



UK REACH REGULATION

Agency statement on transparency and the use of independent scientific knowledge and advice (ISA)

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GLOSSARY AND ABBREVIATIONS

Annex XIV	Annex XIV (14) of UK-REACH provides a list of substances subject to authorisation.
Annex XV	Annex XV (15) of UK-REACH providing general principles on the preparation of dossiers.
Annex XVI	Annex XVI (16) of UK-REACH outlines the information that may be addressed when submitting a socio-economic analysis.
Appropriate Authorities	This means the Secretary of State (Defra), and Ministers of Scotland and Wales, as defined in Article 4A of UK REACH.” Probably best to keep to this for consistency.
Article 54	Article 54 of UK-REACH ‘Publication of information on evaluation’.
Article 69	Article 69 of UK-REACH ‘Preparation of a proposal’.
Article 77	Article 77 of UK-REACH ‘Tasks’
Article 109	Article 109 of UK-REACH ‘Rules on transparency’.
Article 117	Article 117 of UK-REACH ‘Reporting’.
Article 123	Article 123 of UK-REACH ‘Communication to the public of information on risks of substances’.
Article 124	Article 124 of UK-REACH ‘Other responsibilities’.
ASOs	Accredited Stakeholder Organisations (ASOs) are organisations who represent their field of competence within the UK.
Authorisation	A process under UK REACH to manage the risk from Substances of Very High Concern on Annex XIV. Applicants must apply to the Agency to seek authorisation to use these substances.
Authorisation Consultation Meeting	A meeting between the applicant for an authorisation, HSE/EA and other parties who may have submitted information through the public consultation on alternative substances and technologies.
Case Teams	A group of HSE/EA experts who are responsible for drafting the opinion. This can sometimes feature independent experts from the REACH Independent Scientific Expert Pool (RISEP).
Challenge Panel	A group of RISEP members, scientific experts from HSE, EA, SEPA, NRW and the public health authorities from England, Scotland and Wales who are responsible for scrutinising and challenging draft opinions produced by the Case Team. HSE/EA staff and RISEP experts involved in the Case Team for a substance will not be on the corresponding Challenge Panel.
Civil Service Code	The statutory basis for the management of the Civil Service and a set of values that Civil Servants and all those participating in Civil Service activity must obey.
COC	Committee On Carcinogenicity (COC).
COT	Committee On Toxicity (COT).

CRD	The Chemicals Regulation Division (CRD) is a division of HSE and is responsible for the regulation of biocides, pesticides, detergents, chemicals covered by REACH, and for compliance with the Classification, Labelling and Packaging (CLP) Regulation.
EA	The Environment Agency (EA) is a non-departmental public body of Defra providing regulatory and scientific input into UK-REACH.
ECHA	The European Chemicals Agency (ECHA) is an agency of the EU responsible regulatory activity of EU-REACH.
EIR	Environmental Information Regulations (EIR) 2004
EU	European Union (EU).
EU-REACH	The EU's regulation of chemicals, 'The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)' Regulation (EC) No 1907/2006.
Defra	Department for Environment, Food and Rural Affairs (Defra), a Government department responsible for the policy of the environmental and chemicals.
DPA	Data Protection Act (DPA) 2018.
DWP	Department of Work and Pensions (DWP), the Government department which is the parent department of HSE.
FOIA	Freedom of Information Act (FOIA) 2000
GB	Great Britain (GB) which includes: England, Scotland and Wales
GDPR	General Data Protection Regulation (GDPR) 2016
Government scientific agencies	Includes agencies such as: Environment Agency, Public health authorities of England, Scotland and Wales, Scottish Environmental Protection Agency and Natural Resources Wales.
HSAC	Hazardous Substances Advisory Committee (HSAC)
HSE	1) The Health and Safety Executive (HSE) is a non-departmental public body of DWP. 2) HSE is identified as the lead Agency for UK-REACH in the regulation.
ISA	Independent Scientific knowledge and Advice (ISA). The method of engaging experts independent of the Agency to provide scrutiny of Agency developed opinions, and on other matters as deemed necessary.
Opinion/ Agency Opinion	As part of the process for both restrictions and applications for authorisation the Case Team uses the information available to evaluate and prepare an opinion related to the risks of substances, as well as the socioeconomic impact of possible legislative actions on chemicals.
Political party	A party who is involved in political activity and is registered with 'The Electoral Commission'.
Principles of Good Complaint Handling	A set of principles set out by the 'Parliamentary and Health Service Ombudsman'
Principles of Scientific Advice to Government	A set of principles set out by the 'Government Office for Science'.

PSIS	Pre- Submission Information Session (PSIS) undertaken between HSE/EA and applicants for authorisation. This is non-legislative but can help applicants to understand the process and information required to submit an application.
RAC	European Chemicals Agency’s Risk Assessment Committee (RAC).
Restriction	A risk management measure proposed where it is considered there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances that needs to be addressed on a GB-wide basis.
Restriction Opinion Case Team	A group of HSE/EA staff who will formulate the draft opinion for a restriction.
Restriction Proposal Drafting Team	A group of HSE/EA staff who will prepare the Annex XV dossier for a restriction.
RISEP	REACH Independent Scientific Expert Pool (RISEP). A list (pool) of experts that can be used to provide advice independent of the Agency.
RISEP Secretariat	RISEP is supported by a secretariat, which is provided by HSE. Its role includes organising the work of RISEP experts and supporting them in matters of administration and protocol.
RMOA	Regulatory Management Options Analysis (RMOA) is a process that is used to clarify whether regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern.
SEAC	ECHA’s Socio-Economic Assessment Committee (SEAC)
Seven Principles of Public Life	Seven principles set out by the ‘Committee on Standards in Public Life’.
Scientific Advisory Committee	Official committees who provide scientific input to Ministers/Departments of the UK Government.
Socio-economic Analysis/ Impact	The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented.
Stakeholder	Organisations and individuals who are interested in, impacted by and or involved in UK-REACH.
SVHCs	Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs). The substance groups with SVHC properties include: <ul style="list-style-type: none"> • CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction) • PBTs (substances that are Persistent, Bio accumulative or Toxic for the Environment)

	<ul style="list-style-type: none"> • vPvBs (substances that are very Persistent and very Bio accumulative) • substances of equivalent concern (such as endocrine disruptors or sensitisers)
The Agency/ UK Agency	The Health and Safety Executive is defined in the regulation as 'The Agency'.
Titles VII	Titles VII of UK-REACH 'Authorisation'.
Titles VIII	Titles VIII of UK-REACH 'Restrictions On The Manufacturing, Placing On The Market And Use Of Certain Dangerous Substances, Mixtures and Articles'.
UK-REACH	Means the EU REACH Regulation as amended by the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (as amended by other domestic EU Exit regulations).
Universal Ethical Code – Rigour, Respect and Responsibility	A set of values that all scientists must follow set out by the 'Department for Business, Energy & Industrial Strategy'.

SUMMARY

Article 77 in the UK REACH Regulation makes provisions for the Agency (the Health and Safety Executive) to obtain and use independent scientific knowledge and advice (ISA) in the formation of relevant Agency opinions. It also requires the Agency to publish a statement on how it gathers and uses this advice, as well as how it will ensure a high degree of transparency when carrying out its functions under UK REACH.

This document fulfils the requirement for that statement and has been produced and published by the Agency following consultation with stakeholders and the public. The statement is published to make transparent to all stakeholders the Agency's approach to gathering and using ISA. It is part of ensuring on-going transparency in the process of, and trust in, regulatory decisions and processes.

Under EU REACH, scientific advice was produced through committees (Committee for Risk Assessment (RAC) and Committee for Socio-Economic Assessment (SEAC)), with Member States nominating independent experts to sit on these bodies. This arrangement is impracticable on a one-country basis.

The Agency will instead develop draft opinions through Case Teams and review opinions via Challenge Panels. ISA may be required to complement the Agency's internal knowledge on Case Teams and will be required to provide a critical voice on Challenge Panels. The Agency will therefore set-up a REACH Independent Scientific Expert Pool (RISEP), inviting experts with suitable qualifications and experience to apply.

UK REACH requires the Agency to act in a way that ensures a high degree of transparency. This statement details how the Agency will operate in a transparent way, including making internal processes and activities public, and communicating clearly and consistently with the public and stakeholders. This will also include the engagement of Accredited Stakeholder Organisations within the UK REACH process.

Objectives

This statement communicates to stakeholders and the general public how independent scientific knowledge and advice (ISA) will be embedded within the UK REACH regime, and also how the Agency will carry out functions under UK REACH with a high degree of transparency.

This includes:

- An overview of the relevant parts of UK REACH.
- The roles and responsibilities in which the REACH Independent Scientific Expert Pool (RISEP) will be invited to participate to help the Agency develop scientific opinions.
- A broad overview of the circumstances where it might be appropriate to use existing knowledge and advice rather than commission new ISA

- Expectations of RISEP experts and the skills, expertise and qualifications required to become part of RISEP, as well as more general skills that are required for RISEP experts.
- Transparency in UK REACH.
- The involvement of stakeholders in the process.

Overview of development

The ISA process has been primarily developed by Health and Safety Executive (HSE) and Environment Agency (EA) scientists, who have experience of the EU REACH system via their involvement in the work of the European Chemicals Agency's Risk Assessment Committee (RAC) or Socio-Economic Assessment Committee (SEAC). Throughout the development of the process we have closely cooperated with the Department for Environment, Food and Rural Affairs (Defra)¹ as well as officials from Scottish and Welsh Governments to ensure that the development of opinions can facilitate decision making in UK REACH.

This has also included some stakeholder engagement, both at early stages in designing the approach to using ISA and when the process was further developed. Additionally, the Agency has included a public consultation stage which will ensure we gather wider stakeholder views, balancing this with the need for this statement to provide a high-level perspective of the ISA process and that more detailed guidance on the process will be made available. It is also expected that a level of comfort with the ISA process as a whole will develop with familiarity, as well as increased stakeholder engagement once the UK REACH regime starts in earnest. A summary of the public consultation has been included in Annex 6.

This statement may need to be revised in the future as experience of worked examples become apparent. Future consultations and feedback will be considered on revisions

¹ Defra owns the overall policy responsibility for UK REACH for UK government.

