National Audit Office

Regulating after EU Exit

Regulation

REPORT

by the Comptroller and Auditor General

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Report by the Comptroller and Auditor General

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Gareth Davies
Comptroller and Auditor General
National Audit Office

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Key facts

428

the number of applications for regulated product authorisations the Food Standards Agency (FSA) was progressing at the end of 2021, compared with the anticipated number of 150

46%

staffing increase in the Health and Safety Executive's (HSE's) Chemicals Regulation Division between September 2020 and March 2022

£19.7m

Competition and Markets Authority's (CMA's) EU Exit funding in 2020-21 (in 2021-22 prices)

31 December 2020	date that the transition period ended following the UK's exit from the EU
May 2024	date that HSE expects its biocide and plant protection transformation programme to be complete
Autumn 2022	expected date that the CMA's Subsidy Advice Unit will be operational
25%	staff time spent training in HSE's Chemicals Regulation Division in 2021-22, as reported by HSE
115%	increase in staffing in FSA's Science, Evidence and Research Division between July 2018 and January 2022
25%	CMA's vacancy rate for legal services roles in March 2022

Summary

Background

1 Government uses regulation to deliver public policy outcomes in a wide range of areas, for example, to ensure food safety, protect the environment, or promote competition in the UK economy. As a European Union (EU) member state, the UK operated within an EU regulatory framework, with many regulations harmonised to facilitate the European single market. On 31 January 2020, the UK left the EU and entered a transition period during which the UK continued to operate within the regulatory structures of the EU. The transition period ended on 31 December 2020, ending the direct applicability of EU regulations in the UK and the UK's participation in EU regulatory institutions and cooperation arrangements. To facilitate a smooth transition, EU regulations were transferred into UK law at that point.

2 The government views the UK's exit from the EU as an opportunity to change how regulation is designed and implemented, with the aim of stimulating innovation, ensuring competitive markets and removing unnecessary administrative burdens. In January 2022 the Cabinet Office published a paper which set out the ambition for the UK to be "the best regulated economy in the world" and established five high-level principles for future regulatory policy. Government has appointed a new Minister for Brexit Opportunities and Government Efficiency, and also established the Brexit Opportunities Unit within the Cabinet Office to review and reform existing policy and regulation and support the scrutiny and introduction of new regulation.

3 Leaving the EU has changed the operating environment for many UK regulators. They have new responsibilities for developing regulatory policy at a national rather than EU level, and they have taken on new regulatory functions previously carried out by the EU and its institutions. They have also lost access to a range of data sharing and cooperation arrangements. For many regulators these are likely to be significant changes.

4 Nearly 18 months after the end of the transition period, this report is an opportunity to assess how regulators have managed the transition and are responding to the opportunities and challenges of EU Exit.

Scope

5 This report considers three regulators whose work has been significantly affected by EU Exit. The report seeks to draw out common issues to help inform regulators and policy departments as they develop regulation after EU Exit, both in the three areas covered and more broadly across government.

6 We have examined:

- the Health and Safety Executive's (HSE's) role in chemicals regulation, in particular the Chemicals Regulation Division;
- the Food Standards Agency's (FSA's) role in regulating food safety and standards; and
- the Competition and Markets Authority's (CMA's) roles in enforcing competition and consumer protection law; operating the Office for the Internal Market; and preparing to provide subsidy advice within the UK subsidy control regime.

7 We examine:

- **preparing for transition and readiness for Day 1**: government aimed to ensure a smooth transition after the end of the transition period. We have therefore examined regulators' efforts to ensure continuity at the end of the transition period on 31 December 2020;
- **operational capability**: government aimed to incorporate EU laws and regulation into UK law following transition as a starting point for UK regulation outside of the EU. We therefore examine the extent to which regulators have built their operational capability to deliver their new functions in terms of resources, capacity, workload, data and intelligence, and regulatory cooperation; and
- **developing long-term regulatory strategies**: the UK government has recently set out its broad longer-term aims for regulation outside EU regulatory structures. We therefore examine the extent to which regulators and policy-makers have developed long-term strategies to deliver those aims, including engagement across the UK and internationally.

8 This report does not assess the long-term effectiveness of the three current regulatory frameworks as the regulators are at an early stage in developing their new competencies. We do not directly compare their individual performance.

