ROYAL SOCIETY OF CHEMISTRY

SUSTAINABILITY

The case for a national Chemicals Agency

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The Royal Society of Chemistry would be happy to discuss any of the issues raised in our statement in more detail. Any questions should be directed to the RSC Policy & Evidence Team at **policy@rsc.org**.

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Foreword

Chemicals are an integral part of everyday life and well-regulated chemical innovation can bring huge benefits, from driving economic growth to supporting the green transition.

At the same time, there is mounting global evidence of the risks that some substances can pose if they are not managed properly. Increasingly, long-term exposure to chemicals, from PFAS and heavy metals to herbicides, is being linked to a range of major health issues, from cancer to dementia.

The current regulatory regime for chemicals in the UK is not fit for purpose, failing to support innovation or to adequately protect our waterways, soil, air and built environment. To take just one example, not a single UK river has a "good" chemical score as defined by the Water Framework Directive, which was adopted over 20 years ago.

While we have a national agency to oversee food standards, and a national regulator of health products and medicines, we do not yet have a unified approach to chemicals regulation as part of a national chemicals strategy.

Instead, responsibility falls to a range of government departments and agencies, leading to fragmentation, duplication of efforts and a lack of clarity.

In addition, the civil service is under-resourced and struggling to recruit and train skilled staff, making it difficult for government to keep up to date with the latest developments in chemicals and testing.

This not only increases the potential for drastic consequences for people and the environment, but it also presents significant barriers for businesses, which are hampered by rising regulatory complexity, uncertainty and costs.

There is a real danger that companies may struggle to remain viable under the growing regulatory burden or choose to relocate outside of the UK.

These challenges have only been exacerbated by the increased volume of work for civil servants following the UK's departure from the European Union. However, as the Government reviews regulation for the post-Brexit era, there is also a unique opportunity for reform.

We urgently need a new approach to chemicals regulation that protects human health and the environment against the life-cycle risks of chemicals; supports innovation and economic growth; and offers good value for money for taxpayers.

That is why the Royal Society of Chemistry is calling for the establishment of a national Chemicals Agency to spearhead a coordinated, centralised and systems-thinking regulatory regime.

While this will require considerable political will and redistribution of existing resources, and potentially additional investment, it has the potential to deliver major benefits.

With our strength in the chemicals sector, the UK can be a world leader in both the manufacture and regulation of chemicals.

A national Chemicals Agency could support a wider UK chemicals strategy by providing a clear, effective framework that enables rapid and safe innovation, facilitates trade and attracts inward investment.

Most importantly, it would enable risks to be anticipated and mitigated *before* irreversible harm occurs.

The Food Standards Agency was only created in the wake of the BSE crisis. Let's not wait for a crisis on a similar scale before we take chemicals regulation seriously.

Professor Gillian Reid CChem FRSC FRSE
President, Royal Society of Chemistry

A Introduction

The current UK regulatory framework for chemicals is not fit for purpose.

We interact with chemicals every day, whether through the **water we drink**, the **products we use** or the **air we breathe**.

There is also mounting evidence of the dangers that chemicals can pose if they are not properly managed, from increasing the risk of **cancer**[1] and **dementia**[2] to polluting our **natural environments**[3].

Yet the current regulatory regime for chemicals in Great Britain (GB) is ineffective and in urgent need of revision. It:

Is mainly reactive and short-term in its approach to managing risks to human health and the environment. There is increasing awareness that chemicals may carry significant risks over the medium to long term across their life cycles, yet there is concern that the current regime may not be robust enough to manage these, due to insufficient resource and a lack of central coordination or accountability.[a]

Hampers innovation and economic growth due to its fragmented and inconsistent nature. This creates confusion and extra costs for businesses and researchers, as well as potentially limiting export opportunities for individual companies and the Government's ability to secure trade agreements and develop international collaborations.

Offers poor taxpayer value for money due to lack of information sharing and coordination across government departments, leading to duplication of efforts. Resource and skills constraints within government also mean there is a lack of responsiveness to the latest developments in chemicals testing and risk management, creating additional unnecessary complications and costs for both regulators and businesses.

These challenges have only been exacerbated by a larger workload for regulators following the UK's exit from the EU.[b]

[a] Departments involved in chemicals regulation include the Department for Food, Environment and Rural Affairs (Defra), the Environment Agency (EA), the Health and Safety Executive (HSE), situated in the Department for Work and Pensions, the Office for Product Safety and Standards (OPSS) (situated in the Department for Business and Trade) and a number of other bodies.

[b] Northern Ireland must continue to follow EU chemical regulations as required in the Northern Ireland Protocol post EU exit.

We urgently need a more integrated pollution prevention and chemicals control regime that considers the full life cycle of chemicals, and supports a broader chemicals strategy for the UK.

Chemicals are everywhere and therefore chemicals regulation affects nearly every business. The most directly impacted sectors alone – the chemical and pharmaceutical industry – add £18 billion of value to the UK economy every year, from total annual turnover of £50 billion[6].

The chemicals sector also contributes to the UK economy in its position at the head of many supply chains within manufacturing and its employment of a well-remunerated, high-skilled workforce.

Yet rather than providing the regulatory climate to support world-class innovation, there is a real risk that under its current system the UK will be left behind.

The UK needs a regulatory regime for chemicals that:

Protects human health and the environment against both short and longer-term risks across the life cycle of chemicals.

Drives innovation and economic growth by giving businesses and researchers clarity over what is required of them, adapting promptly to new developments in testing and risk mitigation, facilitating international trade agreements and collaboration, and enabling sustainable jobs in the chemicals sector.

Delivers taxpayer value for money by maximising coordination across government, with an adequately resourced and skilled staff, to deliver a 'one substance, one assessment' approach – and use the latest science to enable regulatory innovation, especially in areas where advanced materials are being used in innovative technologies.

The post-Brexit transition period offers a unique opportunity to establish a world-leading regulatory regime that supports the Government's strategic aims.

After the EU Withdrawal Agreement came into full effect on 1 January 2021, the UK has been in a post-Brexit transition period where many EU laws have been transposed to the UK and must now be reviewed and adopted, modified, or removed.