1. INTRODUCTION

Following the UK's exit from the European Union, the EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals² (REACH) became retained law within Great Britain as "UK REACH" at the end of the implementation period. As part of this process, amendments were required due to inoperabilities that arose from the EU-specific language and institutional structures within the EU REACH Regulation³. This statement addresses repatriation of responsibilities contained within the EU REACH Regulation for the use of scientific committees (Committee for Risk Assessment (RAC) and Committee for Socio-Economic Assessment (SEAC)) and use of ISA, which involved Member States nominating experts for appointment to the relevant committees. From a practicability point of view, it would be inappropriate to mirror these arrangements on a single-country basis.

The processes which are covered by the EU scientific committees were examined to ensure that ISA is embedded into UK REACH in a proportionate way, taking account of the availability of experts and the need for the process to be transparent.

Therefore, the authorisation and restriction processes in UK REACH include provisions for ISA to be sought. This follows the decision by Defra Ministers that UK REACH should place a duty on the Agency to seek ISA when forming opinions on applications for authorisation and restriction, including advice relating to reducing the risk to human health and the environment, as well as socioeconomic matters.

Definitions in this statement:

Any reference to "UK REACH" means the EU REACH Regulation (see footnote 1) as amended by the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (as amended by other domestic EU Exit regulations).

Any reference to the "UK REACH regime" means the systems and processes, which are set up to implement UK REACH on a UK-wide basis, including those provisions which implement the Northern Ireland Protocol.

Any reference to "ISA" means independent scientific knowledge and advice provided to the Agency for the purposes of carrying out its functions under UK REACH.

Any reference to "the Agency" means HSE. HSE is identified as the Agency in Article 2A of UK REACH.

Any reference to the "EA" means the Environment Agency. The functions of the EA within UK REACH are defined in Article 2B.

Any reference to "Appropriate Authorities" means the Secretary of State (Defra), and Ministers of Scotland and Wales, as defined in Article 4A of UK REACH.

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals

³ Amendments were made by domestic legislation made under the European Union (Withdrawal) Act 2018

2. LEGISLATIVE CONTEXT AND BACKGROUND

2.1: Legislative basis and interpretation

With respect to the inclusion of ISA in UK REACH, the relevant article in UK REACH is Article 77 and its various paragraphs. Paragraph A5 of this Article requires the Agency to produce and publish a statement on how it obtains and uses scientific advice.

The policy intent of Article 77 and its paragraphs (as set out below) is to ensure ISA is obtained and used to aid the formation of opinions openly and transparently, so that stakeholders can have trust in the process and outcome. This statement therefore covers how the relevant expertise will be recruited and used by the Agency and what the necessary level of expertise is. It also covers broadly how the Agency will deal with issues of uncertainty, conflicts of interest, the role of the expert and the decision-maker in the ISA process and the behaviours expected of experts. An additional aspect of the statement is explaining how the Agency will act in a way that ensures a high degree of transparency when exercising its functions under UK REACH.

Relevant provisions of Article 77 of UK REACH:

A1. When forming opinions the Agency must take relevant scientific knowledge and advice into account (including any relevant knowledge and advice relating to socio-economic matters).

A2. The Agency may take any such knowledge or advice into account when forming an opinion only if—

- (a) the knowledge or advice has been commissioned by the Agency, from one or more suitably qualified or experienced persons who are independent of the Agency, for the purposes of forming the opinion concerned, or
- (b) the knowledge or advice-
 - (i) is already in existence (whether within the Agency or externally),
 - (ii) is produced within the Agency for the purposes of forming the opinion concerned, or
 - (iii) is, in accordance with Article 2B, produced by the Environment Agency or one of the other environmental regulators in connection with the Agency forming the opinion concerned and then passed on to the Agency, and the Agency considers that it is appropriate to take it into account, rather than to commission knowledge or advice in compliance with point (a).

The knowledge or advice that the Agency may take into account in compliance with point (b)(i) includes knowledge or advice which has previously been commissioned by the Agency from one or more suitably qualified or experienced persons who are independent of the Agency for the purposes of forming a previous opinion on any matter.

A3. The Agency must comply with this paragraph if-

- (a) it is forming—

- (i) an opinion in connection with deciding whether to grant an authorisation under Article 60,
 - (ii) an opinion under Article 70 as to whether suggested restrictions are appropriate in reducing the risk to human health or the environment, or
 - (iii) an opinion under Article 71 on suggested restrictions and on the related socio-economic impact, and
- (b) it only takes into account knowledge or advice that is not commissioned in compliance with paragraph A2(a) for the purposes of forming that opinion.

The Agency must-

- (a) produce an explanation of why it considered that it was appropriate to take only that knowledge or advice into account;
- (b) publish the explanation, and
- (c) send a copy of the explanation to the appropriate authorities.

A4. When exercising its functions, the Agency must act in a way that ensures a high degree of transparency.

A5. The Agency must produce and publish a statement of how it will comply with paragraphs A1, A2 and A4.

The Agency must produce and publish the first statement within the period of 3 months beginning with the day after exit day.

The Agency must consult such persons as it considers appropriate before producing the first, or any subsequent, statement.

A6. The statement must include-

- (a) information about the qualifications or relevant experience that are suitable in order for persons to be commissioned to provide knowledge or advice to the Agency;
- (b) examples of situations in which the Agency envisages that it might be appropriate to take existing knowledge or advice (rather than knowledge or advice commissioned as mentioned in paragraph A2(a)) into account.

The underlined text emphasises where there are duties on the Agency. This document fulfils the obligation under paragraph A5 to provide a statement outlining how the Agency will comply with Article 77. It covers matters of expertise and experience, ensuring independence in assessing and forming opinions within the operational context. The statement ensures that these processes of obtaining and using independent scientific advice are governed by:

- A high level of transparency in decision and opinion making; and
- A commitment to taking into account both internal and external independent scientific (including socio-economic) expertise where it is appropriate and relevant to the Agency's decision and opinion making duties for authorisation and restriction, but also on other matters related to UK REACH on a case-by-case basis.

The purpose of this statement is to provide assurance and confidence on the part of stakeholders and the public in the process for forming Agency opinions. It is also part of building and maintaining trust in the opinion-making. As a standalone document it fulfils duties under UK REACH and sits alongside and complements more general published information such as the Government Chief Scientific Adviser's Guidelines on the Use of Scientific and Engineering Advice in Policy Making⁴.

2.2 Background:

The desired outcome of the Agency's authorisation and restriction processes is to provide the Appropriate Authorities with scientific opinions concerning the assessment of applications for authorisation and restrictions. The procedures for opinion development follow fixed deadlines. The opinions must meet the requirements set out in Titles VII and VIII of UK REACH (relating to authorisation and restriction), which in turn enables the Defra Secretary of State to be able to meet their legal obligations on decision making as also specified in these titles.

Regulatory scientists and experts in the Agency and EA will usually be the most appropriate experts to assess applications for authorisation and restriction dossiers and develop the scientific opinions, having the relevant regulatory and scientific knowledge and expertise. Nevertheless, Article 77 of the UK REACH Regulation states that the Agency must take relevant scientific knowledge and advice into account when forming its opinions. In this respect, advice and input from scientific experts independent of the Agency, Government and current interest groups is necessary to provide independent challenge, as well as supplementary experience, knowledge and skills to develop scientifically robust assessments of applications for authorisation and restrictions.

When developing the process for the use of ISA to form opinions in UK REACH, it was concluded that the flexible approach of developing a pool of experts to be used when needed was more beneficial than using new or existing scientific expert committees. New or existing scientific expert committees operating entirely independently of the Agency would be unlikely to be able to undertake these tasks effectively because:

- A standing committee may struggle to produce the range of opinions, skills and necessary challenge which are required in the UK REACH regime; and
- Legally, the Agency must produce the opinion and an independent committee could therefore not do this instead of the Agency.

This does not limit the Agency from consulting new and existing committees for other aspects of the UK REACH process – for instance for advice on evaluation of novel substances.

The Agency therefore proposes to incorporate the requirement for independent scientific advice and scrutiny by including this as part of its newly established *Challenge Panel* processes. In addition, in some cases there may be a role for some independent experts within the Agency's *Case Teams* which are responsible for the

⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/293037/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf

drafting of opinions. This will be determined by the Agency and EA on a basis of the required needs as explained below. A combination of Agency and independent scientists will therefore collectively assess, scrutinise and develop the Agency's opinions - more detail on this is given in section 4. This way, the opinions remain those of the Agency whilst independent scientific advice is incorporated through the input and scrutiny of the independent experts involved in the Challenge Panels. The Challenge Panels will make recommendations and provide endorsement of the opinions through seeking to achieve consensus between all the experts. However, individual experts are free to dissent from the consensus view and this dissension would be documented within the process, as well as within the final opinions sent to the Appropriate Authorities (see section 4 for further details) which will be published on HSE's website.

Given the highly case-specific nature of the scientific expertise and knowledge required across individual applications for authorisation and restriction dossiers, the independent scientific experts will be recruited to a pool of independent scientific experts known as the *REACH Independent Scientific Expert Pool (RISEP)*. The composition, roles and required expertise of the pool are set out below in Part 4.4 of this statement.

Experts will be selected from the pool to mainly serve on Challenge Panels but sometimes on Case Teams, matching their specific expertise and knowledge to that required for the nature of the application for authorisation or restriction

3. AGENCY PROCESS ON AUTHORISATION AND RESTRICTIONS

3.1 Authorisation:

The aim of the authorisation process under UK REACH is to ensure the good functioning of the GB market while assuring that the risks from substances of very high concern (SVHCs) are properly controlled, and that these substances are progressively replaced by suitable alternatives where these are economically and technically feasible.

