to submit a full registration by 1 December 2008.
- **Evaluation** of registration dossiers and substances. *Dossier evaluation* is carried out by ECHA and consists of compliance checks on registration dossiers, and reviews of testing proposals submitted. *Substance evaluation* is carried out by Member States and consists of further evaluation of substances where these may pose a risk to human health or the environment.
- **Authorisation** is required for substances of very high concern. Where alternatives cannot be substituted, dutyholders will need to apply for authorisation for specific uses where the risks can be adequately controlled, or where there is a socio-economic case for continuing use of the substance. Non-authorised uses of authorisable chemicals is prohibited.
- **Restrictions** are placed on the marketing and use of substances where the risks to human health and the environment are deemed to be unacceptable. ECHA has a co-ordinating role in the examination of proposals for new restrictions.

27. These components are reflected within REACH by a wide range of duties being placed on manufacturers, importers, suppliers, downstream users and others. Some of these duties replaced former legislative requirements, but others were entirely new. The duties themselves can be divided up into three general areas: **registration** related duties, **supply chain** related duties, and **use** related duties, and enforcing authorities have been allocated enforcement duties on this basis.

28. Enforcement effort should be focussed on the most important requirements of REACH (from an enforcement perspective), i.e. those duties that contribute significantly to ensuring that risks to human health or the environment are adequately controlled. Details of the duties under REACH that are priorities to achieve these ends are provided below. Where non-compliance is found, enforcement action should be aimed at correcting the contravention and preventing (further) damage, and identifying and addressing underlying problems with an organisation’s management system that allowed the contravention(s) to occur.

Registration related duties

29. Registration is fundamental to the operation of REACH. Without it, insufficient information will be prepared to improve product data and to identify hazards, risks and risk management measures. 'Evaluation' is also considered under this heading, as evaluation can result in requirements on registrants to provide complementary registration information where appropriate.

30. The following articles are priorities for enforcement:

- **Article 5:** this contains the 'no data, no market' principle and states that substances on their own, or in articles or preparations, shall not be manufactured or placed on the market unless they have been registered in accordance with Title II. Articles 6, 7, 17 and 18 contain the specific duties to register, and articles 10, 12 and 14 build on these provisions and specify what information has to be provided with a registration. In particular, Article 14 requires manufacturers, importers and producers of articles to prepare a chemical safety report (CSR), and a chemical safety assessment (CSA) where required, for each substance subject to registration in quantities of 10 tonnes or more per year.
- **Articles 22(1), 22(2) and 24(2):** which require registrants to update their registration information as appropriate, and links to the overarching provision in Article 5.
- **Articles 40(4), 41(4), 46(2) and 50(4):** which contain requirements to submit information to ECHA regarding evaluation.

Supply chain related duties

31. Information provision both down and back up supply chains is again critical to the successful operation of REACH. Inspection of safety data sheets has been carried out for many years, so this is not a new task for enforcing authorities. What is new are the requirements concerning exposure scenarios that have to be annexed to safety data sheets, information requirements when a safety data sheet is not needed, information about substances of very high concern in articles, and requirements to pass information back up the supply chain in certain circumstances.

32. The following articles are priorities for enforcement:

- **Article 31:** this contains a variety of duties aimed at ensuring recipients are provided with a safety data sheet, which will contain exposure scenarios consistent with the information in the CSA/CSR (if required). This is particularly important since this is the key provision to ensure registration information is passed down the supply chain.
- **Article 32(1):** which requires suppliers of substances or preparations who do not have to supply safety data sheets under article 31 to provide the recipient with certain information.
- **Articles 33(1) and 33(2):** which contain requirements on suppliers to communicate information on substances of very high concern in articles to recipients and, on demand, also to consumers. This is important information for the recipients to receive, so that they can ensure that the article can be handled safely.
- **Article 34:** which requires new information on hazardous properties, or any other information that might call into question the appropriateness of the risk management measures on a safety data sheet, to be passed up the supply chain.
- **Article 56(1):** this requires manufacturers, importers or downstream users not to place substances included in Annex XIV (i.e. subject to authorisation) on the market for a use unless that use has been authorised, or the use has been exempted from the authorisation requirement.

- **Article 65:** this requires the holder of an authorisation to include the authorisation number on the label before placing the substance on the market for an authorised use. This is important information for the downstream user when checking if his use is within the authorisation for that substance.
- **Article 67(1):** which states that a substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction, shall not be manufactured or placed on the market unless it complies with the condition of that restriction.

Use related duties

33. REACH places the main responsibilities on manufacturers and importers, for instance to gather and assess data and, through use conditions and exposure scenarios, inform downstream users about uses. However, unlike earlier legislation, REACH requires downstream users to either stick to these use conditions or exposure scenarios, or to themselves take over the responsibility. This is primarily to ensure that the information gained through registration and evaluation, and passed down the supply chain, is effectively used to control risks, i.e. that the system created by REACH is more than a mere paper exercise.