Government departments and devolved nations are already working on new principles for how chemicals regulations should operate in Great Britain, and new technical guidance will need to be written. They are also working on an update to UK REACH and developing a wider UK Chemicals Strategy. However, delays and uncertainty have characterised the transition process.[7]

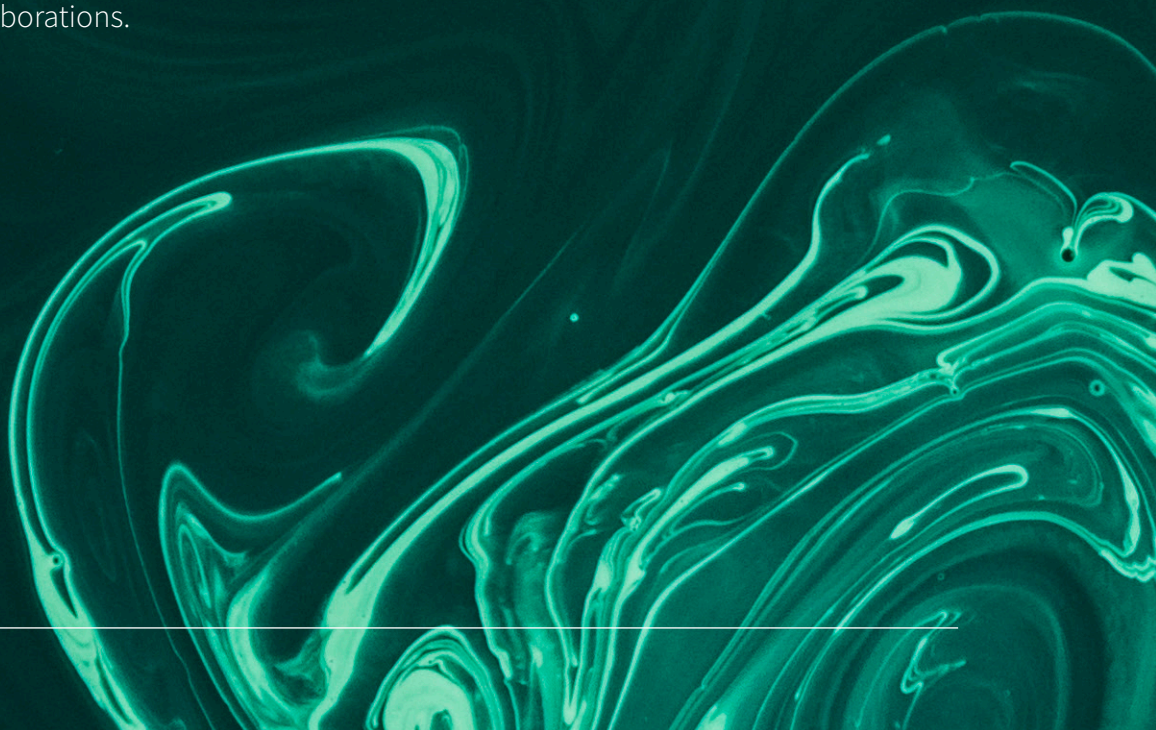
We have a unique opportunity to develop a more streamlined, coherent and effective regulatory framework that enhances the UK's position as a leading scientific nation.

We propose a national Chemicals Agency to spearhead a coordinated, centralised and systems-thinking approach to the management of chemicals.

We have set out initiatives that could be implemented independently of each other if necessary and that represent the gold, silver and bronze standard for UK chemicals regulation. These are a national Chemicals Agency, a Centre for Chemicals and Risk Research, and a cross-governmental chemicals regulation training and networking programme respectively. The latter two initiatives could help to lay the foundation for further investment and development.

The optimal solution is a national Chemicals Agency that is visible, strongly branded, independent and trusted worldwide.

This new agency would bring increased confidence in chemicals regulation for both industry and society, and it could impact positively on the ability to secure trade agreements and foster international collaborations.



Potential geographic scope of a Chemicals Agency

The Northern Ireland Protocol governs the post-Brexit status of Northern Ireland (NI) in relation to the EU and Great Britain, in particular concerning customs and goods movement across the border. It also defines where regulatory responsibilities sit, whether in the UK government or remaining with the EU.[8] Chemicals is one area where NI has remained under the EU regulatory regime.

Some changes have been made with the more recent agreement of the Windsor Framework. For example, all medicines on the NI market will be regulated by the UK regulator, whereas before they were subject to EU regulation. However, chemicals are still governed by the EU.

The unique situation in Northern Ireland means that a Chemicals Agency would initially be the regulator for Great Britain (taking into account devolution where applicable). This national chemicals regulator would have the potential to expand its scope to Northern Ireland, subject to the evolving relationship with the EU and to devolution considerations where applicable.

B Key challenges in the current system

The key challenges facing the current system mean that maintaining the status quo is not a realistic option. These are:

- A short-term and reactive approach to risk
- A lack of clarity for business
- A lack of coordination leading to inconsistent decision-making
- Inefficiencies that are poor value for money
- Cumulative barriers to UK trade, investment and influence

A short-term and reactive approach to risk

Chemical manufacture and use is an area where a lack of scrutiny and regulatory action can give rise to serious incidents that can endanger human health and the environment.

Recent history has demonstrated what can happen when regulatory regimes are fragmented and there is no central agency accountable for anticipating, monitoring and managing risks. For example, the Food Standards Agency (FSA) was established in the aftermath of the BSE crisis[9]. More recently, the Building Safety Regulator was established in 2022 after the Grenfell Tower fire in London in 2017.[10]

It is particularly important that regulators anticipate and proactively manage longer-term risks, as many potential impacts arise from cumulative exposure to chemicals over a sustained period.

The chemicals regulation system also needs to have the flexibility to proactively adjust to changing science and evidence. Where there are threats of serious or irreversible damage, the precautionary principle requires that reasonable action be taken, even if the science is still uncertain.

The current system, however, is mainly reactive and short-term in its approach. This is due both to limited resources and the fact that responsibility for oversight spans several government departments[4], which makes it hard to get a holistic view of potential risks.

There is already mounting evidence of the harm that may be resulting[11], from **unacceptably high** levels of 'forever chemicals' in our drinking water[12], to the fact that **not a single UK river** has a "good" chemical score[13].

We cannot afford to wait for significant harm to human health or the environment to occur before reforming the regulation of chemicals.

CASE STUDY

Could 'mad cow disease' have been avoided?

The spread of bovine spongiform encephalopathy (BSE) to humans in 1994 exposed serious gaps in the food regulatory system. Nearly 200 people died due to foodborne illness in the 1990s and the UK beef industry lost £2.2 billion (2023 prices).

The crisis led to the founding of the Food Standards Agency (FSA) in 1999. In setting out the case for the new agency,[14] the Government noted that public confidence in food safety was low in large part due to the perceived conflict of interest of the regulator at the time, which was tasked both with protecting public health and sponsoring the agriculture and food industries. The provision of independent and impartial scientific advice was not prioritised.

The FSA is a non-ministerial department and a regulator responsible for protecting public health and the public's interests in relation to food. Its remit involves developing policy and standards, carrying out research, overseeing regulatory monitoring and enforcement and providing advice to the public.