Key findings

The regulators' new responsibilities and preparing for transition

9 All three regulators are taking on significant new responsibilities as a result of EU Exit. HSE is now the main regulator for chemicals in the UK, with an expanded role, including in evaluating chemical risks and authorising chemicals for use under the biocides and plant protection product regimes. FSA now has expanded responsibility for assessing food and animal feed safety risks and making recommendations to ministers, including for the authorisation of regulated products. CMA has expanded responsibilities for assessing mergers, and for enforcing competition law in large international cases with a UK impact. It has also established the Office for the Internal Market to monitor and report on the UK internal market and is setting up a unit to provide advice to public bodies on state subsidies (paragraphs 1.11, 2.3, 3.3 to 3.7, 4.3, 4.12 and Figure 8).

10 The regulators implemented measures aimed at ensuring continuity after the end of the transition period, which in a number of cases involved delaying new regulatory requirements or extending deadlines. These measures included, for example, FSA putting in place new processes to handle food-related incidents across the UK, and CMA working with the European Commission to determine how competition cases under way at the end of the transition period would be handled. In some areas new regulatory requirements were delayed or deadlines extended. For example, government has repeatedly postponed introducing full import controls on high-risk food imports from the EU, which until recently were due to be implemented in 2022 and are now planned to come into force from the end of 2023. It also agreed that existing EU registrations and authorisations held by chemical companies based in Great Britain could be transferred to the UK system without a fee, and extended the deadlines set in the initial transitional provisions for companies to meet the full data requirements (paragraphs 1.8, 1.9, 2.4, 2.5, 2.13, 3.8, 4.4, 4.5, 4.7, 4.15).

Building operational capability post-transition

Resourcing and capacity

11 The regulators all received funding for their new responsibilities. All three regulators were allocated additional funding before EU Exit to carry out preparatory work. For FSA, its EU Exit funding allocation for 2020-21 of £14.5 million (in 2021-22 prices) was included in its business-as-usual funding for subsequent years. HSE's total budget for its Chemicals Regulation Division has grown by 39% between 2018-19 and 2022-23 (in 2021-22 prices). CMA has used its previous additional EU Exit funding, which in 2020-21 was £19.7 million in 2021-22 prices, as an indicator for future resource needs to support its new responsibilities and workload (paragraphs 2.6, 3.5, 3.9, 4.9, 4.10 and Figures 2, 6, 9 and 10).

12 All three regulators are finding it a challenge to recruit the specialist skills they need in some key areas. CMA has long-standing challenges in competing with the private sector when recruiting and retaining staff with legal, economic and digital skills for its competition and mergers work. In March 2022, it had a vacancy rate of 25% for legal roles. FSA has already expanded its Science, Evidence and Research Division from around 59 full-time equivalent (FTE) posts in July 2018 to around 128 FTE in January 2022, a 115% increase, and is facing challenges in recruiting increasing numbers of staff with expertise in toxicology. It is also looking to new working models to manage challenges in the supply of veterinarians. HSE has increased staffing in its Chemicals Regulation Division by 46% between September 2020 and March 2022, and has also faced challenges in recruiting experienced toxicologists. It is focused on developing scientific skills in-house, and reports spending 25% of staff time in the Chemicals Regulation Division on training in 2021-22. HSE expects it will be a further four years before it reaches the full capacity it has planned for its post-EU Exit regulatory regime. There is a risk that capacity constraints could delay regulatory decisions. For example, HSE has extended approvals for biocidal active substances due to expire in 2021-22 to at least 2023 while it develops its biocide active substance assessment programme (paragraphs 2.7, 2.8, 2.15, 3.10, 3.11, 4.11 to 4.13 and Figure 7).

13 A number of factors have made regulators' planning for their workloads challenging. For example, CMA has seen fewer merger cases than it planned for in 2020-21 following the economic impact of the COVID-19 pandemic. FSA has experienced a much greater demand for authorisations of new regulated products than expected, progressing 428 applications at the end of 2021 compared with the 150 it anticipated, in part because of new requirements for cannabidiol (CBD) food products already on the market to go through the authorisation process. For HSE, the level of demand for the new regimes was not clear until after the end of the transition period when companies began to participate in them. This makes it harder for the regulators to assess what their workload will be in the longer term, and how to plan their capacity to meet it (paragraphs 2.9 to 2.11, 3.12 to 3.14 and 4.12 to 4.14).

Operational processes and plans

14 Regulators have lost access to data- and information-sharing arrangements with EU regulators and are continuing to explore ways to mitigate the impact on their work. All three regulators used EU databases for regulatory activities such as risk identification or to carry out detailed enforcement work. For example, FSA has lost full access to the Rapid Alert System for Food and Feed, which it used to exchange information about food safety risks and their management. The regulators all identified loss of data- and information-sharing arrangements with EU counterparts as having a negative impact on their ability to assess risks or carry out their work. They are seeking to mitigate the loss in a number of different ways, for example, using other international systems, publicly available data or setting up data-sharing arrangements on a case-by-case basis where possible (paragraphs 2.16, 2.17, 3.15, 3.16 and 4.15).