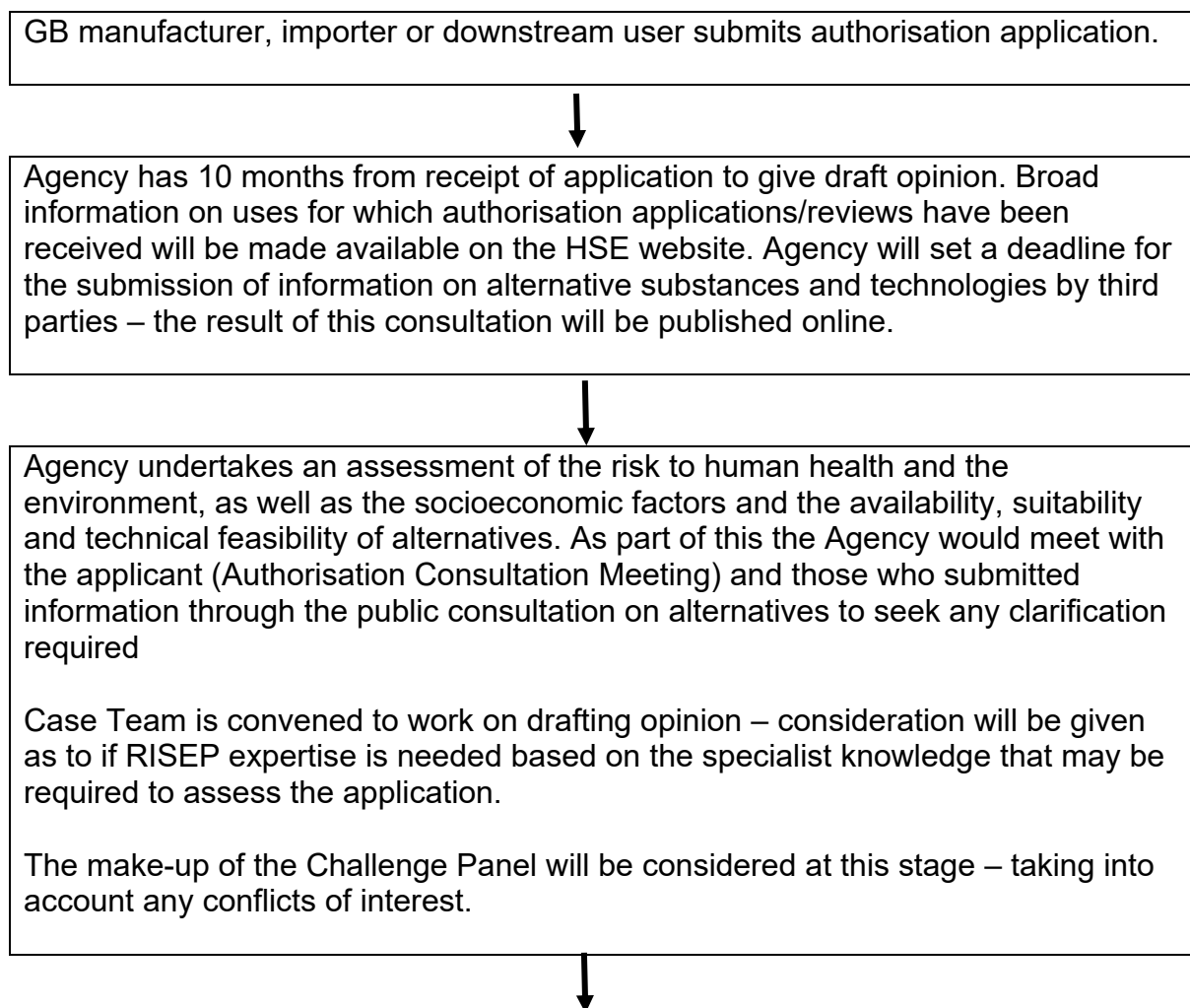
Authorisation application is a regulatory permissioning regime in which applicants seek approval to use SVHCs which are on the authorisation list of UK REACH (Annex XIV). Applications for authorisation can be prepared by GB manufacturers, importers or downstream users of a substance on the Authorisation List. Authorisations are granted by the Defra Secretary of State subject to the consent of the Scottish and Welsh Ministers, following an opinion (including necessary ISA) from the Agency based on an assessment of the submitted information.

The process starts when a notification to submit an application for authorisation or request for a pre- submission information session (PSIS) is received by the Agency. After receiving the authorisation application, the Agency Case Team evaluates it and prepares an opinion – as described in the flow chart below. The opinion making stage will also include ISA, with experts being engaged as appropriate within the process, but primarily at the Challenge Panel stage when experts from RISEP will review and scrutinise the draft opinion (more detail on this is given in Section 4 below). The final opinion of the Agency is sent to the Appropriate Authorities for a decision, as well as the applicant. A summary of the decision of the Defra Secretary of State on the Application for Authorisation is published and made publicly available.

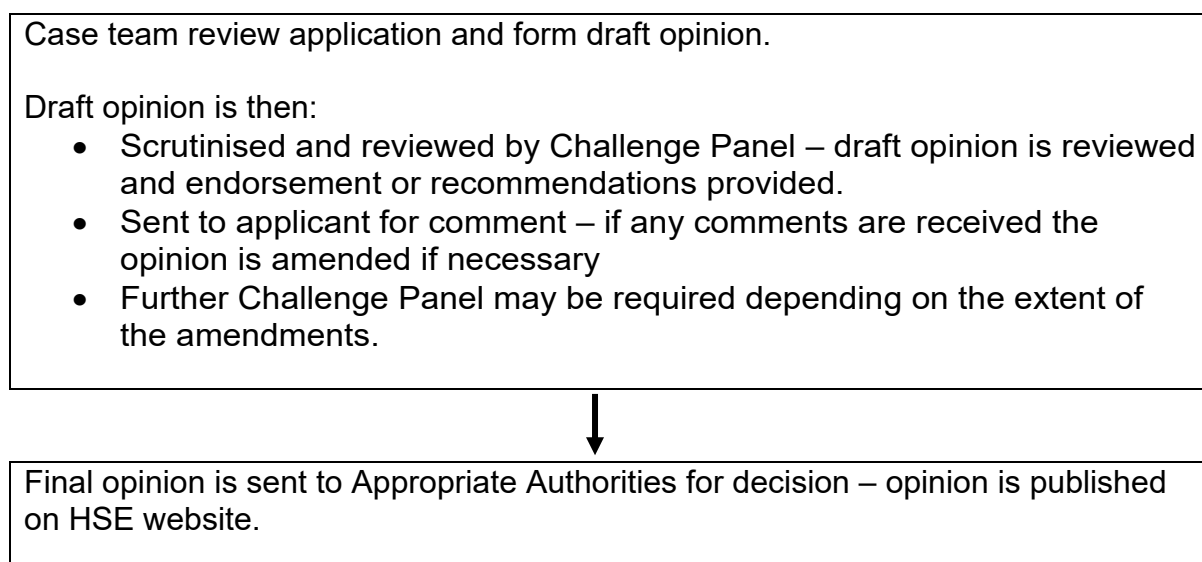
In accordance with the authorisation process established by UK REACH, the Agency is required to formulate an opinion in relation to an application for authorisation as follows (this also includes reviews of existing authorisations):

UK REACH Article	Authorisation Opinion Requirement on the Agency
64 (4a)	An assessment of risk to human health and/or the environment arising from the use(s) of a substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.
64 (4b)	An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third-party contributions submitted during the consultation on alternatives.

Authorisation Process⁵:



⁵ This process may be reviewed and revised upon practical experience of its operation and subject to the confines of the legislation. Any changes will be communicated in a further revision of this statement or on the Agency website.



3.2 Restriction

UK REACH restrictions are proposed when it is considered that there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances that needs to be addressed on a GB-wide basis.

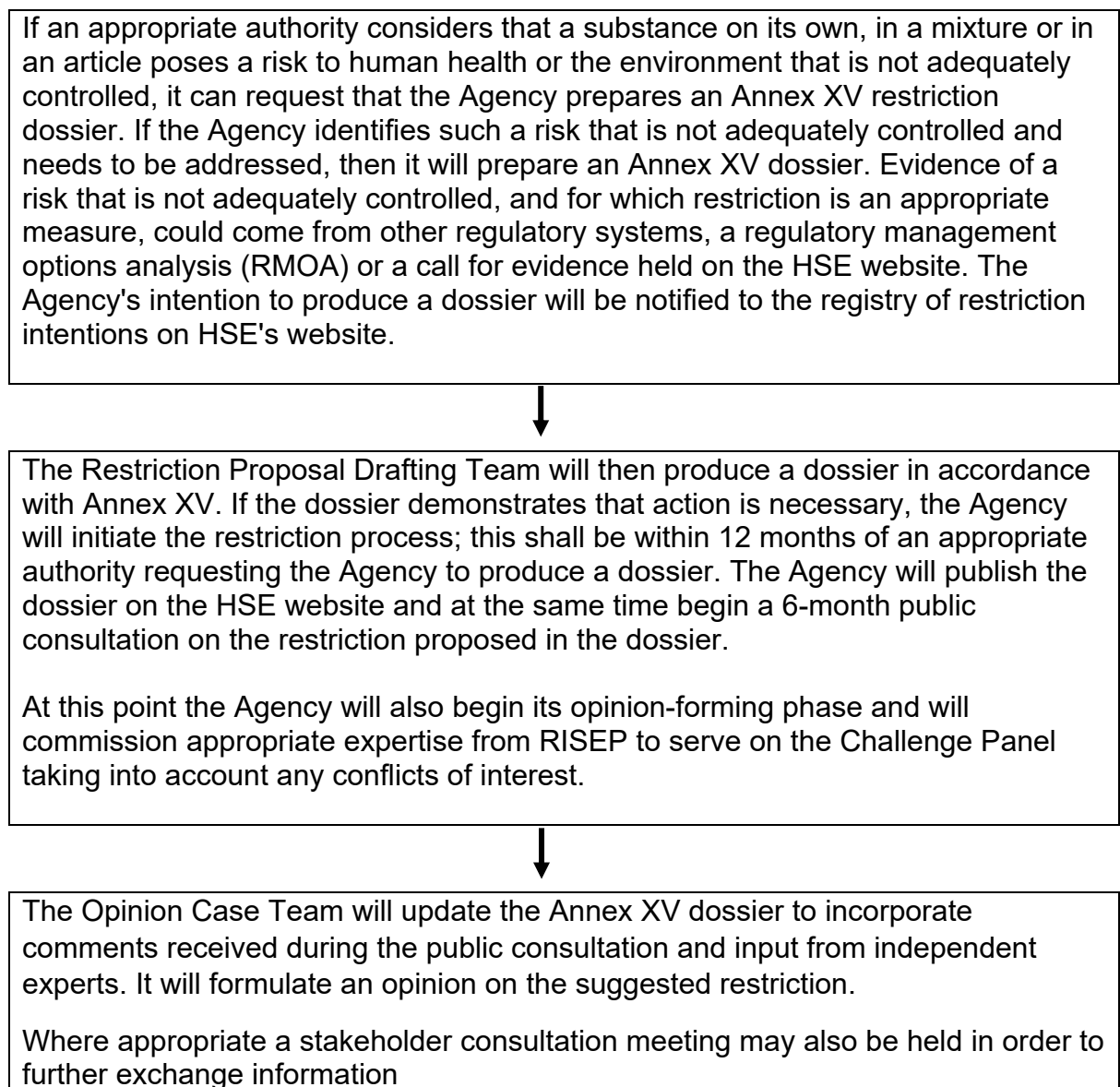
To assess this risk the Agency will produce a dossier which can be instigated either by the Agency itself or via a request from an Appropriate Authority. The purpose and contents of this dossier are identical to those in EU REACH. The content and format are set out in UK REACH Annex XV, and Annex XVI for any socio-economic analysis included. This dossier, which is produced by a Restriction Proposal Drafting Team, will then be made available on the Agency website for interested parties to provide comments, information or socio-economic analysis.