The new system has restored public confidence in food, and it has also brought benefits to UK businesses. For example, the US banned beef imports from the UK after the BSE crisis. In 2020, this ban was finally lifted due to the rigorous standards in place from the FSA.

A lack of clarity for business

Practitioners and commentators on chemicals regulation in the UK note that the residual transposed regulatory framework in Great Britain for chemicals is complex , limited in outputs, and fragmented across several authorities.[15]

Chemicals law is functioning, but in a limited and inefficient way that does not support industry.[c] There is a lack of clarity on the data requirements needed to register chemicals under UK REACH, and businesses are concerned about divergence from the EU causing supply chain issues and barriers to market access.

Companies, particularly those with complex supply chains, are finding it challenging to operate in a regime that is fragmented, diverging and uncertain.

There is evidence that regulatory fragmentation can increase costs for companies, while reducing productivity, profitability and growth[16].

In addition, the current regulatory system is often not equipped to deal with rapidly emerging technologies, presenting barriers to businesses and slowing the adoption of new innovations that are being created in response to complex challenges such as climate change.[17] This could even potentially further delay the UK realising its net zero ambitions.

This issue is especially inhibitory for small and medium-sized enterprises that are operating under strict financial and resourcing constraints and may struggle to adapt to multiple data and regulatory processes for accessing markets in different jurisdictions.

In the UK, there has been a movement toward pro-innovation regulation, which are regulatory frameworks or policies that are designed to foster and support innovation within various industries.[18] This approach is meant to be collaborative, flexible, responsive, and iterative, cultivating the benefits of new technologies while also ensuring appropriate regulatory oversight.

In addition to novel chemical entities, regulation should also recognise innovation in processes in feedstocks. For example, the switch from fossil fuels to more sustainable and biological sources of carbon-based molecules is one area where significant growth and change is expected coming years. UK regulatory authorities need to be prepared to facilitate this shift without detriment to environmental quality or human health.

[c] https://ukandeu.ac.uk/wp-content/uploads/2022/01/UKICE-Manufacturing-After-Brexit-Report_FINAL-2.pdf

CASE STUDY

SMEs face regulatory chaos

Chemistry SMEs are the bedrock of the chemicals innovation ecosystem, developing transformational breakthroughs in critical areas such as sustainable energy and industry to personalised medicine and early detection of diseases. They are almost twice as likely than the average SME to invest in research, development and innovation.

They also face specific challenges compared to their peers in other sectors, including long product development times and high initial investment needs. They can ill afford further barriers, but also must ensure their products are safe for consumers, workers and the environment.

In particular, the use and disposal of chemicals is highly regulated, and chemistry SMEs are often operating in sectors with further strict regulatory frameworks, such as the energy or pharmaceutical sectors. 22% of chemistry SMEs cited UK government regulations as a barrier to innovation, as compared to 18% of other SMEs.

Nium, a British startup working towards the production of clean ammonia, is one example of an organisation battling compliance headaches. Dr Yubiao Niu, the company's co-founder and CTO, has first-hand experience of grappling with the UK's current regulatory landscape and said its complexity costs SMEs time and money.

"There are so many pieces of regulation around, you feel like you almost need a dedicated expert studying those regulations," he explained. "For us to have someone like that at this stage is quite a high cost."

Divergences between UK and EU REACH post-Brexit have exacerbated the regulatory issue. The company is still in its formative stages, but Dr Niu noted such complications have already impacted its business model and approach to technological development.

He said: "There are times when you buy a chemical from suppliers that they ask for a certain licence or certificate and we sometimes just stop there. We might just want to do one experiment with a specific chemical, but we realise that due to paperwork it may take two or three weeks to achieve this."

While the company is agile enough to identify substitute chemicals, there have been instances where Nium has been forced to forgo important experiments.

Dr Niu (pictured right) explained: "This has a real impact on our capacity for innovation. It will slow down the technology development a little bit because as a start-up, you tend to move quite fast and then this goes the other way."

Green ammonia is seen as a 'fuel of the future' but Dr Niu believes uncertainty still affects would-be investors in the UK. The other issue is a lack of support, with Nium only learning that they have to overcome various compliance hurdles with very short notice.

"A UK chemicals strategy would definitely be very helpful for the start-up working in the chemical field," Dr Niu said. "We need a more concrete roadmap or guidelines around specific new areas from the UK to make sure we are going in the right direction."

A lack of coordination leading to inconsistent decision-making

Uses of chemicals also cross sectoral boundaries and thus do not always align with existing regulatory structures, leading to duplication and overlap, but also gaps and inconsistent results.[20]

Individual chemical and product laws do not require coordination, and departmental structure and funding does not facilitate seamless interaction.

One government department may examine a chemical under one regulatory regime and not coordinate with another department or agency interested in the same chemical.

Civil servants responsible for evaluating the same substance but in different contexts do not always have access to the same technical data, nor is it easy to share data and expertise across departments. The UK also no longer has access to EU data systems or chemicals safety data, as this was not part of the UK's withdrawal agreement from the EU.

For example, after leaving the EU, the HSE lost access to the IT systems that support REACH and biocide regulations. Defra has created a new system to support REACH registrations and submission of chemicals safety data. The HSE has also developed new systems to replace the EU biocide, plant protection, and CLP (Classification, Labelling and Packaging) IT systems.

Developing the Defra system alone has already cost £32.2 million, as of 2022, and UK REACH reforms are expected to necessitate further updates to this system.[21]

This makes a 'one substance, one assessment' approach difficult, and is increasingly leading to inconsistent decision-making.

CASE STUDY

Inconsistencies between cosmetics regulations and REACH

The UK was a major influence for the ban on animal testing for cosmetic ingredients, which came into force in the EU Cosmetic Regulations from March 2013. These regulations were transposed into GB law following that country's exit from the European Union, and through organisations such as the National Centre for the 3Rs (reduction, refinement and replacement in animal testing; NC3Rs) the UK is at the forefront of developing new approach methods (NAMs)[22] for application in new types of chemical risk assessment.

However, a host of legal and technical contradictions between the Cosmetics Regulations and REACH regulations currently exist, which have never been fully resolved – and is a topic that UK regulators may be able to address if chemical evaluation is centralised.

The recent case of homosalate, used as a UV filter in sunscreens, exemplifies this. During an EU REACH compliance check in 2018, the ECHA identified the regulatory need for new safety data to be derived from studies in rodents: an oral route OECD TG 408 90-day systemic toxicity study, an OECD TG 414 pre-natal developmental study and an OECD TG 443 one-generation reproductive toxicity study.