15 There has been limited progress on regulatory cooperation with the EU following EU Exit. The Trade and Cooperation Agreement provides for voluntary regulatory cooperation, such as exchange of information on good regulatory practices. While the regulators and policy-makers we spoke to all expressed their willingness to put this into action, they have not been able to make much progress. The EU–UK committee on regulatory cooperation has met once, in October 2021, and agreed to meet annually in future. While the UK has stated its readiness to progress specific cooperation on both chemicals regulation and competition enforcement, as set out in the Trade and Cooperation Agreement, discussions have not yet begun with the EU (paragraphs 1.2, 1.3, 2.20, 2.21, 3.15, 3.16, 3.22 and 4.16).

16 The three regulators' plans to move from interim arrangements to fully functional regulatory regimes are still in progress. HSE put in place interim arrangements for its plant protection and biocides regimes, which it considers are resource-intensive for it to deliver and may slow down products getting to market. The programme of work it has put in place to transform these interim arrangements will not be completed until May 2024. FSA is still working to embed new data sources, such as customs data, which it plans to use to enhance its risk assessment process. CMA's Subsidy Advice Unit expects to be operational in autumn 2022 (paragraphs 2.5, 2.17, 3.6, 4.8, 4.12 to 4.14 and Figures 5 and 12).

Longer-term strategic development

Developing regulatory strategies for the UK

17 Regulators and policy-makers in all three areas are at an early stage in setting their strategic direction following EU Exit. FSA has recently published its long-term strategy, its first after EU Exit, which sets out broad ambitions but has not yet made public detail on how regulation may change in practice. A new Chemicals Strategy, led by the Department for Environment, Food & Rural Affairs (Defra), has been in development since 2018. Defra told us work had been deprioritised to focus on implementing EU Exit and it expects that engagement with stakeholders on the strategy would begin in spring 2022. HSE's strategy for the next 10 years is due to be published soon. The Department for Business, Energy & Industrial Strategy (BEIS) set out its response to a consultation on 'Reforming competition and consumer policy' in April 2022, which proposes a number of reforms to competition policy but emphasises that many will need new legislation to be implemented. As set out in the Regulators' Code, regulators should ensure their regulatory approaches are transparent (paragraphs 1.7, 2.18, 3.17 to 3.19, 4.18 and 4.19).

Governance of the UK internal market

18 Regulators are working with others to get governance arrangements for the UK internal market up and running. Where competencies are devolved, such as on food safety or environmental protection, it is possible that regulators across the four UK nations will have different regulatory decisions to enforce. The UK government and regulators are working with the devolved administrations to develop common frameworks governing regulatory approaches in these areas. As at January 2022, the common frameworks relating to chemicals and pesticides, and food and feed safety and hygiene were operating on a provisional basis and are undergoing scrutiny by Parliament. In December 2020, the government passed the UK Internal Market Act, covering trade in goods and services within the UK and establishing an Office for the Internal Market. Both the Scottish and Welsh governments have stated their opposition to the Act (paragraphs 1.11 to 1.13, 2.19, 3.20, 3.21 and 4.20).

Influencing development of regulation internationally

19 All three regulators have taken steps to strengthen their international relationships, for example to improve operational effectiveness or to influence strategic direction on regulation. Outside the EU, the regulators are beginning to develop strategies for increasing their presence internationally, including strengthening their involvement in organisations such as the World Health Organization, United Nations committees and standards-setting bodies. For example, in September 2020, CMA signed the Multilateral Mutual Assistance and Cooperation Framework with its counterparts in four countries to strengthen cooperation on multi-jurisdictional investigations. FSA is increasing its engagement with the International Food Safety Authorities Network (INFOSAN) and sits on its advisory group (paragraphs 2.22, 3.22 and 4.21).

Conclusion

20 All three regulators covered in this report have taken on significant new responsibilities and were allocated additional funding as a result of the UK leaving the EU. The regulators implemented measures aimed at ensuring continuity in their respective sectors on Day 1 after the transition period ended, in some cases this involved delaying new regulatory requirements, or extending deadlines. All three are building capability to match their increased responsibilities but are facing operational challenges that need to be addressed as they move away from interim arrangements. These include recruiting people with the necessary skills, bridging information and data gaps, and planning for the future when there is uncertainty over long-term workloads in some key areas.