The Agency will then formulate an opinion via a Restriction Opinion Case Team of experts from the Agency, as well as the EA. This Opinion Case Team will consist of the Restriction Proposal Drafting Team but may also include independent experts on the basis of required needs, who will be consulted as required (see Section 4). The opinion will be produced based on consideration and review of the relevant parts of and information/evidence in the dossier, and the comments/analyses submitted as part of the public consultation. During the opinion development a stakeholder consultation meeting may also be held for gathering and sharing information, as well as enabling challenge and scrutiny by stakeholders of the restriction proposal evidence. The Agency’s dossier and opinion will be reviewed by a Challenge Panel made up of independent experts from the RISEP pool and Agency staff who were not part of the Case Team, as well as other experts from relevant Government scientific agencies. The relevant opinion making requirements in UK REACH are:

UK REACH Article	Restriction Opinion requirement on the Agency
70	Within nine months of the date of publication referred to in Article 69(6), the Agency shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or

	the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the dossier, and the views of interested parties referred to in Article 69(6)(a).
71 (1)	Within 12 months of the date of publication referred to in Article 69(6), the Agency shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion

Restriction Process⁶:



⁶ This process may be reviewed and revised upon practical experience of its operation and subject to the confines of the legislation. Any changes will be communicated in a further revision of this statement or on the Agency website.



Within 9 months of the publication of the Annex XV dossier on HSE's website, the Opinion Case Team will, incorporating the advice of the Challenge Panel, produce an opinion on risk assessment and draft opinion on socio-economic analysis.

Within 12 months of the publication of the Annex XV dossier, the Agency will hold a 60-day public consultation on the draft opinion on socio-economic analysis and, taking comments received into account and incorporating the advice of the Challenge Panel, the Opinion Case Team will update the Annex XV dossier and finalise the opinion.

Independent experts from RISEP will provide independent scrutiny and challenge of the Annex XV dossier and the impact of comments received during both public consultations, as well as ensuring the opinion represents a robust summary and reflection of the evidence contained in the dossier, procedure followed and advice of the challenge panel.



The final opinion will be adopted, sent to the Appropriate Authorities, and published on the HSE website.

4. USE OF INDEPENDENT SCIENTIFIC ADVICE:

The Agency will recruit experts to the REACH Independent Scientific Expert Pool (RISEP) to work with them primarily to develop opinions for authorisation applications and restrictions. However, there may be other circumstances where the Agency would consider using RISEP specialist knowledge. RISEP is not a scientific advisory committee but is established as a pool of individual experts to support the UK Agency in developing its scientific opinions by providing independent challenge and supplementary experience, knowledge and skills.

Recruitment for RISEP began in February 2021 and the pool aims to combine technical/scientific knowledge with a good level of experience, ensuring that expertise provides a representative and proportionate balance of science and regulatory perspectives (see section 4.4. for further details). Individual experts will not be required to participate in all RISEP-related activities but will be invited where necessary to advise the Agency according to required needs (see Section 4.1). Consideration will be given to experts from outside of GB, however experts should note the arrangements for paid expenses if they do apply.

RISEP will work in conjunction with:

- Scientific experts and advisors from HSE and other Government agencies who participate in the work of the Agency, including:
 - Environment Agency

- Scottish Environmental Protection Agency
- Natural Resources Wales
- Public health authorities of England, Scotland and Wales

In addition to calling on experts from RISEP, the Agency will also seek advice from the existing Government Scientific Advisory Committees (such as Committee on Toxicity (COT), Committee on Carcinogenicity (COC), Hazardous Substances Advisory Committee (HSAC) etc) where it is appropriate to do so. As mentioned above it will be inappropriate to consult such committees as a whole on the development of individual restriction and authorisation opinions. However, individual members from these committees may be co-opted into RISEP for a time-limited and specific purpose where necessary, and without the need for appointment through the usual application process (although they would still have to declare any relevant interests/conflicts). Members of such committees are also able to apply for appointment to RISEP in their own right as ordinary appointees to RISEP.

4.1 RISEP roles and responsibilities

RISEP experts will be primarily invited to participate in Challenge Panels and sometimes Case Teams. However, it is also possible that experts from RISEP or other experts (who may not need to be independent as they would be used for a specific, limited purpose - but would nevertheless be required to declare any relevant interests/conflicts) could be used outside the opinion forming process of Case Teams or Challenge Panels. This could include, for instance, the interpretation of particularly complex or novel information or industrial processes of which the Agency may have limited understanding.

Case Teams will be responsible for developing the Agency's draft scientific opinions for restrictions and applications for authorisation as well as restriction dossiers. Because of the time commitment required, RISEP experts will not typically participate in the restriction Case Teams, however they may be co-opted in as a member of the Case Team where it is considered additional expertise is required; This could be, for instance, to bolster in-house Agency experience or provide specialist knowledge of a sector, type of chemical or testing strategy. RISEP experts may be asked to sit on authorisation Case Teams to gain first-hand experience of drafting an Agency opinion.

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Challenge Panels will be responsible for scrutinising and reviewing the Agency's draft scientific opinions as part of the authorisation and restriction processes. This interaction may happen at key points during the opinion development process e.g. after public consultation for restrictions. One of their key roles will be to review the final opinion before this is sent to the Appropriate Authorities. Experts involved in a specific Case Team will not participate as representatives on the corresponding Challenge Panel for that particular case.

As requested by the RISEP secretariat, work on Case Teams and Challenge Panels:

- Will require attendance at regular standing meetings,

⁷ In this case, this person would not sit on the Challenge Panel for the substance that they worked on the Case Team for.

- May require contribution of their expertise and advice during other ad-hoc meetings,
- May require written work, phone and video conferences

Until the volume of work on restrictions and applications for authorisation becomes clearer, it is difficult to give a minimum/maximum number of RISEP experts required. This will also vary with the size and complexity of the restriction/application for authorisation and level of advice required pursuant to section 4.2.

RISEP Secretariat – RISEP is supported by a secretariat, which is provided by HSE. Its role includes organising the work of RISEP experts and supporting them in matters of administration and protocol.

4.2 Circumstances of ISA use:

As detailed in UK REACH, the Agency must take relevant scientific knowledge and advice into account when forming opinions on restrictions and applications for authorisation. However, where the knowledge or advice is already in existence and the Agency considers that it is appropriate to take this into account and not commission ISA then the Agency must:

- Produce an explanation of why this was considered appropriate; and
- Publish this explanation and send a copy to the Appropriate Authorities.

There will be circumstances where ISA may not be commissioned for at least some part of the opinion-making processes; this may include but not be limited to:

- Reviews of previously granted GB authorisations where it is considered that there is no new evidence or suitable alternatives which need to be taken into account, or where the change to circumstances of the original authorisation are minimal and/or part of a wider decision.
- Similar authorisations on the same substance and use, where an opinion has previously been adopted and that has incorporated ISA. If the substance is used in the same way for the same purpose then commissioning ISA to consider the same exposures, processes and socio-economic justification would not seem an effective or necessary use of expertise.
- Decisions on restrictions that have gone through the EU process and where the restriction report and opinions can be assessed as being applicable to and equivalent for circumstances in GB, so as to enable these to be read across.

Example 1:

The Agency receives applications for authorisation under UK REACH for the use of chromium compounds in the surface treatment of metals. This use is relatively common and therefore we could potentially receive numerous applications – some

possibly as part of consortia.

Some of these applications could be similar with respect to:

- Use: prevention of corrosion and oxidation, for example “chrome plating of sanitary furniture”
- Exposure: similar conditions, controls and processes.
- Socio-economic profile/acceptable substitution alternatives

Example 2:

If the Agency and EA prepare a restriction dossier on a proposal that has gone through the EU REACH restriction system, they will refer to the publicly available information where appropriate. In assessing this information, it might be deemed that both:

- The risk assessment opinion from RAC includes relevant hazard data, uses and exposures (both human health and environmental) that can be assessed as covering GB circumstances and,
- The socio-economic assessment from SEAC also covers relevant costs and benefits of action and is comparable to the socio-economic situation in GB.

In this case the information could be read-across and the process streamlined.

In these cases, the ISA process could be streamlined within the confines of the legislation; this would ensure a more cost-effective use of Agency resource and taxpayers' money as well as ensuring consistency in opinion, whilst still ensuring its scientific integrity. In most cases, it will be prudent to ensure at some level that the Challenge Panel scrutinises and endorses the opinion of the Agency - even if this is just to affirm the decision not to commission the whole ISA process under the circumstances described above. As the Challenge Panels will be open to stakeholders, there would also be a chance for stakeholders to provide evidence to justify why ISA should be commissioned. This will be kept under review in the process and as circumstances dictate such as the production of explanations why ISA was not commissioned.

4.3 Agency expectations of RISEP independent scientific advisers:

The Agency expects independent scientific advisers, either individually or as part of a group, to:

- Demonstrate scientific integrity, to keep themselves and any relevant team properly informed.

- Ensure they have access to all of the relevant facts and evidence, especially any used to support the formation of opinions.
- Be alert to uncertainties and differences in judgement or opinion and advise on any impact on a decision.
- Distinguish personal opinion from judgement, the former given in the absence of assessment of e.g. relevant facts whilst the latter is based on assessment and analysis.
- Engage with those who do not share their judgement to identify how best this might be resolved.
- Provide explanation and justification of judgements and be prepared to be challenged.
- Manage group think and/or undue influence of particular experts with strong views.
- Focus on what matters most for decisions rather than what is challenging or interesting.
- Ensure that they work in accordance with RISEP's Terms of Reference.
- Not divulge any information that is provided to them in confidence and in accordance with the RISEP Guidance and Declaration on Confidentiality.

The Agency will require independent scientific experts to seek to come to firm conclusions based on consensus and fully informed by the data and information available, but they will not be expected to form conclusions where this is not justified due to incomplete or inaccurate data. The Agency does not expect that full consensus on all scientific and technical issues will always be possible; where there are uncertainties or disagreements with the scientific position taken, these should be indicated and communicated directly in plain language to decision makers.