This substance is only used in cosmetics, and the cosmetics sector cannot ethically or legally perform these studies due to the ban on animal testing in support of cosmetic safety evaluation. However, the raw materials supplier can do the testing for the purposes of REACH. The European Scientific Committee on Consumer Safety can use the data generated for REACH in the safety evaluation of the cosmetics, even though it goes against the intention of the animal testing ban.

As of May 2023, the Government announced a ban on new licenses granted for for animal testing on chemicals that are solely used as cosmetics ingredients. However, the legal framework for this ban still needs to be settled, and legacy licenses are under review.* This example illustrates how the current chemicals regulatory system can have different, and sometimes contradictory requirements for data that may vary across sectors and regime.

*UK Government, Regulation Update, 17 May 2023: https://hansard.parliament.uk/commons/2023-05-17/debates/23051752000009/RegulationUpdate

Inefficiencies that are poor value for money

Regulatory functions are siloed, with each body undertaking technical work independently. Information sharing across departments is not the default, wasting scarce resources by duplicating basic scientific work.

For example, the Office for Product Safety and Standards (OPSS) in the Department for Business and Trade (DBT) has a dedicated Science team which 'ensures OPSS has access to scientific evidence and advice for the development of policy, and the delivery and enforcement of product safety regulations in OPSS. It is a multidisciplinary team including scientists, covering specialisms including analytical chemistry, biology and toxicology.'[23]

Technical work on chemicals in products is undertaken separately from that done in other departments that also deal with chemicals, such as the HSE.

There is also a skills shortage related to regulation. The applied research disciplines of exposure science, toxicology and applied chemicals safety assessment, and relevant socio-economic assessment skills, have declined significantly over the past two decades in the UK, with few universities involved in the practice.

The British Toxicology Society report on skills gaps provides the evidence that there is a skills shortage in toxicology, for example. However, demand for skills related to safety and regulation has increased across chemistry-related jobs, in particular for legal, regulation, and policy chemistry roles.[24]

While the civil service has recruited new talent, this includes many recent graduates who lack experience and the applied technical expertise required for delivering sound chemicals evaluation and regulation. As a result, 25% of the HSE Chemical Regulation Division's staff time is taken up by training.[5]

Overall, the civil service is finding it hard to attract and retain workers skilled in chemicals regulation.[25] This makes it difficult to keep up with fast-paced developments in chemicals and assessment methods.

Current structures and resource limitations in the civil service significantly hamper its ability to deliver effective and efficient chemicals regulation.

New approach methods to risk assessment: A missed opportunity?

The cosmetics and agrochemicals industry sectors are already using new approach methods (NAMs) for use in next-generation risk assessment (NGRA) for chemicals, but these new methods are not always accepted by regulators, possibly due to unfamiliarity and low confidence in NAMs compared to traditional approaches, and legal and economic barriers.

The slow adoption of NAMs could be a missed opportunity to expedite regulatory assessment and reduce costs for both industry and government.[26]

Support for research into and validation of NAMs should be a key aspect of the UK's chemicals regulatory system. The government can support the adoption of NAMs by prioritising validation in key areas.

Cumulative barriers to UK trade, investment and influence

The UK has the potential to be a global leader in chemicals regulation, building on its strong chemical science skills base and industry. Yet the structural and resource constraints listed above create unnecessary barriers to research and innovation, deterring inward investment and hampering economic growth.

They also impede the UK's ability to keep up to date with the latest scientific and regulatory developments, which risks damaging its credibility and influence on international regulatory developments. In addition, the lack of clarity and consistency risks weakening the UK's position as it negotiates new international trade agreements post-Brexit.

Confidence in a country's regulatory regime can help promote trade. For example, following the rigorous standards imposed by the FSA to strengthen the UK's food system post-BSE (see page X for more detail) a US ban on beef imports from the UK was lifted in 2020.

The UK is missing an opportunity to leverage its strong chemicals-using industry base and establish itself as a leading destination for inward investment in chemicals R&I, and influential voice in international regulation.

The status quo is not a realistic option

Reforming the regulatory framework for chemicals will require bold policy ambition and a significant investment of time and resources.

However, doing nothing is not a realistic option. The pressures on the current regime are clear: despite significant recruitment of new staff, resources are strained with the volume and complexity of work post EU exit. There is a sense of 'firefighting', rather than leading at the cutting edge of world-class regulation.

There is a risk that costs for consumers may rise and that businesses may fail due to lack of investment. Alternatively, companies may decide to relocate outside of the UK due to the regulatory regime becoming too burdensome to navigate.

For example, companies will have to apply and pay for chemical registration once at home and again in the EU, the UK's largest trading partner, if they want to sell there.

Protections for the public and the environment may also deteriorate if regulators cannot prioritise chemicals management from a holistic viewpoint.

In addition to the mounting business and economic costs, contamination, pollution and health outcomes are likely to worsen if hazardous chemicals are not well regulated.

CASE STUDY

The Chemicals and Pesticides Provisional Common Framework: A proposed solution to a complex challenge

In February 2022, Defra published the Chemicals and Pesticides Provisional Common Framework in a laudable attempt to bring more coordination and connectivity to chemicals regulation across the devolved administrations following the UK's departure from the EU. However, several significant challenges remain in the context of the sheer complexity of the regulatory landscape:

Limited scope: The Health and Safety Executive (with support from the Environment Agency) has taken responsibility for GB REACH, prior informed consent (PIC) regulations CLP, pesticides and biocides post-Brexit, and so the Framework is focused on these parts of chemicals regulations. However, it does not cover chemicals as used in other contexts such as product ingredients or contaminants in foods and medicines. These are regulated by the Office for Product Safety and Standards, Food Standards Agency and Medicines and Healthcare products Regulatory Agency, linked to other government departments.

Lack of guidance on implementation. This Common Framework indicates how decisions can be made for UK-wide implementation. However, it doesn't discuss how the technical work will be delivered, how enforcement and monitoring will be achieved, and how the chemicals regime will work as a system in the years ahead. It is also not clear how the current technical infrastructure will keep up to date with scientific developments, and there is the potential for inconsistencies across departments.

Lack of transparency on overall accountability and governance. For example, the Framework proposed a role for a UK Chemicals Governance Group (CCG), which first met in June 2019. This is the conduit between Ministers, the HSE Board, a Chemicals Delivery Board, a Plant Protection Board and a Biocides Delivery Board. However, little has been said about the role of this group and how it affects decision-making for chemicals today. It is not clear if this group is still active or who is a member.

Lack of Parliamentary scrutiny and final Ministerial approval. To date, the Framework is still listed on the UK government website as provisional.[28] Parliamentary review at both the national and devolved levels is still required, after which there will be a review and updating of the Framework before it receives final Ministerial approval and is re-published. Therefore, there is still uncertainty surrounding the content of the Framework.