21 Government has set out a broad ambition for regulatory reform and sees opportunities for improving regulation outside the EU. All three regulators and the respective policy departments are at an early stage with developing strategies for reaching their future state, while still having to manage the operational challenges that have already arisen following EU Exit. Until long-term strategies are fully developed, there is a risk that regulators' current plans to meet operational challenges may be wasted effort and not align with longer-term ambitions.

Recommendations

22 Our recommendations cover the three regulated areas examined in this report and may also be of wider benefit to regulators and policy departments in other regulated areas. We recognise that experience varies across the three areas covered, and that progress may already have been made by individual regulators in some areas covered below.

a **While government as a whole is still working on its future direction for regulation, regulators need to develop, with policy-makers, their long-term strategies and objectives.** In line with our principles of effective regulation, these should articulate a clear line of sight linking high-level and statutory objectives to detailed operational objectives, plans and priorities. This will enable them to build their capacity and processes and prioritise their workload to ensure their detailed objectives support overall desired policy outcomes.

b **Now there is more clarity on demand for new regulatory functions, regulators should review the plans they developed before EU Exit in the light of what they now know about their capacity and their workload.** They should test the realism of their current plans and take any necessary steps to ensure their operational effectiveness is maximised as well as looking for efficiencies in delivery. These reviews should consider what scope and need the regulator has to:

- build capacity and skills;
- flex deadlines or work programmes to match workload to resources;
- use other international channels to cooperate and influence regulatory changes; and
- build new tools for risk identification.

c **Regulators should ensure that, as soon as they are able, they provide clarity to stakeholders on their direction of travel and the timelines for any planned changes.** As set out in good practice guidance, this is important to allow stakeholders to plan and to hold regulators to account.

d The challenges faced by the three regulators we have examined in detail may be similar to those faced by others across government as they develop their post-EU Exit plans. **We therefore recommend that government draws on the findings in this report as it considers the future of regulation after EU Exit more widely – for example, in its work in response to the consultation on the framework for better regulation.**

Part One

Introduction

1.1 Government uses regulation to deliver public policy outcomes in a wide range of areas, for example, to ensure food safety, protect the environment, or promote competition in the UK economy. As a European Union (EU) member state, the UK operated within an EU regulatory framework, with many regulations harmonised to facilitate the European single market. To ensure continuity at the end of the transition period, Parliament approved the transfer of EU regulations into UK law, with amendments to ensure the legislation was operable. In general, regulatory functions that were the responsibility of European agencies were transferred to regulators in the UK, and the decision-making powers of the European Commission were returned to ministers across England, Wales and Scotland.

1.2 Outside the EU, the UK has more flexibility to set its own regulatory regimes. However, the Trade and Cooperation Agreement between the UK and the EU sets out specific areas (including labour and environmental protections) where both the UK and the EU are prohibited from weakening or reducing their levels of protection below what was in place at the end of the transition period.

1.3 While working-level relationships with the EU and member state organisations were disrupted by the process of negotiations, the Trade and Cooperation Agreement allows for voluntary regulatory cooperation, such as exchange of information on good regulatory practices. However, while the regulators and policy-makers we spoke to all expressed their willingness to put this into action, they have not been able to make much progress. The EU–UK committee on regulatory cooperation has met once, in October 2021, and agreed to meet annually in future. There are specific areas where the Trade and Cooperation Agreement sets the foundation for more detailed future cooperation, including on chemicals regulation and competition enforcement. While the UK has stated its readiness to increase cooperation in these areas, discussions have not yet begun with the EU.

Government's broad ambitions and actions for change

1.4 The UK government views the UK's exit from the EU as an opportunity to change how regulation is designed and implemented, with the aim of stimulating innovation, ensuring competitive markets and removing unnecessary administrative burdens. In June 2021, the government's independent Taskforce on Innovation, Growth and Regulatory Reform set out proposals to reform the regulatory landscape. Following this report, from July to October 2021, the government carried out a consultation on reforming the framework for better regulation and plans to carry out a review of the status and content of all retained EU law.

1.5 The government has set out general ambitions for regulatory reform. In January 2022 the Cabinet Office published a paper which responded to the 2021 consultation. It set out the ambition for the UK to be "the best regulated economy in the world" and established five high-level principles for future regulatory policy. It also set out a target to cut £1 billion of business costs from retained EU law.

1.6 Government has appointed a new Minister for Brexit Opportunities and Government Efficiency, and also established the Brexit Opportunities Unit within the Cabinet Office to review and reform existing policy and regulation and to support the scrutiny and introduction of new regulation. The unit has commissioned all government organisations to set out what legislation they have which was retained from the EU and what plans they have to make amendments. It is not clear when the unit will complete its review, or what action it will then take or suggest to departments.