4.4 Skills, expertise and qualifications required:

Experts on RISEP must possess the necessary qualifications and experience in order to allow the Agency to ensure the quality and robustness of scientific and technical evidence relied on to produce its opinions. The Agency will be called upon to deliver scientific assessments and opinions that may cover a wide range of areas of competence. Accordingly, a wide range of expertise will be required within RISEP to ensure that all relevant aspects can be addressed. Experts must therefore have significant relevant experience and expertise, reflecting the broad range of sciences and perspectives relevant to applications for authorisation and restriction proposals.

A high level of expertise in one or more of the required expertise fields as indicated in the table below.

Type of expert, including specialist knowledge and skills	Level of experience preferred (e.g. academic qualification, previous experience etc.)⁸
<p><i>Environmental risk assessors</i></p> <p>(i) Detailed understanding of the approaches to setting acceptable limits based on hazard</p> <p>(ii) Ability to assess environmental exposure arising from chemical manufacture and use (using both modelling and monitoring, recognising their strengths and limitations) with an understanding of chemical use at industrial sites and by consumers</p> <p>(iii) Detailed knowledge of the efficacy of different risk management measures. Cross-sectoral experience preferred.</p>	<p>Significant post graduate experience in a relevant discipline (a post-graduate qualification is not a pre-requisite) working in a field that is relevant (e.g. for a chemical regulatory body, industry, consultancy or in research & development).</p> <p>Experience and ability to evaluate is more important than a specific qualification as such.</p>
<p><i>Human health: toxicologists</i></p> <p>(i) Detailed understanding of the hazards that define relevant hazardous substances (all relevant hazards, data sets, assessment, criteria, guidance).</p> <p>(ii) Ability to develop dose-response relationships for the hazards that underpin relevant substances.</p> <p>(iii) Substantial expertise in risk assessment, preferably as described in ECHA guidance</p>	<p>Significant post graduate experience in a relevant discipline (a post-graduate qualification is not a pre-requisite) working in a field that is relevant (e.g. for a chemical regulatory body, industry, consultancy or in research & development).</p> <p>Experience and ability to evaluate data are both critically important.</p>
<p><i>Human health: exposure and control specialists</i></p> <p>(i) Substantial experience of workplace inhalation and/or dermal exposure assessment, including atmospheric and biological data assessment and modelling.</p> <p>(ii) Expertise in consumer/general population exposure assessment</p> <p>(iii) Sound knowledge of ECHA guidance on worker exposure scenarios.</p> <p>(iii) Detailed understanding of exposure control hierarchies,</p>	<p>Significant post graduate experience providing practical occupational hygiene advice to a variety of industry sectors.</p> <p>Experience and ability to evaluate data are both critically important.</p>

⁸ To note experience is not detailed in years to ensure we are not discriminating against applicants on grounds of age.

control measures, acceptable standards.	
Chemists or regulatory scientists Broad experience of how chemicals are used industrially or by consumers/population. Cross-sectoral experience and/or some research experience preferred.	PhD or MSc plus significant post graduate experience (academic or consultancy/ government/industry)
Economists To include welfare, public sector, environmental and health economists. Specifically with the following specialist knowledge: chemicals regulation and analysis of impacts on firms and markets; methodologies for health and environmental impact assessment & analysing the costs and benefits of chemicals regulation; the analysis of technical feasibility of alternatives and their costs. Knowledge about substitution of substances of relevant concern.	Ideally, PhD or MSc plus significant post graduate experience (academic or consultancy/ government/industry)

Required general skills

- Ability to make effective contributions to multidisciplinary expert groups advising on complex scientific and technical questions.
- Strong analytical and judgement skills, with independent thinking and being open to challenge.
- Well-developed interpersonal and communication skills with an ability to discuss, negotiate and build consensus on what are sometimes complex scientific and technical matters. Excellent command of written and spoken English.
- Aptitude for understanding of issues outside of their own specialist area and judgement on the implications of proposals.
- Ability to work under pressure and keep to timetables.

5. TRANSPARENCY IN THE UK REACH REGIME

5.1 Overarching transparency in UK REACH

As part of UK REACH the Agency is required to act in a way that ensures a high degree of transparency. This section of the statement sets out how the Agency will comply with this requirement.

Within UK REACH, HSE as the Agency will:

- Make details of the Agency's processes and activities available on the HSE REACH website and publish the Agency's Work Programme annually.
- Undertake reporting responsibilities required by UK REACH, such as publication of an annual report on evaluations under Article 54, and various reports under Article 117.
- Operate a helpdesk in accordance with Article 124, which will be backed up by communication initiatives such as presentations and events to keep in close connection with Agency stakeholders.
- Publicly consult on draft opinions and, where necessary, publish intentions of the Agency online, for instance maintaining a registry of intentions for which a dossier is planned or underway for a proposed restriction. This also includes publishing recommendations for inclusion of substances on the authorisation list in accordance with A58 and the production of a dossier for Substances of Very High Concern (SVHC) as per Article 59 .
- Take into account and respond to comments received from public consultations.
- Develop and maintain appropriate contacts with stakeholders (section 6 gives further details on where stakeholders can be involved in the UK REACH regime and the proposal to use Accredited Stakeholder Organisations (ASOs)).
- Inform and provide appropriate guidance to the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment, in accordance with Article 123.
- Develop rules under Article 109 to ensure the availability to the public of regulatory, scientific or technical non-confidential information on the safety of substances on their own, in mixtures or in articles.
- Establish and maintain a database containing information on registered substances and publish this information where appropriate in accordance with UK REACH.
- Make public the names and qualifications of experts engaged in RISEP, details of declarations of RISEP experts' conflicts of interest will be registered annually and also published.

- Publish agendas and notes of minutes from key stakeholder meetings (such as Challenge Panels) on HSE’s website.
- Publish and publicly consult on this statement to ensure all stakeholders have a chance to comment on the ISA process.

5.2 HSE as an Executive Non-Departmental Public Body (NDPB)

HSE is defined as the Agency in UK REACH. HSE is an Executive NDPB of the Department of Work and Pensions (DWP). Therefore, HSE is a governmental body and as such:

- is a public authority in its own right for the purposes of the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations (EIR);
- will ensure any personal data is gathered and handled in accordance with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018;
- responds to comments, suggestions and complaints in accordance with “Principles of Good Complaint Handling”⁹ and;
- the civil service code¹⁰ applies to all HSE employees. The code includes integrity, honesty, objectivity and impartiality as core values. It sets out standards of behaviour, which underpin these values, and are followed by HSE employees when carrying out duties as UK civil servants in the best interests of the wider public.

5.3 FOI:

In accordance with FOI HSE’s default position is to favour disclosure, if it is lawful to do so. HSE has guidance on how we deal with requests for information to be disclosed. HSE will consider each request to determine if exemptions apply and if the public interest test under FOI is met.

5.4 EIR:

Environmental information is exempt from FOI but will be considered for request from HSE under EIR¹¹. This includes information provided for UK REACH within the limitations of EIR.

EIR also works on the principle that disclosure of information should be the default and information should only be withheld from disclosure when the regulations allow it.

The rest of this section captures how the ISA process and recruitment has been developed with transparency as a key factor.

⁹ [Our Principles | Parliamentary and Health Service Ombudsman \(PHSO\)](#)

¹⁰ [The Civil Service code - GOV.UK \(www.gov.uk\)](#)

¹¹ [Health and Safety - Environmental Information Regulations \(EIR\) \(hse.gov.uk\)](#)

5.5 RISEP recruitment and governance

Part of the recruitment process for RISEP ensures that within the application process the terms and conditions of appointment to RISEP are made clear. This includes:

- The circulation of draft terms of reference and code of practice (see Annex 1 and 2).
- Guidance on conflict of interest and terms of confidentiality (see Annex 3 and 4).
- Declarations of interests/political activity were made as part of the RISEP application process (see Annex 5),

Sharing the recruitment process and specification fully ensured that all parties applying for RISEP were aware of the circumstances of their application and terms of engagement and, as this was circulated within the public domain, this was freely available and open to external scrutiny.

In the RISEP recruitment process, both an independent assessor and a scientific expert from a government department outside the Agency will be brought in to ensure selection decisions incorporate an external perspective and are taken in a fair and transparent way.

5.6 Public consultation and visibility of RISEP discussions

Steps for public consultation on opinions developed with the aid of ISA are built into the regulations. This will give third parties the ability to feed comments and information into the process, where these comments can be taken account of by the Agency and responded to publicly.

For applications for authorisation there is also an opportunity for stakeholder engagement during the Authorisation Consultation Meeting (ACM – equivalent to a triologue in the EU system) session with the Agency, where applicants and third parties can clarify evidence and ask/answer questions pertaining to the authorisation.

With respect to the Challenge Panels, which will take place to scrutinise and endorse Agency opinions, agendas and minutes of meetings (redacted as necessary so not to disclose Confidential Business Information) will be published on the Agency website. These will be available to view for all stakeholders. Section 6 below gives more detail on stakeholder participation.

5.7 Dealing with differences of opinion in the process

As covered above in sections 4.3 and 4.4 we do expect that both uncertainties in technical evidence, and differences in judgement will occur.

The Agency recognises that it may not be possible to have full consensus within all interpretations of the scientific data, and indeed part of the purpose of taking ISA is to gain a range of views. However, one of the objectives is to achieve consensus, so it is hoped that any extreme differences may be able to be resolved in the process, with discussion and further understanding of the issue in the Challenge Panel or meetings held within the processes with applicants or following public consultations.

If the difference in interpretation cannot be overcome within this process, then the

Agency shall request that the expert(s) with diverging views write(s) a position paper indicating their reasoning for taking their minority position. Recommendations from RISEP experts will be summarised in the Annex of the Agency opinion template. The template will provide the Appropriate Authorities with a note of major/minor recommendations, corrections on the basis of RISEP advice/challenge and Agency reasoning with respect to recommendations not taken account of in the final opinion.

5.8 Conflicts of interest in RISEP

As part of the initial application process experts will be asked to declare their interests (see Annex 3), having an interest may not necessarily mean having a conflict in interest and would not automatically disqualify or limit participation in RISEP. However, where this interest could be considered a conflict of interest, or where this would require multiple exclusions from the participation of the work of RISEP the candidate would not be appointed to serve on the panel.

A declared interest will be taken account of by the Agency in seeking to draw from the pool. An individual will not be asked to participate if this interest could call into question the independence of the process, compromise the objectivity of an opinion or recommendation and undermine public trust in the process.