C Three initiatives for improving the regulatory regime for chemicals

We have identified three steps that can be taken to improve chemicals regulation in the UK, up to and including the creation of a Chemicals Agency.

The Chemicals Agency would be the gold standard for a future UK chemicals regime. The other options represent silver and bronze standards, which could support the delivery of the current UK chemicals regime or a new Chemicals Agency.

See **table 1** for an overview of the key benefits of each option.

GOLD NATIONAL CHEMICALS AGENCY

At a glance

A National Chemicals Agency would enable the UK to be a worldwide regulatory leader. It would use the best science and evidence to help prevent harm to health and the environment, promote responsible innovation, economic growth and trade, and maximise taxpayer value for money.

What is it?

A flagship national Chemicals Agency, responsible to Parliament, but independent of any single department that would:

- Provide a centralised home for chemicals information, monitoring data and technical evidence and have regulatory powers in defined areas (respecting the role of the devolved nations).
- Consolidate all relevant information of chemicals made, used or shipped into the UK.
- Consider the life cycle of the substance as used in society and through the waste stream, and provide evidence for regulation that supports a circular economy.
- Coordinate and provide advice and support to existing regulators, e.g. HSE, EA etc.
- Act as a centre of excellence to attract and develop a workforce skilled in chemicals research, testing and regulation, and provide a place where careers could be nurtured and developed.
- Liaise with the rest of the world to influence chemicals management and regulation.

GOLD NATIONAL CHEMICALS AGENCY

What are the benefits?

Optimal risk management capacity, with regulators able to be agile and responsive to emerging scientific developments, e.g. taking account of innovations in testing and risk prediction. This would enable maximum protection for people and the environment due to ability to establish holistic view of risks and manage chemicals over the life cycle.

Far greater clarity for businesses on regulation and how to navigate the regulatory system, supporting innovation and confidence to invest.

Optimal coordination across government, due to having one agency responsible for overseeing, advising and collaborating with all regulatory agencies. This would ensure decision-making was consistent across government and minimise duplication of efforts and resource waste.

Streamlined 'one substance, one assessment' approach that maximises the protection of the public and the environment, while minimising regulatory burden and cost both for both government and businesses.

UK established as a world leader in chemicals research, innovation and regulation – attracting further inward investment. This would increase consumer confidence in goods produced in the UK and strengthen the UK's position in trade negotiations.

UK becomes a leading influence on international chemicals regulation and policy due to being recognised as a centre of excellence.

What are the potential costs?

- Initial estimates suggest annual operating costs of approximately £30m per year, although this may not need to be new funding (see page 36 for more information).
- Estimated total investment required over the initial 10-year set-up period could be £240 to £245 million. This is minus the conservative estimate of £15m to £20m in income.
- There is the potential for this to be cost neutral once revenue generation and redeployment of existing budget is accounted for.
- Further detail would be required, but notably significant potential income from REACH registrations has not been included in the above estimate of income due to current uncertainty.

See **section D** for more detail on how such an agency could be developed and function.

SILVER

CENTRE FOR CHEMICALS AND RISK RESEARCH (CCRR)

At a glance

A national Chemicals Research and Risk Institute would put the UK at the forefront of regulatory science and could provide invaluable advice and support to a future Chemicals Agency.

However, it would not solve the organisational challenge created by overlapping jurisdictions and lack of information sharing among government departments – as well as the inefficiencies and increased regulatory burden and lack of clarity for industry that this entails.

What is it?

A new independent national Centre for Chemicals and Risk Research (CCRR). This dedicated research institute would:

- Be tasked with maintaining world-class science for application in chemicals safety evaluations, including but not limited to researching, collecting, managing, and interpreting data on chemicals, chemical safety, exposure science, and NAMs.
- Provide independent advice to government in the UK and globally, e.g. to the UN science-policy panel for chemicals, waste and pollution prevention.
- Provide science and technology training (as outlined on pages 23 and 24) to support the next generation of regulators and industry scientists.
- Develop innovative approaches to regulation. For example, the Institute could partner with UK Research and Innovation (UKRI), academic partners, and industry sponsors to plan and co-fund projects designed to support the evolution of chemicals regulation science and approaches for the mid to long term.
- Offer funded post-graduate programmes and potential service offerings.

SILVER

CENTRE FOR CHEMICALS AND RISK RESEARCH (CCRR)

Similar centres could be used as a working model for the Institute. For example, the Centre for Environment, Fisheries and Aquaculture Science (Cefas) is an executive agency sponsored by the Department for Environment, Food and Rural Affairs (Defra), with a research focus on the aquatic environment, biodiversity and fisheries.

UKRI also sponsors research institutes, which can be wholly owned by UKRI, embedded in a university, or legally independent. Alternatively, the centre could be entirely sponsored by or in partnership with an existing academic institution.

Existing programmes could also be expanded upon, such as the Centre for Doctoral Training programme on managing chemical risks in the environment.

What are the benefits?

This would deliver the same benefits as the bronze standard plus the following additional advantages:

More proactive and robust approach to risk management, with the Institute providing up-to-the-minute advice to regulators on scientific developments as they apply to chemical evaluation and regulation.

Increased innovation, inward investment and trade due to promoting the UK's reputation as a home of innovative and effective chemicals regulation.

Enhanced UK influence on international chemicals policy and regulation due to strong capacity for independent analysis and credibility.

What are the expected costs?

- This would require significant policy commitments for the UK to desire to be a world leader in scientific research that supports world-class chemical regulation.
- Costs would be variable depending upon scope and scale, but likely in the order of millions. It could start modestly within an independent academic setting, for example a team of 5-10 staff, dedicated to performing research on state-of-the-art chemicals safety science and grow over a period of years – or could be modelled after existing independent research centres such as the John Innes Institute.
- There is the potential for revenue generation to help cover costs through service offerings to industry, e.g. chemical assessment toolkits.

BRONZE

CROSS-GOVERNMENTAL CHEMICALS REGULATION TRAINING AND NETWORKING PROGRAMME

At a glance

A cross-governmental chemicals regulation training and networking programme would develop a pool of talent in government that could be deployed in a future Centre for Chemicals and Risk Research or Chemicals Agency.

It could help to address the skills gap and improve career development and retention in the civil service, allowing regulators to manage risks more effectively and enhancing collaboration, consistency, and clarity for business to a degree. However, without dismantling structural barriers to coordination, it is likely that some inconsistencies, inefficiencies and confusion would remain – and the UK would continue to fall behind in chemicals research and innovation.

What is it?