1.7 The government's Regulators' Code sets out the principles regulators must consider when developing policies and operational procedures, including the importance of engaging with those they regulate and ensuring their approach to their regulatory activities is transparent.[1] Consideration of these principles will be particularly important as the UK develops its future regulatory approach outside the EU.

1 Department for Business, Innovation & Skills, Regulators' Code, 2014.

Preparing for EU Exit

1.8 The regulators prepared for EU Exit against a backdrop of uncertainty.

- The date of EU Exit: the date the UK would leave the EU was revised on a number of occasions, moving from 29 March 2019 to 31 January 2020 with a transition period until 31 December 2020.
- The future relationship with the EU: until the Trade and Cooperation Agreement was agreed on 24 December 2020, regulators still had to be prepared for a 'no-deal' scenario.
- The Northern Ireland Protocol (the Protocol): the UK and the EU agreed that a number of grace periods should apply to certain aspects of the Protocol to give government and businesses more time to prepare for the changes to come. The UK and the EU are in discussions regarding the Protocol and it is now not clear when those grace periods may end, or if the terms of the Protocol will change.

1.9 On 31 January 2020, the UK left the EU and entered a transition period during which the UK continued to operate within the regulatory structures of the EU. The transition period ended on 31 December 2020, ending the direct applicability of EU regulations in the UK and the UK's participation in EU regulatory institutions and cooperation arrangements. To facilitate the transition, the government intended there to be no major policy changes at the point of exit. It passed the European Union (Withdrawal) Act 2018, which converted EU law as it stood at the moment of exit into domestic law and provided for amendments to be made via secondary legislation to correct laws that would otherwise no longer operate appropriately. The expectation was that any substantive policy changes would be made by Parliament and the devolved legislatures at a later date.

Trade

1.10 Outside the EU, the UK now sets its own trade policy. The regulators have had a greater role to play in providing technical advice to support trade negotiations, usually contributing through the departments that lead in specific areas. As the UK conducts more trade negotiations, this area of work is likely to grow. Regulators may also have continuing responsibilities once trade negotiations have concluded to ensure that UK arrangements meet the agreed standards and to assess the quality of arrangements in trading partners.

Devolution and the internal market

1.11 There is more opportunity now for the devolved administrations in the UK to set their own regulatory standards in the areas where they have devolved competencies. The impact of this on UK regulators will depend on the extent to which regulation in those areas is devolved, and this is different for each of the three regulators we looked at in detail. The Competition and Markets Authority (CMA) operates across the whole of the United Kingdom. The Food Standards Agency (FSA) operates across England, Wales and Northern Ireland, with varying levels of policy responsibility in the different areas for various aspects of its work. The Health and Safety Executive (HSE) operates across England, Scotland and Wales, and for chemicals regulation it also provides support and technical expertise to Northern Ireland government departments and the Health and Safety Executive for Northern Ireland (a separate body).

1.12 In December 2020, the government passed the UK Internal Market Act (the Act) covering trade in goods and services within the UK. This means that in most cases a good, which complies with regulations permitting its sale in the part of the UK it is produced in or imported into, can be sold in other parts of the UK, without complying with equivalent regulation there (referred to as the mutual recognition market access principle). The exception to this is Northern Ireland, where under the Protocol goods moving to Northern Ireland must follow certain EU rules. Devolved administrations have stated their opposition to the Act. The Scottish Parliament agreed "not to consent to the United Kingdom Internal Market Bill, as it reduces and constrains the competence of the Scottish Parliament". The Welsh government applied for permission to issue a legal challenge to the Act, stating that it limits the scope of its devolved powers. Although the High Court and Court of Appeal refused this challenge on the grounds that it was premature, they made no judgment on the outcome of any future specific challenge.

1.13 The UK government is developing, together with the devolved administrations, common frameworks governing regulatory approaches in areas of devolved competency. The principles for these common frameworks were developed in 2017, and work has been ongoing since that time. As at January 2022, the common frameworks relating to chemicals and pesticides, and food and feed safety and hygiene, were operating on a provisional basis and undergoing scrutiny by Parliament.[2] The Act provides for some exclusions to the market access principles in certain cases including food safety and chemicals regulation and uses the common frameworks as an example process for considering exclusions or proposing new ones.

2 FSA is responsible for the regulation of feed given to food-producing animals ('animal feed') to protect consumer and animal health and welfare.

1.14 Leaving the EU has changed the operating environment for many UK regulators. They have new responsibilities for developing regulatory policy at a national rather than EU level, and they have taken on new regulatory functions previously carried out by the EU and its institutions. They have also lost access to a range of data-sharing and cooperation arrangements. For many regulators these are likely to be significant changes.