RISEP experts will be asked to declare any change in circumstance post-appointment and on an annual basis. The RISEP secretariat will maintain and publish details of declared interests which will be available on the Agency website.

If an external party believes that there is a conflict of interest within the Challenge Panel, they should provide evidence to support this claim to the RISEP secretariat.

5.9 Role of Appropriate Authorities in the opinion-making process

The Appropriate Authorities are involved in making the final decisions on restrictions and applications for authorisation, this will be informed by the opinion provided by the Agency taking into account the advice of RISEP.

As part of the transparent process for ISA in UK REACH, the Agency will:

- Consider and respond to any requests for clarification by the Appropriate Authorities which can be made during the review of draft opinions and on the final opinion.
- Invite the Appropriate Authorities to Authorisation Consultation Meetings (ACMs) and Challenge Panels to ensure that they can gain a greater understanding of the issues which underpin the proposal.
- Ensure that there is a level of independence between the opinion formation and decision-making functions within UK REACH. This will be considered in responding to requests from the Appropriate Authorities and in ensuring that any involvement in the process by Appropriate Authorities is managed, proportionate and transparent¹².

¹² This aims to replicate the independence in the opinion formation by ECHA and the decision making by the EU Commission.

6. Involvement of Accredited Stakeholder Organisations and other stakeholders

To facilitate engagement and participation with stakeholders, the Agency will seek to actively involve and engage with stakeholders throughout many of the REACH processes including those where ISA is incorporated in the process. For reasons of practicality and organisational constraints, the Agency's approach to engagement with stakeholders is, for some aspects of the various processes, based on a cooperation model involving the concept of Accredited Stakeholder Organisations as outlined below.

The purpose of stakeholder engagement and participation in the work of the UK Agency is to:

- Help build trust, confidence and accountability in the work of the Agency and thereby contribute to ensuring transparency and openness.
- Benefit from the scientific and technical expertise and knowledge of stakeholders and therefore ensure scientific excellence in the Agency's work.
- Where appropriate, benefit from the direct interest representation, input and views of the different stakeholders, thereby ensuring well informed, balanced outcomes that have broad acceptance.
- Whilst respecting the requirement to protect confidential data and associated Agency considerations, contribute to the communication efforts of the Agency to all the various stakeholder groups.

6.1 Accredited Stakeholder Organisations (ASOs)

This is a concept also used by the EU in their processes, and the Agency will be asking for an expression of interest from stakeholders in order to foster closer cooperation within UK REACH. Setting up the concept of ASOs offers the Agency the opportunity to interact and work with a manageable number of relevant stakeholders representing a large proportion of relevant interest groups in the UK. As such, only ASOs will be able to participate in certain meetings and activities (for example, related to Authorisation Applications) as a matter of routine.

ASOs are umbrella organisations from different field and sectors and should be representative of their field of competence within the UK. ASOs may contribute with their scientific and technical expertise and may bring with them perspectives from their organisation's collective experience. They will have contacts with relevant actors in their field of expertise and can help the Agency to produce and distribute information to the stakeholders whom the Agency might otherwise not reach.

All ASOs are asked to sign a declaration of interest, a code of conduct, and a declaration of confidentiality, before they can participate in some meetings such as Authorisation Consultation Meetings and Challenge Panel meetings. If there is a

change of participant, the declarations need to be signed again. This applies also for any experts accompanying the stakeholders in the meetings.

6.2 Opportunities for engagement in UK REACH

The table below mentions *just some* of the opportunities for stakeholders to engage in the UK REACH regime:

Process	Description	Who should engage?
Regulatory Management Options Analysis (RMOA)		
The Agency publishes an intention to prepare an RMOA	Interested stakeholders contact the Agency to express interest in the topic and share any relevant information they have with the Agency to consider in the analysis. This can take place at any time during the preparation of the RMOA.	Registrants and any other interested stakeholder.
The Agency engages directly with stakeholders where necessary to clarify specific points in any information that has been provided	Contacted stakeholders respond to questions.	Targeted stakeholders including registrants.
Agency shares the draft RMOA with stakeholders that have engaged during the drafting process.	Stakeholders comment on draft RMOA and provide supporting evidence where they wish to challenge information or conclusions in the RMOA.	Engaged stakeholders
Identification of Substances of Very High Concern (SVHCs)		
Agency publishes an intention to propose a substance as an SVHC	Interested stakeholders contact the Agency to express interest in the topic and share relevant information for the Agency to consider. This can take place at any time during the preparation of the SVHC proposal	Registrants and any other interested stakeholder.
Agency holds a public consultation on the SVHC proposal.	Stakeholders provide comments on the proposal	Registrants and any other interested stakeholder, particularly those who may be affected if the substance is identified as an

		SVHC.
Agency holds a public consultation on the draft recommendation on additions to the authorisation list. The consultation will last for 3 months	Stakeholders provide comments on the draft recommendation	Interested stakeholders
Authorisation		
Pre-submission Information Session (PSIS)	Future applicants for authorisation may request a PSIS to ask case specific questions and clarify regulatory and procedural issues related to the authorisation application process.	Applicants for authorisation
Submission of Authorisation Application	Applicants submit their application in accordance with the legal requirements using the given templates for authorisation applications. A public version of the authorisation application will be published on the Agency's website.	Applicants for authorisation
Development of Broad Information on Uses	Authorisation applicants are consulted by the Agency and asked for their input into the development of the <i>Broad Information on Uses</i> to ensure the consultation on alternatives is specific, meaningful and efficient (maximising relevant submissions from 3 rd parties and limiting follow-up questions from the Agency).	Applicants for authorisation
Public Consultations on Alternatives (substances and technologies)	Following publication of the Broad Information on Uses and the start of the Consultation on Alternatives, Third Parties can provide the Agency with information on possible alternatives (substances and technologies) that is relevant to the authorisation application being considered	All stakeholders
Written Q&A's on Application and Consultation Responses on Alternatives	Applicants may be requested by the Agency to provide written responses to questions and provide additional information and clarifications in relation to their application, as well as to comment on the information from the	

	consultation on alternatives. Third Party Stakeholders submitting information to the public consultation on alternatives may be requested by the Agency to provide additional information and clarifications regarding their submission on alternatives.	
Authorisation Consultation Meeting	Applicants, third party stakeholders who submitted information to the public consultation on alternatives, as well as other Accredited Stakeholders will be invited to attend the Authorisation Consultation Meeting in order to provide information about alternatives, as well as to provide scrutiny and transparency. Authorisation Consultation Meetings include a Q&A session, during which everyone invited to attend can ask questions and express his/her views.	Applicants for authorisation Third party stakeholders who submitted information to the public consultation Accredited Stakeholders
<i>Challenge Panel Meetings</i>	Applicants and Accredited Stakeholders will be invited to observe Challenge Panel meetings, though sectoral stakeholder organisations may be invited on a case-by-case basis for particular items on the agenda. Stakeholders will be allowed access as observers with only a limited opportunity for some technical questions and statements to the challenge panel.	Applicants for authorisation Accredited Stakeholders
<i>Commenting on Draft Opinions</i>	In line with UK REACH article 64(5), the Agency shall send its draft opinions to the applicant for comment. In accordance with the legislation, Third Party Stakeholders have no role.	Applicants for authorisation
Restrictions		
Call for evidence (this is an optional step since there is no legal requirement to undertake this)	Interested stakeholders submit relevant information in response to a call for evidence. Information to be provided within the specified timeframe.	Registrants, users, importers and any other interested stakeholder.
Registry of Intentions	Interested stakeholders are not specifically requested to submit information but may contact the Agency either to provide or request information or meetings in relation to the restriction intention.	Registrants, users, importers and any other interested stakeholder.
Public consultation on the restriction dossier	Interested parties are invited to provide information in relation to the published restriction dossier. The information may	Registrants, users, importers and any other interested

	be in response to specific questions asked by the Agency or general comments (supported by evidence) about the proposal	stakeholder.
Notify registrants of the restriction proposal	The Agency will inform registrants of the substance(s) proposed to be restricted that the restriction process will be initiated. This step does not constitute an invitation to comment or submit information	Registrants
Challenge Panel	Accredited stakeholders will be invited to attend Challenge Panel meetings, which form part of the opinion-making process and will review the risk assessment and socio-economic analysis. Accredited stakeholders will be able to ask questions but will not provide advice to the Agency	Accredited stakeholders
Public consultation on the draft socio-economic analysis	Interested parties are invited to provide information in relation to the draft socio-economic analysis. The information may be in response to specific questions asked by the Agency or general comments (supported by evidence) about the draft socio-economic opinion	Registrants, users, importers and any other interested stakeholder

Annex 1: RISEP Terms of Reference

RISEP is not a Scientific Advisory Committee and has no legal regulatory role as a consolidated group, nor does it operate as an entity in its own right. As such, these terms of reference only relate to the activities of RISEP in so far as they apply to individual experts.

RISEP has been set up to support the UK Agency in developing its scientific opinions by providing independent challenge, as well as supplementary experience, knowledge and skills. Specifically, the remit of RISEP is to provide independent scientific advice primarily concerning the assessment under UK REACH of Applications for Authorisation to use Substances of Very High Concern (SVHC), as well as proposals for Restriction of substances. RISEP experts shall provide advice and recommendations in helping to prepare and review the Agency's scientific opinions on Applications for Authorisation and Restriction proposals.

In helping the Agency to develop its opinions, RISEP's remit is to provide expertise and advice on the quality and scientific robustness of the assessment of:

- the risk to human health and/or the environment arising from the use(s) of a substance for which authorisation is being sought, and if relevant, an assessment of the risks arising from possible alternatives.
- the appropriateness and effectiveness of risk management measures as described in the authorisation application.
- the socio-economic impacts related to granting or refusing an authorisation.
- the availability, suitability and technical feasibility of alternatives.

as well as:

- whether suggested restrictions are appropriate in reducing the risks to human health and/or the environment.
- the related socioeconomic impact of suggested restrictions.
- At the request of the Agency, RISEP experts may also be asked to provide advice and expertise on other aspects concerning the safety of substances within the remit of the Agency

RISEP experts shall take an active role in the Agency's Opinion-making in accordance with the above remit by:

- undertaking assessment of Authorisation Applications and Restriction proposals in support of the development of the UK Agency's draft scientific opinions as part of the Authorisation and Restriction *Case Teams*.

- scrutinising and reviewing the UK Agency's draft scientific opinions as part of the Authorisation and Restriction *Challenge Panel*. Experts involved in a particular *Case Team* will not sit on the corresponding *Challenge Panel* for that particular case.
- Attending any meetings of the *Challenge Panel* and *Case Teams* as necessary.
- Contributing their expertise and advice during other related meetings, written work, phone and video conferences as requested by the RISEP secretariat.