A cross-governmental chemicals regulation training and networking programme. This could:

- Be delivered and accredited by credible third party/academic institution(s) quickly and at relatively low cost in the immediate term.
- Incorporate training routes into career pathways.
- Include cross-departmental networking opportunities, e.g. secondments and cross-government fora.
- Offer staff attractive opportunities for training, accreditation and development.

BRONZE

CROSS-GOVERNMENTAL CHEMICALS REGULATION TRAINING AND NETWORKING PROGRAMME

What are the benefits?

Enhanced capacity for risk management due to a more skilled regulatory workforce, enabling the beginning of a shift to a more proactive and longer-term approach.

Enhanced coordination and cooperation between departments, somewhat improving consistency of decision making and clarity for business.

Some improvements in efficiency due to more information sharing and more skilled staff.

What are the expected costs?

- This would likely cost in the order of tens to hundreds of thousands of pounds depending on staff numbers, training provider and extent of training.
- All relevant departments would contribute a small proportion of the cost (both financially and "in-kind") to a centralised budget for cross-government training and networking.
- Immediate investment could fund formalised applied training programmes in chemicals safety assessment and risk evaluation.
- Training courses could be designed to become partly or fully self-financing, especially with industry buy-in and international roll-out of online modules, for example.

Table 1: Overview of three initiatives for improving UK chemicals regulations

	BRONZE	SILVER	GOLD
	Cross-governmental chemicals regulation training & networking programme	**A new independent national Centre for Chemicals and Risk Research (CCRR)**	**National Chemicals Agency**
BENEFITS	**+**	**++**	**+++**
A more expert and joined-up regulatory workforce	✓	✓	✓
Improved recruitment and retention due to training, accreditation and development opportunities	✓	✓	✓
More efficient assessment and decision-making	✓	✓	✓
Increased coordination across government departments	✓	✓	✓
Puts UK at forefront of regulatory science		✓	✓
Regulators stay at the forefront of scientific developments		✓	✓
Innovation supported by increased chemicals risk and risk management capability		✓	✓
Increased inward investment by promoting UK's innovative regulation		✓	✓
Enhanced UK influence on international chemicals policy and regulation		✓	✓
Cements UK as world leader in chemicals research, innovation and regulation			✓
Life-cycle approach to risk, allowing a truly proactive and long-term approach to protecting people and the environment			✓
Streamlined 'one-substance, one-assessment' approach			✓
Optimal regulatory responsiveness to emerging scientific developments			✓
Greater clarity and more rapid decision-making for businesses and innovators			✓
Minimisation of duplication of efforts and waste of resource across government			✓
Increased confidence among consumers & public in the safety of chemicals and products developed in the UK			✓
Trade benefits from increased global confidence and trust in UK regime			✓
Maximised innovation and inward investment due to cementing UK as world leader in chemicals research and regulation			✓
UK established as a leading influence on international chemicals regulation & policy.			✓
SETUP COSTS	**£**	**££**	**£££**
Potential for revenue generation	✓	✓	✓
Potential for cost neutrality			✓

D Establishing a national Chemicals Agency

Remit of the Agency

The new Chemicals Agency would know the intrinsic properties and hazards of chemicals, share that knowledge with context-specific risk assessors and policymakers making decisions across sectors on chemical use in UK and internationally, and play a co-ordinating role across government departments and existing agencies.

These functions could be modified as needed, but as a starting point we suggest the following are included in its remit:

- **Host the appropriate number of skilled technical and administrative specialists** who understand and can interpret the technical data on the intrinsic hazards of industrial chemicals, including pesticides and biocides hazard data.
- **Host a centralised repository of all chemistry, exposure, toxicological and epidemiological data for chemicals on the UK market,** including new types of evidence from new approach methods (NAMs) for use in next-generation risk assessment (NGRA).
- **Implement and act as the regulator for Classification, Labelling and Packaging (PLC),[h] Prior Informed Consent (PIC),[i] Plant Protection Products, Biocidal Products, and UK REACH** registrations, evaluations, authorisations and restrictions – work programme prioritised by the Chemicals Agency.
- **Provide scientific and technical guidance and training to industry** on the data it needs to generate for chemicals and how it is applied in risk assessments.
- **Enable a 'one substance, one toxicological assessment' approach**, by overseeing cross-government coordination of chemicals regulation and providing consistent technical information and evidence to other parts of government that perform chemicals risk assessment on the use or presence of hazardous chemicals in different contexts. This would require departments to consider exposure data that would be shared with the Chemicals Agency.
- **Host staff that represent the Chemicals Agency in international technical forums and conventions** relating to global chemicals policy and regulatory guidelines development (e.g. at OECD, UN level).
- **Act as a driver for relevant scientific and technical research to support regulatory innovation.**
- **Scientific advisory committees (SACs) providing independent scrutiny and advice**, such as the REACH Independent Science Expert Pool (RISEP) and the Committee on Toxicity (COT), for example would continue to be important and be aligned with the Chemicals Agency's responsibilities.

The new Agency would complement existing regulatory and legislative structures. Therefore it would NOT be responsible for the following areas:

- **Making new chemicals law.** This would remain the responsibility of Parliament, with the Agency providing guidance as needed.
- **Acting as a regulator/enforcer for all the wider regulations relating to product manufacturing and environmental policy.** This would remain under the responsibility of the relevant existing agencies and ministers, with the Agency providing guidance as needed.
- **Context specific policy-making.** The Chemicals Agency would provide evidence, support and guidance to other bodies, but they would retain ownership of their specific policy areas. For example, it could centrally review the classifications and hazard characteristics of a given chemical and make this data available to the respective regulators to consider the implications for their remits, as follows:
  - The **Health & Safety Executive (HSE)** would be responsible for assuring worker safety, exposure assessment and Control of Substances Hazardous to Health (COSHH);
  - The **Environment Agency** would be responsible for environmental protection with monitoring and exposure assessments of air, land and water;
  - The **Office for Product Safety and Standards (OPSS)** would be responsible for all consumer products safety and resources from waste;
  - The **Food Standards Agency (FSA)** would be responsible for implementing regulations on chemical contaminants in foods and in food packaging;
  - The **Medicines and Healthcare products Regulatory Agency (MHRA)** would be responsible for implementing regulations on for chemical contaminants/coatings/ excipients in medicines and medical devices;
  - The **Health Security Agency (HSA)** would be responsible for public health.

All of these context-specific applications would call on the centralised UK Chemicals Agency to provide consistent technical evidence on the intrinsic toxicological, epidemiological, and biological data and risk assessment on substances.