34. The following articles are priorities for enforcement:

- **Article 37(5):** this requires downstream users to identify and apply appropriate risk management measures recommended to them in the safety data sheet or other information sources available to them. This is one of the most important of all REACH articles for enforcing authorities. In addition, if the downstream user does not keep within the exposure scenario, or uses a substance against the advice of their supplier, then they must take appropriate action. This will mean choosing one of the following options:
 - a) changing their use to bring it within the exposure scenario;
 - b) finding another supplier who is able to support the use;
 - c) replacing the substance or process with an alternative substance or process;
 - d) making the use known to the supplier, with the aim that this becomes an identified use (Article 37(2));
 - e) alternatively, should downstream users not wish to make their use known to their suppliers (e.g. for reasons of commercial confidentiality), or should the supplier not accept their use, downstream users must prepare a chemical safety assessment (Article 37(4), though there are some exceptions) in order to satisfy the Article 37(5) duty to identify and apply appropriate measures to adequately control risks arising from that use. They must also report certain information to ECHA about their use (Article 38(1), though again there are certain exceptions).
- **Articles 56(1) and 56(2):** these provisions contain the core requirement that the use of substances of very high concern is only allowed if that use has been authorised and is in accordance with the conditions of the authorisation, or that the use has been exempted from the authorisation requirement.
- **Article 66(1):** this requires a downstream user, using a substance according to his supplier's authorisation, to notify ECHA within three months of the first supply of the substance. This is important information for enforcing authorities, to enable them to check whether the conditions in authorisations are being observed by downstream users.
- **Article 67(1):** this states that a substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction, shall not be used unless it complies with the condition of that restriction.

Management systems to ensure compliance with REACH

35. Where dutyholders are found to be in contravention of REACH, inspectors should, where appropriate, assess the suitability of management systems to determine the organisational factors that allowed the contravention to happen. Unless weaknesses in those systems are identified and corrected, similar contraventions may re-occur. The need for dutyholders to have suitable and sufficient management systems to ensure compliance with occupational health and safety and environmental protection legislation is well established. This strategy seeks to extend the same principles to REACH compliance.

Interventions

36. Enforcing authorities will undertake a range of interventions, both proactive and reactive, to ensure dutyholders comply with REACH. The following paragraphs set out the various kinds of intervention that enforcing authorities may wish to consider, though the exact scope and nature of interventions will depend on the enforcing authority's organisational priorities and resources.

37. Compliance with REACH may be considered at visits to any premises where substances, preparations or articles are manufactured, imported, supplied or used.

Advice, education and promotion

38. The impact on compliance of providing good advice, educating dutyholders and promoting the law should not be underestimated. For REACH, this is all the more important given the technical and often complex nature of the legislation. The Hampton report states that good advice "can reduce administrative burdens by reducing the time taken to comprehend regulations, and any data requirements under them. It can increase the probability of compliance, and hence regulatory outcomes".

39. Enforcing authorities should help and encourage dutyholders to understand and meet their obligations under REACH more easily. This includes the provision of readily accessible advice and guidance. Dutyholders can also be provided with the details of the UK REACH CA's website, which contains a range of guidance leaflets and other material, including links to further information. For specific or complicated enquiries, dutyholders can be provided with the details of the UK REACH CA's Helpdesk.

40. Much work has been undertaken by numerous organisations with an interest in REACH, including enforcing authorities, trade associations, ECHA, and businesses themselves. Enforcing authorities are encouraged to continue this momentum, and in particular may wish to hold further educational events such as seminars, conferences etc about general or specific requirements of the legislation. Such techniques are particularly valuable in securing compliance as advice is given simultaneously to numerous dutyholders. Enforcing authorities may also wish to consider targeted, intelligence-based information campaigns on certain substances or within particular industry sectors to supplement inspection activities.

Inspection

41. For the purposes of this strategy, 'inspection' is the proactive process that involves collecting information to make an assessment of a dutyholder's current level of compliance, by comparing their activities to the legal requirements and benchmark standards relevant to the activities in question. Information may be obtained by reviewing relevant documents held by the dutyholder, and/or interviewing people, and/or monitoring or observing site conditions, standards or practices where activities subject to the requirements of REACH are carried out under the dutyholder's control. It follows that REACH inspection activity can occur at or away from a dutyholder's premises.

42. Enforcing authorities should develop their own arrangements for inspection, using the most appropriate inspection type to suit the circumstances and taking into account the resources available to them. Enforcing authorities should select dutyholders for inspection on a justifiable basis. This would typically (though not invariably) imply a risk-based approach to selection, for instance:

- through the application of targeted, intelligence-driven systems or procedures designed to identify specific dutyholders thought to be non-compliant (the Environment Agency in particular has developed sophisticated mechanisms for capturing and tracking substance and supply chain information);
- by the degree of hazard or risk, e.g. those dutyholders who manufacture, import, supply or use particularly hazardous substances;
- by the volume of substances the dutyholder manufactures, imports, supplies or uses, as the case may be (whether numerous substances, or single substances in very large quantities);
- according to the dutyholder's relative significance or position in a supply chain, particularly where their actions have the ability to influence the activities of a range of other dutyholders (so that intervention takes place at the point in the supply chain where the greatest enforcement effect is achieved);
- from inspection history, e.g. dutyholders with a poor record of compliance or who appear to be failing to heed previous advice; or
- on the basis of a dutyholder's industry sector, where information indicates that compliance is an issue in that sector.