Although RISEP does not operate as a Scientific Advisory Committee, RISEP experts shall nevertheless provide independent scientific advice and operate in line with the principles of scientific advice to government.

RISEP experts shall make their scientific advice and recommendations available to the Agency in a way which aims to be comprehensive, clear and timely.

RISEP has no chair but is supported by a secretariat whose role includes organising the work of the experts and to support them in matters of administration and protocol.

The Director of Chemicals Regulation Division of HSE will maintain overall oversight of the work of the experts from RISEP.

Annex 2: RISEP Code of Practice

1. Introduction

1.1 The REACH Independent Scientific Expert Pool (RISEP) operates in accordance with the [Principles of Scientific Advice to Government](#) and the [Universal Ethical Code – Rigour, Respect and Responsibility](#) which is a statement of the values and responsibilities of scientists. However, against this general background – it is good practice to set out specific elements of a bespoke Code of Practice for RISEP. This Code of Practice therefore sets out the standards that experts are expected to adhere to, the governance of RISEP related business, and various other administrative and practical arrangements.

2. Role and Purpose

- 2.1 The RISEP is an independent scientific expert pool for the UK Agency.
- 2.2 The RISEP is not a Scientific Advisory Committee and has no legal regulatory role as a consolidated group, nor does it operate as an entity in its own right. It consists of individual experts who are independent of the Agency and work to a defined terms of reference.
- 2.3 RISEP's purpose is to provide the UK Agency with access to independent, impartial and expert advice, on request or otherwise. RISEP experts are independent of Government, industry bodies and interest groups with an interest in the work of the UK Agency.

3. Standards for Experts

- 3.5 Experts will at all times:
- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide and the management of RISEP;
 - be accountable to the Health and Safety Executive for their activities and for the standard of advice they provide;
 - follow the [Seven Principles of Public Life](#);
 - comply with this code and ensure they understand their duties, rights and responsibilities and that they are familiar with the function and role of RISEP and any relevant statements of Government policy;
 - not misuse information gained in the course of their public service for personal gain or political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations; and

- not hold any paid or high-profile unpaid posts in a political party, and not engage in specific political activities on matters directly affecting the work of RISEP. When engaging in other political activities, experts should be conscious of their public role and exercise proper discretion.

4. Governance of RISEP Business

Expertise

- 4.1 Experts are appointed for their personal scientific expertise, and for the relevance of that expertise to RISEP's remit and work.
- 4.2 If the UK Agency does not have access to appropriate expertise on RISEP to consider a specific issue, relevant experts may be co-opted on a specified short-term basis to RISEP. These advisers must be invited in writing and their role specified. They shall be subject to this Code.

What is expected of RISEP experts

- 4.3 Experts should:
- engage fully in consideration of the issues, taking account of the full range of relevant factors, including guidance issued by the UK Agency;
 - ensure that they work in accordance with RISEP's Terms of Reference;
 - not divulge any information that is provided to them in confidence and in accordance with the RISEP Guidance and Declaration on Confidentiality
 - respond appropriately and promptly to complaints
- 4.4 Experts are expected to read and prepare documents, comments and views, as required by the work and tasks of RISEP.

5. Other Administrative and Practical Arrangements

Communication with the UK Agency

- 5.1 Communication between RISEP experts and the UK Agency will generally be through the RISEP secretariat. In such cases where the RISEP expert wished to raise an important issue relating to their duties as a RISEP experts, they should firstly seek resolution of the issue with the secretariat. In exceptional circumstances this will be raised with the Director of the Chemicals Regulation Division for final resolution.

Role of the RISEP Secretariat

- 5.2 RISEP experts are supported by a Secretariat provided by the Health and Safety Executive. The secretariat can be contacted by emailing

RISEP@hse.gov.uk.

5.3 The role of the RISEP secretariat includes:

- Supporting the RISEP experts in delivering their work;
- Advising the RISEP experts on the relevant processes and procedures related to their work;
- Ensuring that the proceedings in which RISEP experts are involved are properly documented;
- Keeping an accurate public record of the work in which RISEP experts are involved.
- Ensuring RISEP experts comply with relevant codes and standards for the good governance of business that RISEP experts are involved in.
- Ensuring RISEP experts do not exceed their remit.
- Providing the channel of communication between the RISEP experts and the UK Agency, as well as any other internal and external interests.
- Providing standard secretariat services, including – arranging and recording meetings, circulating papers, maintaining any websites related to the work of RISEP experts, maintaining the Register of Expert's Interests, publishing opinions and other documents related to the work of RISEP experts, handling claims for fees and travel and subsistence from RISEP experts, handling FOI requests pertaining to the work of RISEP experts, liaising with internal and external interests who wish to engage with the work of RISEP experts.

6. Personal Liability of Experts

6.1 Legal proceedings by a third party against individual experts of advisory bodies are very exceptional. An expert of RISEP may be personally liable if:

- they make a fraudulent or negligent statement which results in a loss to a third party;
- they commit a breach of confidence under common law or a criminal offence under insider dealing legislation, by misusing information gained through their position.

6.2 However, the Government has indicated that individual experts who have acted honestly and in good faith will not have to meet out of their own personal resources any personal civil liability which is incurred in the execution or purported execution of their advisory functions, save where the person has acted recklessly.

7. Terms of Appointment

- 7.1 Appointments to RISEP are made in accordance with the principles set out in the Nolan Report on Standards in Public Life, also known as the 7 Principles of Public Life. Appointments are for a term of three years, with the possibility of reappointment.
- 7.2 Experts are asked to provide a declaration of commitment to RISEP annually, though they are free to terminate their involvement at any time according to personal circumstances. The Health and Safety Executive may also terminate an appointment in certain circumstances, for example if experts fail to perform as expected of them. A notice period of not less than 3 months should be provided by either party upon wishing to terminate an appointment.

8. Fees and Expenses

- 8.1 RISEP experts are entitled to claim daily fees (£400 per day) for the time they spend on RISEP business. This covers any work undertaken, including preparation and attendance at meetings. All fees paid are taxable.
- 8.2 Reasonable travel and subsistence costs are separately reimbursed on presentation of receipts, in accordance with HSE's normal rules, up to a specified limit.

9. Openness and Publication of Documents – General Principles

- 9.1 Information about RISEP and the work that its experts are involved in is published on the UK Agency's website. The work in which RISEP experts are involved is expected to be done in an open and transparent manner and to follow relevant guidance and rules. Information relating to the work of RISEP experts is subject to the provisions under the Freedom of Information Act 2000 (the Act).
- 9.2 The dates of open meetings that RISEP experts are involved in, as well as the agendas and minutes will be found on the web pages of the Agency. Meeting minutes will be published following agreement. Outcomes of these meetings, including all opinions, will be made available on the Agency website. To allow maximum participation possibilities to Stakeholder Observers, the general rule that is applied is that documents and meetings are always open for Stakeholder Observers when possible.
- 9.3 However, there will be some exceptions to this general principle of openness, for example:
- Where individual papers contain commercially sensitive information such as product formulations/specifications, methods of manufacture, company evaluations and safety assessments, or other confidential business information, the general principle of the common law duty of confidentiality will apply, except in cases where the information was

provided under legislation which deals specifically with disclosure and non-disclosure. Papers, which are deemed to be confidential, will be marked “Confidential” by the RISEP secretariat and their contents should not be disclosed beyond the individual RISEP experts.

- Draft papers, reports or opinions which are due to be published at a later date but are not yet in the public domain should not be disclosed beyond the individual RISEP experts.

9.4 Questions or approaches from the media should be directed to the RISEP secretariat. Although experts are encouraged to promote the role of RISEP in general terms, if asked for views on subjects that have been or are being considered by RISEP experts, they should always consult with the RISEP secretariat.

10. Declaration of Interest and Management of Conflicts

10.1 RISEP experts must not be influenced, nor appear to be influenced, by their private interests in the exercise of their advisory duties. There is a conflict of interest where the impartiality and objectivity of a decision, opinion or recommendation of RISEP experts, is or might in the public perception be compromised by an interest held by, or entrusted to, an individual working on RISEP related activities. Having an interest does not necessarily mean having a conflict of interest. Declaring an interest does therefore not automatically disqualify you or limit your participation on RISEP related activities.

10.2 On appointment, RISEP experts must have completed the Declaration of Interests and comply with the eligibility criterion as set out in the Guidance on Conflict of Interests in Annex 4. All interests that may interfere or may be seen as interfering with the work undertaken by RISEP experts in the public interest must be declared. The timeframe for declaring interests includes all current interests and those that existed during the last 5 years preceding the declaration. With regard to family ties, all relevant interests held by any members of household (spouse, partner and dependent children) also must be declared. Guidance on the different interests that are required to be declared is included in Annex 4.

10.3 Experts must inform the secretariat of any change in their personal interests at any time following appointment. They will also be asked to declare relevant interests on an annual basis. A declaration of any interest should also be made at any meeting RISEP experts are involved in if it relates specifically to a particular issue under consideration. Experts should not participate in the discussion or determination of matters in which they have an interest, and should normally withdraw from the meeting if their interest is direct and pecuniary or otherwise does not comply with the Guidance on Conflict of Interest.

10.4 The RISEP secretariat will: maintain and publish details of interests declared on

the Agency's website; ensure potential conflicts of interest are identified to experts during the course of RISEP experts work; and record relevant details in minutes of meetings (which will be published on the Agency's website).

Annex 3: Guidance on Conflict of Interests

As one element to safeguard the independence, integrity and credibility of the scientific advice provided by RISEP experts, the following guidance is in place for managing potential Conflicts of Interest. This guidance ensures that a balance is taken between getting the right expertise to guarantee high quality science-based advice and opinion making, and at the same time strictly avoiding conflicting interests influencing, or seen as influencing, the advice and opinion-making process.