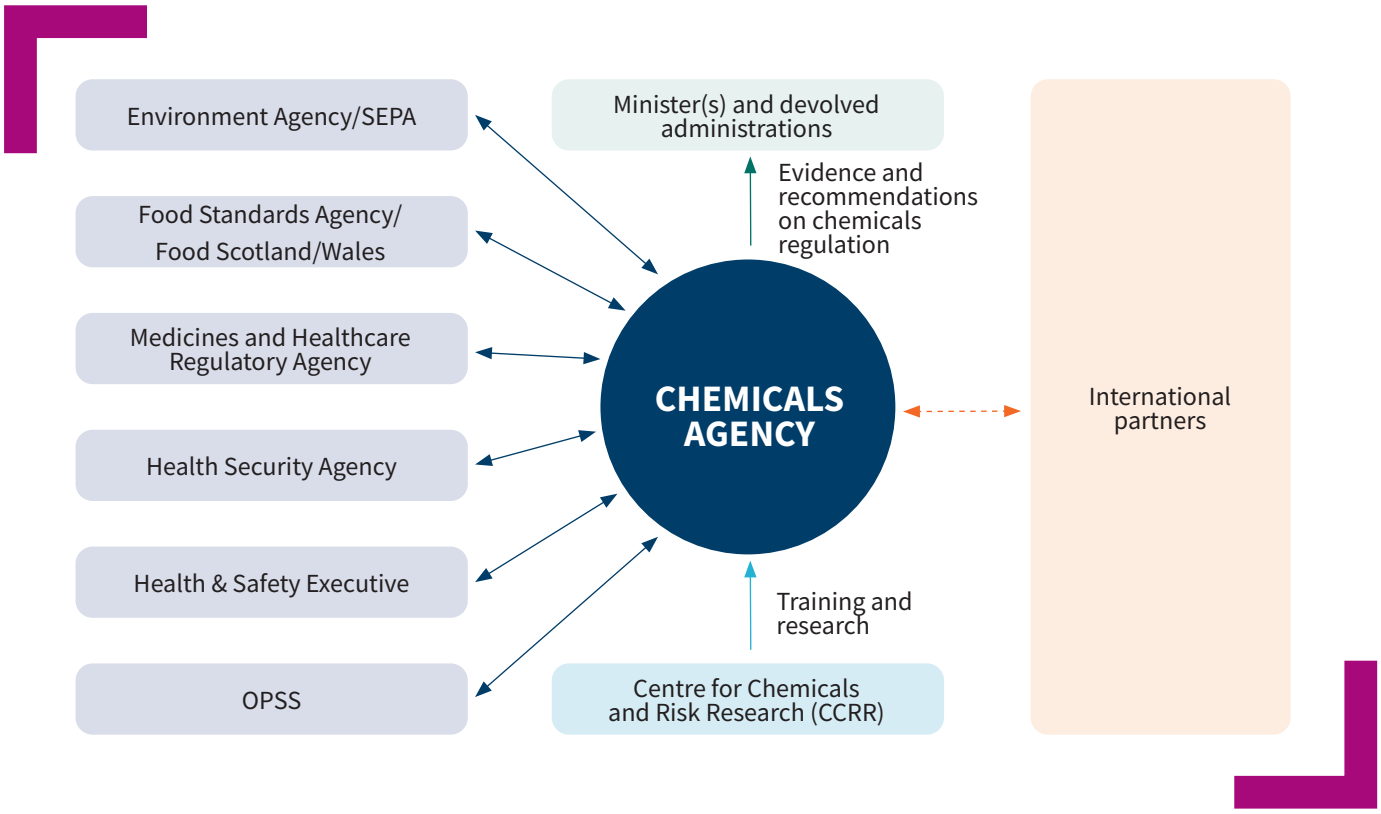
The Chemicals Agency should be clear if it interprets data differently to other national or international regulators such as the European Chemicals Agency or US Environmental Protection Agency. Discussions could be had internationally on divergences and similarities between respected authorities.

How the Agency would operate within the wider regulatory structure

The new Chemicals Agency is at the centre of a hub-and-spoke model, coordinated to all parts of government where data and evidence on chemicals hazards are needed.

Ministers and devolved administrations would retain accountability for chemicals legislation and complex, national-level decisions, while the Chemicals Agency would be accountable for technical and operational decisions relating to regulation.

The following diagram shows how the new agency would relate to other governmental bodies:



Managing the change

The establishment of a national Chemicals Agency would mean merging and consolidating expertise from across government departments, changing roles and structures, providing new infrastructures and potentially new legislation. This would require significant operational resource. We have outlined some of the key challenges below:

Existing staff in various government departments would undoubtedly be impacted, both positively and negatively.

It is expected that a Chemicals Agency would have a workforce located across the country working in hybrid mode, with a central office hosting approximately 15% of staff.

Based on estimates of similar agencies, we estimate that the new Agency would require approximately 550 staff, either moved from existing departments or recruited to fill new roles as necessary.

Mitigation: The prospect of stronger career paths and enhanced skills development should be envisaged to counter any negative impacts of short-term upheavals.

As significant organisational change would be happening, the day-to-day work of regulating chemicals would be affected.

Arguably, the necessary regulatory work is not currently being delivered at a useful pace with the current system and the regulatory future over the next five years already looks uncertain. According to the National Audit Office in 2022, 'HSE told us it takes up to five years for staff to become fully competent and expects it will be a further four years before it reaches the full capacity it has planned for its post-EU Exit regime.'[29]

Therefore, it may be an ideal time to make the transition to a new system, as much upheaval is already occurring in the transition to the post-Brexit regime. However there may be some short-term disruption to regulatory operations.

Mitigation: A plan to continue business as usual would have to be developed to ease the transition to the new agency during the preparation phase.

This level of structural change required means the establishment of a Chemicals Agency would need to be a high-level political decision, as a key part of a new national chemicals strategy.

The current economic climate means there needs to be a clear economic and social benefit to justify any new investment.

However, confidence in chemicals, the protection of human health and the environment, and the benefits of an effective regulatory regime to industry and trade, are all strategically important for the mid- to long-term economic future of the UK.

Mitigation: The new Chemical Agency should form part of a wider new chemicals strategy that sets out the UK's ambitions to build on its strong chemicals industry, and the role the Chemicals Agency can play in achieving this, as well as in protecting the public from harm.

International considerations: Considering alignment or divergence with EU regulations

The UK has a range of options when it comes to aligning with international regulation, from developing an entirely new suite of regulations and guidance for chemicals, moving away from the current transposed EU laws, to rejoining the European Chemicals Agency (ECHA) and resuming the chemicals regulation regime that was in place before its exit from the EU, to approaches in between.

A national Chemicals Agency would function well with any approach to international alignment and improve the implementation of chemicals regulation, regardless of the approach taken.