1.15 Nearly 18 months after the end of the transition period, this report is an opportunity to assess how regulators have managed the transition and are responding to the opportunities and challenges of EU Exit.

Part Two

The Food Standards Agency (FSA)

2.1 Failures in food safety can have catastrophic consequences for human life, public confidence, the wider economy and international trade. The regulation of the food system is important for ensuring that food is safe and is what it says, and consumers can make informed choices about what they eat.

2.2 FSA is a non-ministerial government department that works to protect public health and consumers' wider interests in relation to food. It has responsibility for food and feed safety and standards regulation, working with local authorities to enforce these regulations. FSA has different policy responsibilities across England, Wales and Northern Ireland **(Figure 1** on page 20). In Scotland, Food Standards Scotland (FSS) is the non-ministerial department with responsibility for food and feed safety, labelling, composition and standards. As set out in Appendix Two, this report focuses on regulation in England.

2.3 European Union (EU) Exit has had a significant impact on the work of FSA. In some areas it has taken on new responsibilities carried out in the EU by the European Commission and the European Food Safety Authority (EFSA) while in other areas the nature of its work has either increased or changed.[3] Key areas include:

- **risk assessment and management**

  FSA now has greater responsibility for assessing food and feed safety risks and advising government on managing these risks. This includes a new responsibility for assessing 'regulated products' such as novel foods, feed additives and genetically modified organisms (GMOs) for food and feed uses, which was previously carried out by EFSA and the European Commission. Outside the EU, FSA manages the authorisation process and makes recommendations to health ministers in England, Wales and Northern Ireland on authorisations;

3 In Scotland, Food Standards Scotland has taken on similar new responsibilities.

- **food safety border controls and trade**

  FSA has additional responsibilities for implementing changes to the UK's food safety-related border controls. This includes, for example, carrying out its own data analysis to determine what levels of checks are needed on imported foods; working with Defra to put in place pre-notification of imported high-risk food and feed from the EU, building its understanding of food safety risks; and supporting the work of the UK Office for Sanitary and Phytosanitary Trade Assurance by providing food and feed safety advice on new market access to import food and feed. Its role has also included working with official laboratories to ensure sufficient capacity and capability for increased sampling of food imports from the EU;

- **food incidents and ensuring food safety**

  FSA is responsible for managing food and feed safety incidents and carries out risk monitoring work to identify potential issues early on. Outside the EU, FSA has had to find alternative and additional sources of data on food and feed safety incidents worldwide. FSA is responsible for administering official controls for food producers which require official veterinarians and meat hygiene inspectors to be on-site – while this work has not changed following EU Exit, it has had an impact on available staffing; and

- **the National Food Crime Unit (NFCU)**

  FSA's National Food Crime Unit (NFCU) was set up in 2015 with the aim of protecting consumers and the food industry from food crime within food supply chains. In the context of EU Exit, FSA is building its capacity and is seeking additional investigative powers to strengthen its capability.

Figure 1

Division of policy responsibilities for food regulation across the United Kingdom in 2022

Policy responsibility for food regulation varies across the UK. Responsibilities in England are split between the Food Standards Agency (FSA), the Department for Environment, Food & Rural Affairs (Defra) and the Department of Health & Social Care (DHSC)

Policy area	Policy scope	Policy responsibility			
		England	Wales	Scotland	Northern Ireland
Food and feed safety and hygiene	Covers food and feed production, including: ● risk analysis; ● food safety labelling; ● hygienic handling, production, storage and distribution of food; ● incident handling; and ● food and feed law enforcement (official controls)	FSA	FSA	Food Standards Scotland (FSS)	FSA Under the Northern Ireland Protocol, EU regulations continue to apply in Northern Ireland
Food compositional standards and labelling	Encompasses policies, regulations and enforcement relating to: ● food information to consumers; ● standards relating to specific products such as natural mineral waters, chocolate, honey and fruit juice; and ● lot marking	Defra	FSA		
Nutritional labelling, composition and standards	Includes policies and regulations relating to: ● nutrition and health claims made on foods; ● addition of vitamins and minerals to foods; ● composition and labelling of foods for specific groups, such as infants; and ● nutrition declaration on food labelling	DHSC	Welsh government		

Source: National Audit Office analysis of government documentation

Preparations for Day 1

2.4 Because of the ongoing uncertainty regarding the future relationship with the EU, FSA focused on implementing a 'minimum viable product' for a no-deal scenario and reported that this programme of work was substantially complete in time for the earlier planned EU Exit date of 29 March 2019. By the end of the transition period, key EU Exit preparations included:

- **risk assessment and management:** A new risk analysis process (developed in collaboration with FSS) went live on 1 January 2021. This separated FSA's science-led risk assessment and policy-led risk management functions and established how the four nations of the UK would work together, including how FSA would work with FSS. By the end of the transition period, FSA had a working online tool to enable businesses to make regulated product applications and had established a means of keeping track of these applications;
- **food incidents:** FSA put in place new processes to handle food-related incidents across the UK. To mitigate the loss of full access to EU systems, it developed new surveillance tools to identify emerging food safety risks. An initial off-the-shelf system for incident management that was in place by 2019, was replaced by a bespoke system in preparation for 1 January 2021; and
- **import and trade surveillance:** FSA developed a surveillance tool to identify and monitor risks from imported products. It collates and shares data with local authorities and port health authorities, helping to inform imported food controls and sampling. The service continues to evolve and has been in place since before the end of the transition period.

2.5 At the end of the transition period, FSA judged that in the short term, it had met its objective that there should be no material worsening of its ability to deliver consumer protection, as measured by the number of food incidents recorded before and after the end of the transition period. FSA identified, however, areas where further work was needed.

- **Imports:** Ensuring the introduction of pre-notification of imported high-risk food and feed, which the government had delayed several times, and which was finally introduced on 1 January 2022. Full import controls from the EU have also been delayed several times. Until recently, they were due to be implemented in 2022 and are now planned to come into force from the end of 2023.
- **Official laboratories:** Supporting laboratories in Great Britain and Northern Ireland to ensure sufficient capacity and capability. This included working to ensure Northern Ireland had sufficient laboratory capacity and laboratories in Great Britain had the capacity to manage increases in samples taken of food imports from the EU.

Building operational capability

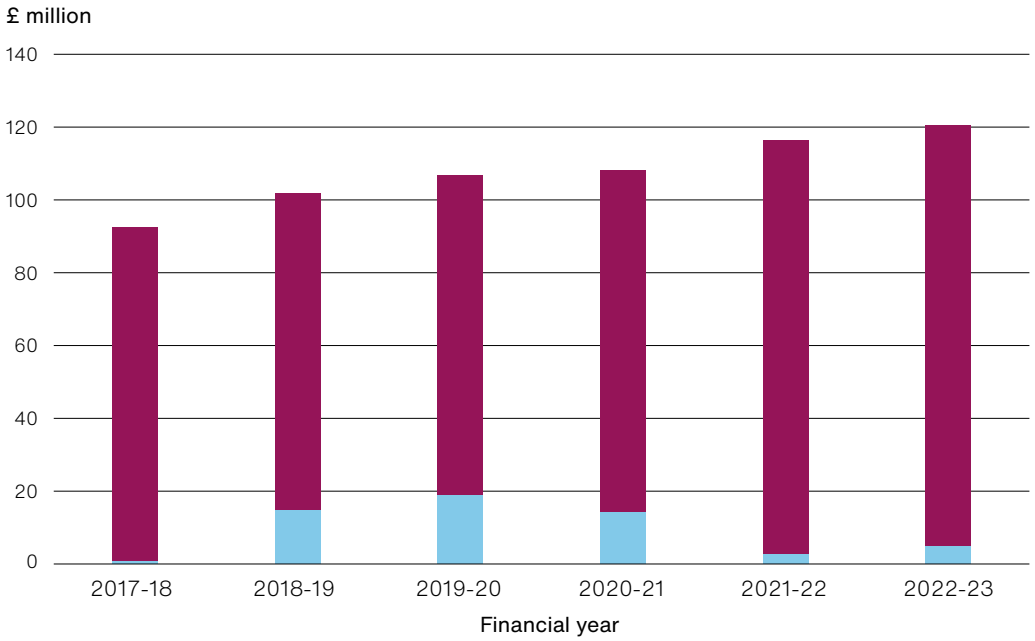
Capacity and capability

2.6 FSA has received additional funding in preparation for the UK leaving the EU. Between 2017-18 and 2021-22 it was allocated ring-fenced funding to support its EU Exit planning (**Figure 2** overleaf). It used this for a range of purposes – for example, in 2020-21 it used part of its allocation of £14.5 million (in 2021-22 prices) to recruit more than 100 new staff and provide grants to local authorities and port health authorities to support their preparations for the end of the transition period.