There is a conflict of interest where the impartiality and objectivity of a decision, opinion or recommendation of RISEP experts, is or might in the public perception be compromised by an interest held by, or entrusted to, an individual working on RISEP related activities. Having an interest does not necessarily mean having a conflict of interest. Declaring an interest does therefore not automatically disqualify you or limit your participation on RISEP related activities. In this respect the UK Agency has adopted the following criterion regarding appointments to RISEP:

- The following candidates seeking appointment to RISEP shall not be appointed when they have a potential conflict of interest of a general nature or that would potentially lead to multiple exclusions of the individual from participation in the work of RISEP:
 - Candidates being currently (or previously within the past 2 years) employed (in a position of relevant importance) by, or holding a position in a governing body (whether paid or unpaid) of a commercial enterprise;
 - Candidates being an active member of or employed (in a position of relevant importance) currently (or previously within the past 2 years) by an association or other body (except a body established under public law of the UK serving a public interest), with can be considered as an interest group with an interest in the field of activity of the UK Agency;
 - Candidates who currently hold significant investments in a commercial entity manufacturing, importing or supplying substances or mixtures subject to the authority of the Agency (without prejudice to financial interests held through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements, provided that these investments are broadly diversified and the candidate has no influence on their financial management).

Declaration of Interests

All interests must have been declared by RISEP experts prior to their appointment, as well as being confirmed annually, on the Declaration of Interests form. A declaration of any interest should also be made at any meeting RISEP experts are involved in if it relates specifically to a particular issue under consideration. Experts should not participate in the discussion or determination of matters in which they have an interest, and should normally withdraw their participation in the matter if their interest is direct and pecuniary or otherwise does not comply with the Guidance on Conflict of Interest.

The following is intended to indicate the kinds of interests that should be declared. The timeframe for declaring interests includes all current interests and those that existed during the last 5 years preceding the declaration. With regard to family ties, all relevant interests held by any members of household (spouse, partner and dependent children) also must be declared.

Where candidates or appointees are uncertain as to whether an interest should be declared, they should seek guidance from the RISEP secretariat. If candidates or appointees have interests not specified in this guidance, but which they believe could be regarded as influencing their advice, they should declare them. Failure to declare interests could lead to dismissal from RISEP.

Personal Interests

A personal interest involves payment to a candidate or appointee personally. The main examples are:

- Consultancies and/or direct employment: any consultancy, other employment, partnership, directorship or position in or work for an industry or other relevant body held by you or a close family member and which attracts regular or occasional payments in cash, recognition in any other form, or other benefit.
- Fee-Paid Work: any commissioned or fee-paid work for which you or a close family member are paid in cash or kind by an industry or other relevant body including Pressure Groups and Non-Governmental Organisations.
- Shareholdings: any shareholding or other beneficial interest in industry shares that you or a close family member have. This does not include shareholdings through unit trusts or similar arrangements where the expert or family member has no influence on financial management.
- Membership or Affiliation: any membership role or affiliation that you or a close family member has to clubs or organisations with an interest or involvement in the work of RISEP.

Non-personal interests

A non-personal interest involves payment which benefits a department or organisation for which a candidate or appointee is responsible but is not received by them personally. The main examples are:

- Fellowships: any fellowship that you or a close family member holds and which is endowed by an industry or other relevant body
- Support by Industry: any payment, other support or sponsorship by industry which does not convey any pecuniary or material benefit to a candidate or appointee personally, but which does benefit their position or department.

Candidates or appointees are under no obligation to seek out knowledge of work done for, or on behalf of, industry and other relevant bodies by departments/units for which they are responsible, if they would not normally be expected to be informed.

- Trusteeships: any investment in industry held by a charity for which you or a close family member is a trustee.
- Other public appointments: membership by you or a close family member of local authorities, health authorities and trusts, and other relevant voluntary sector bodies.

Annex 4: Guidance on Confidentiality

RISEP experts shall not disclose any information acquired as a result of their work on RISEP, unless otherwise stipulated in UK law, or already publicly available. RISEP experts shall take all necessary measures to ensure that the persons to whom they provide access to their information respect the same obligations that they are subject to.

All RISEP experts having access to RISEP related information shall upon appointment make a written declaration of confidentiality in accordance with the template below.

The obligation to maintain confidentiality shall continue to apply even after their duties and participation as RISEP experts has ceased.

DECLARATION OF CONFIDENTIALITY OF RISEP Experts (to be made on appointment to RISEP only)

I hereby declare that I shall undertake to exercise the greatest discretion with regard to all facts and information coming to my knowledge in the course of or in connection with the performance of my duties related to the work of RISEP. I shall not disclose to any persons any information acquired as a result of such work unless otherwise stipulated in UK law or already publicly available. The above is without prejudice to the sharing of documents with persons assisting me in the discharge of my duties related to the work of RISEP. I shall take all necessary measures to ensure that the persons to whom I provide access to information respect the same obligations that I am subject to. I accept without reservation that I continue to be bound by this obligation also after these duties have ceased.

Name: [Click here to enter text.](#)

Position/Affiliation: [Click here to enter text.](#)

Place: [Click here to enter text.](#) **Date:** [Click here to enter a date.](#)

Annex 5: Political Activity Questionnaire and Declaration on Conflict of Interests

Official Sensitive: Appointments (when completed)

Political Activity Questionnaire

All applicants should complete the question below. This question is asked as it enables the monitoring of political activity of candidates in so far as it is already in the public domain. Neither activity nor affiliation is a criterion for appointment (except where statute dictates specific representation). If you are successful, the information provided will be published with the announcement of your appointment.

Please indicate which of the following activities you have undertaken during the past **five years** by ticking the appropriate box in the table opposite and by providing details of your involvement in the box below. Name the party or body for which you have been active. If you have been, or are, an independent, or have sought or obtained office as a representative of a particular interest group, you should state this. You should tick all relevant categories.

Details of involvement:

- | | |
|--|--------------------------|
| A Obtained office as a Local Councillor, MP, MEP etc..... | <input type="checkbox"/> |
| Stood as a candidate for one of the above offices | <input type="checkbox"/> |
| Spoken on behalf of a party or candidate | <input type="checkbox"/> |
| B Acted as a political agent..... | <input type="checkbox"/> |
| Held office such as Chair, Treasurer, or Secretary of a local branch of a party..... | <input type="checkbox"/> |
| Canvassed on behalf of a party or helped at elections..... | <input type="checkbox"/> |
| Undertaken any other political activity which you consider relevant. | <input type="checkbox"/> |
| C Made a recordable donation to a political party ¹ | <input type="checkbox"/> |
| D None of the above activities apply ... | <input type="checkbox"/> |

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Name of party for which activity undertaken:

The Political Parties, Elections and Referendums Act 2000 requires the Electoral Commission to publish a register of recordable donations (donations from any individual totalling more than £5,000 in any calendar year, or more than £1,000 if made to a subsidiary accounting unit such as a constituency association, local branch, women's or youth organisation). These provisions became effective from 16th February 2001.

Signature:

Date:

Declaration of Interests Form

Declaration of Interests

All applicants should complete the questionnaire below. It is the policy of the Health and Safety Executive to require relevant personal and business interests to be declared by prospective RISEP members to enable a sensible balance to be achieved on the Pool at the time that appointments are made. Guidance on types of personal and business interests is given in the Agency's Guidance on Conflict of Interests found in Annex 4 of the application pack.

Applicants should give details of any business or personal interests which may give rise to real or perceived conflict of interest.

Under the guidance on Conflict of Interests, I wish to declare to the Health and Safety Executive, that my only interests are as follows:

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Personal Interests

1	Direct employment	
2	Consultancies and other fee-paid work	
3	Shareholdings	
4	Clubs and other organisations	
5	Other personal interests	

Non-Personal Interests

6	Fellowships	
7	Indirect support	
8	Trusteeships	
9	Land and property	
10	Other public appointments	
11	Other non-personal interests	

Signature:

Date:

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Annex 6: Summary of Responses to the Draft Statement

Background

Before publishing the final version of the ISA statement, HSE contacted more than 40,000 subscribers to its REACH e-Bulletin to ask them to complete a questionnaire on a draft version of the statement. The survey was launched on 19 February 2021 and closed on 10 March 2021 and received 211 responses.

The respondents represented several different organisations and sectors. 22 respondents identified the main focus of their work as chemical manufacture; 11 respondents worked in chemical imports; and 18 respondents worked in other chemical work.

12 respondents indicated they were involved in trade associations; and 9 respondents indicated they were involved in an academic/expert context. 72 respondents identified the main focus of their work as other sectors. This included sectors such as charities, consultancies, construction, transport, utilities, etc. (66 respondents to the questionnaire did not provide a response to this question).

The questionnaire was developed and launched to help HSE ensure the ISA statement provided a clear explanation on:

- 1) how ISA will be used by the Agency; and
- 2) how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH.

The questionnaire also asked respondents if they wished to provide any further observations or comments about the draft ISA statement.

1. Do you think the draft ISA statement provides a clear explanation on how ISA will be used by the Agency?

112 respondents indicated that the draft ISA statement provided a clear explanation on how ISA will be used by the Agency. 33 respondents indicated the explanation was not clear; and 64 respondents did not know/were unsure if the explanation was clear or not. (2 respondents to the questionnaire did not provide a response to this question).

The main comments provided by respondents for a lack of clarity on the explanation on how ISA will be used related to how the Agency would manage conflicts of interests; how science and policy would interact when forming and making decisions; and more general comments with the content of the draft ISA statement. These general comments related to the use of acronyms; descriptions of the authorisation and restriction processes under UK REACH; and providing a clearer summary of the ISA statement.

In addition, respondents also provided comments on the recruitment to and participation in Challenge Panels and RISEP; the use and availability of data and information; and how far the UK would diverge from or replicate EU REACH models and processes.

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2. Do you think the draft ISA statement provides a clear explanation on how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH?

101 respondents indicated that the draft ISA statement provided a clear explanation on how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH. 25 respondents indicated the statement did not provide a clear explanation; and 47 respondents did not know/were unsure if it provided a clear explanation or not. (38 respondents to the questionnaire did not provide a response to this question).

The main comments provided by respondents on the statement lacking a explanation on how the Agency will ensure transparency related to how the appeals process would operate under UK REACH; and the independence of UK REACH Challenge Panels and RISEP with respect to conflicts of interest and publication of details.

In addition, respondents also provided wider comments on how UK REACH and the Agency would ensure transparency to the same degree as existing models and processes established by EU REACH and ECHA.

How has the consultation information been used?

After the questionnaire on the draft ISA statement closed, HSE collated and reviewed the responses, identifying common issues and themes. HSE has aimed to address comments where appropriate by revising the ISA statement to provide both a clearer explanation on how ISA will be used by the Agency; and how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH.

For example, the revised statement includes a glossary to define specific terminology used in the ISA statement; flow charts showing the authorisation and restriction processes under UK REACH; and a redrafted summary of the ISA statement. Further revisions and updates to the ISA statement were also made to address specific comments to clarify explanations on the use of ISA and ensuring transparency of the Agency.