Timeline

The figure below charts out how a transition to a new Chemicals Agency could occur over a 10 -year timeframe:

Preparation Phase 1: Years 0-1 or 0-2

- Establish a brand for a new 'Chemicals Agency'

  -->Existing staff in HSE/EA/HSE begin to adopt new branding for existing work on chemicals regulation.

- Appoint initial staff, including leadership, administrative functions to plan for Phase 2 start-up and coordinate with other government departments

  -->E.g. Defra, DBT, OPSS, EA, HSA, FSA etc..

- Move administrative staff and technical specialists from government departments into the new Agency

  -->Consolidate the relevant government technical specialists: toxicologists, epidemiologists, NAM specialists, computer scientists, GB REACH specialists.

  -->All staff involved with identifying and characterising chemical hazards would be moved or recruited as needed.

- Establish new CPD training courses with a credible independent academic provider to rapidly upskill the existing workforce in Defra, HSE, EA, FSA etc. on chemicals safety assessment fit for the future.

  -->Startup funding could come from government and industry.

- Consider other international models for national chemicals regimes, as well as the UK's post-Brexit needs and goals, to develop a new, credible, and world leading strategy for chemicals regulation.

Startup Phase 2: Years 2-5 or 3-5

- The Chemicals Agency begins work as an independent technical and regulatory arms-length non-departmental public body that provides expertise and objective evidence on chemicals into government.

  -->The new Agency would be expected to work on a hybrid model, with a central office and people working remotely across the country.

- Consolidate Chemicals Agency as the regulator implementing GB REACH, CLP and PIC, and PPP/ biocides.

  -->Build on UK REACH Independent Scientific Expert Pool (RISEP) approach to independent science review.

- Provide technical guidance on overarching and cross-cutting aspects of chemicals/groups of chemicals, e.g., PFAS, EDCs, chemical mixtures assessments, etc.

- Align the Scientific Advisory Committees on Toxicity, Mutagenicity and Carcinogenicity to the Chemicals Agency.

-->Provide new technical guidance on the use of toxicological/ biological and epidemiological data in risk assessment. Principles of exposure assessment in guidance but specifics with different regulators.

Fully operational Phase 3: Years 6-9

- Fully functional and complete UK Chemicals Agency workforce.

  -->To cover all priority chemicals evaluations for UK, with a team established on life cycle analysis.

- A systems approach to chemicals regulations has been developed.

  -->The new Chemicals Agency is at the centre of a hub and spoke model, coordinated to all parts of government where data and evidence on chemicals hazards are needed.

- Highly trained exposure assessors and risk assessors are in place government departments.

- Career development can be as technical specialists within the agency; working cross department providing knowledge and doing secondments in different departments etc. Learning new skills in exposure and risk assessment.

- Embed associated academic training courses with international regulators – world class provider of technical regulatory know-how.

Cost estimates

Methodology

We commissioned Risk and Policy Analysts Limited (RPA) to estimate the potential costs in order to facilitate a more robust discussion of the aforementioned initiatives.[k]

The approach taken by RPA, within input from the RSC, was to define the scope of a Chemicals Agency, compare it to similar EU and UK agencies, and then estimate the major costs involved in establishing the Agency.

Data was extracted from the UK MHRA, the Swedish Chemicals Agency (KEMI) and the German Federal Institute for Risk Assessment (BfR), which were all identified as having similar responsibilities to the proposed Chemicals Agency.

Cost estimates were modelled over a 10-year timeframe, divided into three phases of preparation, start-up, and operation. The following costs were considered: employee salaries; recruitment; training; building and leasing; computing and IT; advertising; and travel.

Some potential income was also estimated. A Chemicals Agency would be expected to generate income through granting REACH Registrations and Authorisations, pesticides and biocides authorisations and active substance approvals, and other opportunities such as delivering training programmes.

In the RPA study, income from REACH Authorisations was quantified, but income from REACH Registrations and plant protection product income were not estimated due to high uncertainty in the calculation of these figures. Therefore, more work needs to be done to quantify the potential income of a Chemicals Agency.

Estimated costs

The results of the study showed that a Chemicals Agency would incur yearly operating costs of approximately £30 million per year, the largest proportion of which come from staff salaries and IT costs.

Over the 10-year period modelling period, the total cost *before income* was estimated at approximately £255-265 million (net present value). After including an estimated £15-20 million of income over the study period, net costs are estimated between £240 to 245 million over 10 years.

Could the Chemicals Agency be cost neutral?

The costings outlined in this paper do not account for likely revenue generation nor for the fact that some costs could be taken from existing budgets, due to resources being redeployed or no longer needed. There is therefore the potential for the Chemicals Agency to be cost neutral.

Notably, we have not included REACH registration income in our calculations, as the UK system is currently under review and subject to change. This omission may result in a significant underestimate of the potential income to a Chemicals Agency.

For comparison, in the EU, income from registrations is approximately 10 times higher than authorisation income. If this pattern holds true for the UK under the new UK REACH system, then the income from registrations would potentially be able to contribute to the yearly operating costs of a new Chemicals Agency.

In addition, the RPA study did not attempt to quantity costs of the current regulatory system, due to a lack of available data, the fragmented nature of the current system, and the number of actors involved in the process.

There are some figures available for the HSE's Chemicals Regulation Division (CRD), which is one of the largest components of the current system. According to the National Audit Office, the CRD budget for 2022-23 was £31.2 million, which came from a combination of government funding and industry fees. It is assumed that this division (and associated funding) would be largely incorporated into the new Chemicals Agency, leading to net cost neutrality.

E Conclusion – next steps

At the time of publication of this report (June 2024), we call on the next UK Government to:

1. **Release the long-awaited Chemicals Strategy**, to provide a comprehensive, strategic plan from government for the management of chemicals throughout their lifecycle.
2. **Commence negotiations for access to ECHA data**, which will allow for minimal duplication of effort, lower costs for business, and high confidence in reviewing the safety data of chemicals on the GB market.
3. **Provide a timeline for UK REACH reform** and information on the new processes for the registration, evaluation, authorisation and restriction of chemicals processes, which will provide clarity and reassurance for business and enable them to innovate and invest with confidence.
4. **Immediately fund a programme of short training courses** to upskill and fast-track new civil servants. This could expand over time to develop a base of independent scientific expertise and research programmes.
5. **Commit to a national Centre for Chemicals and Risk Research (CCRR)** to ensure UK regulators are informed by the best and most up to date independent scientific evidence and cutting-edge methods, supporting agile safety decision-making for innovative new products that use advanced materials and new technologies.
6. **Commit to a national Chemicals Agency** to enable the UK to be a worldwide regulatory leader. It would use the best science and evidence to help prevent harm to health and the environment, promote responsible innovation, economic growth and trade, and maximise taxpayer value for money.

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