43. The above list is not intended to be exhaustive, and enforcing authorities should apply the most appropriate selection criteria to suit the circumstances. The main aim should be to ensure an effective outcome in terms of compliance; it is worth remembering that careful targeting and intelligence-based selection may yield relatively low numbers of actual inspections but can make more of an impact on compliance than an approach that involves a large number of inspections but carried out with dutyholders selected using less precise means.

44. Inspections themselves should focus on the priority duties in REACH for enforcement (as set out above) as these are the principal means by which the effective operation of REACH can be secured.

Investigation

45. Enforcing authorities will frequently receive information on compliance issues reactively. Enforcing authorities should develop their own arrangements for the investigation of such matters as appropriate, taking into account the resources available to them. Examples could include, for instance:

- complaints made by individuals or businesses about others whom they allege are failing to comply with REACH;
- incidents of ill-health, dangerous occurrences or harm to the environment;
- voluntary approaches from dutyholders who believe they are, or might be, in contravention of REACH;
- information obtained through scientific analysis / testing;
- referrals from other enforcing authorities or public authorities; and
- information obtained through routine inspection activity.

Enforcement

46. Enforcing authorities have the ability to take a range of enforcement action, from verbal or written advice to the service of enforcement notices and (ultimately) prosecution. Decisions on enforcement are, of course, matters for inspectors and their approving officers, guided by the requirements of their organisation's enforcement policy and procedures.

47. Enforcement decisions should always be taken on a case by case basis. It may help inspectors, however, to consider the following factors in taking their enforcement decision:

- the severity of the hazards of the substance in question, and the magnitude of the risks it poses;
- the level of knowledge relating to the possible hazards of the substance and risks it might pose;
- the tonnage of the substance being manufactured, imported and/or supplied;
- the level of actual harm to human health or the environment which has arisen as a consequence of the contravention;
- the extent of the contravention, i.e. how far away from the required standards the dutyholder is judged to be;
- where a contravention is shown to be due (in part or in full) to the acts or omissions of another person, whether the dutyholder took all reasonable precautions and exercised all due diligence to avoid the contravention;
- the size of the dutyholder and its position and influence in the supply chain (for example the effect that considered enforcement action will have on actors down the supply chain, such as downstream users);
- the inspection history of the dutyholder, including whether they have received previous relevant advice or whether there is a history of non-compliance;
- the intention of the dutyholder in non-compliance, e.g. whether non-compliance is deliberate in order to gain commercial advantage;
- the scale of the benefits the dutyholder may be accruing by non-compliance;
- the standard of general conditions and the attitude of the dutyholder; and
- whether the proposed enforcement action is in the public interest and is likely to have positive implications on the compliance of other dutyholders;

Specialist input

48. The UK REACH CA and the Environment Agency's Chemical Assessment Unit can provide specialist input in a number of fields, including toxicology, occupational hygiene and environmental science. The arrangements for commissioning specialist advice are addressed within the enforcement MoU.

Inspector training

49. To ensure the effective implementation of the above strategy, it is important that inspectors are trained to an appropriate level. It is likely that different levels of training will be needed: a basic level of training for a large number of inspectors, and more specialist training for a smaller group. Enforcing authorities may wish to discuss their training needs with the UK REACH CA, which can offer advice and support to enforcing authorities wishing to run training events for their staff.

Monitoring the success of the strategy

50. There will be a number of methods available to monitor the success of the enforcement strategy in securing compliance with REACH. Qualitative mechanisms will include feedback from the UK Enforcement Liaison Group, trade associations, participants in educational events and so on. Quantitative mechanisms will include information on enforcement, such as the number of inspections undertaken, notices served, complaints received and investigated and so on.

51. Full and accurate recording of REACH interventions is required in order to fulfil the UK's obligations under REACH. By article 117, every five years Member States must submit to the Commission a report on the operation of REACH in their respective territories, including a section on enforcement. Article 127 makes it clear that 'enforcement' should be interpreted widely, as it is to include the results of inspections and monitoring. Enforcing authorities should develop their own procedures to ensure such information can be monitored and retrieved when required.

The interaction of REACH and existing legal provisions

52. REACH will impose a variety of duties related to the use of substances. At the same time, REACH provides that it applies 'without prejudice' to existing Community workplace and environmental protection legislation (other than that it repeals or amends). REACH will therefore operate alongside other existing regimes. It follows that compliance with one regime will not excuse a failure to comply with another.

53. However, the interaction between the various regimes may not always be straightforward, and enforcing authorities should consider the need to develop guidance to help dutyholders (and inspectors) understand the interaction between REACH and the other, related health, safety or environmental legislation they enforce.