Figure 2

The Food Standards Agency's (FSA's) annual budget between 2017-18 and 2022-23

FSA was allocated ring-fenced funding to support its EU Exit planning between 2017-18 and 2021-22 and its business-as-usual budget has been increased in response to its additional responsibilities after EU Exit



	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23
Business-as-usual budget (£m)	91.6	86.9	87.6	93.8	113.5	115.4
EU Exit budget (£m)	1.0	14.9	19.2	14.5	3.0	5.1
Total budget (£m)	**92.6**	**101.8**	**106.9**	**108.3**	**116.5**	**120.5**

Notes

1 Figures refer to FSA's Westminster budget, and do not include funding for FSA Wales, FSA Northern Ireland or Food Standards Scotland.

2 The budgets include resource departmental expenditure limits (RDEL), capital departmental expenditure limits (CDEL) and exclude depreciation.

3 FSA's EU Exit funding of £14.5 million in 2020-21 was incorporated into its business-as-usual budget for subsequent years but was not ring-fenced. The additional EU Exit funding in 2021-22 was ring-fenced, while the funding in 2022-23 was not.

4 Figures may not sum due to rounding.

5 Figures are stated in 2021-22 prices.

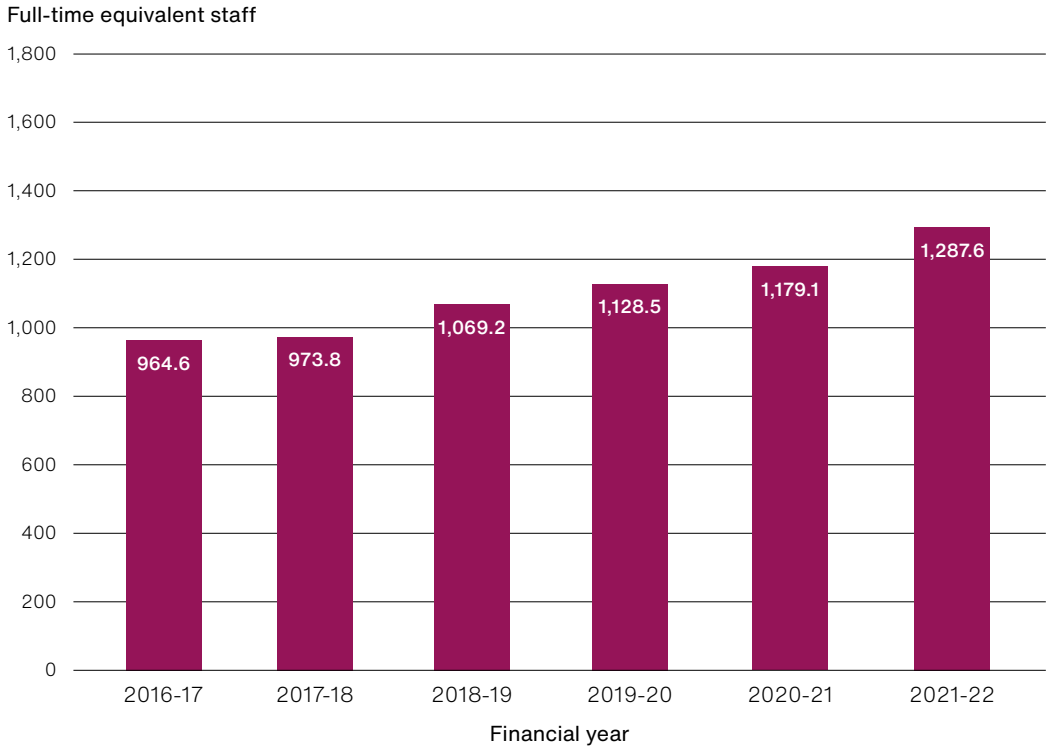
Source: National Audit Office analysis of Food Standards Agency data

2.7 In the light of EU Exit, FSA is taking steps to build its operational capacity and capability in a number of areas not only where it has taken on new roles but also where its existing workload has increased or changed. It has expanded from around 965 full-time equivalent (FTE) staff in 2016-17 to around 1,288 in 2021-22 (**Figure 3**). Between March 2022 and March 2025, FSA has forecast further growth of 84 FTE for what it has identified as EU Exit roles, including additional staff to fulfil its risk analysis responsibilities for regulated products and UK imports and to increase its capacity in its imports and exports team. It is also looking at new working models for roles such as official veterinarians and meat hygiene inspectors, who deliver official on-site controls with food producers, where access to skills has been affected by EU Exit.

Figure 3

The Food Standards Agency's (FSA's) staffing levels between 2016-17 and 2021-22

FSA has grown by 323 full-time equivalent (FTE) staff since 2016-17



Note

1 Figure relates to the number of FSA staff in England and does not include staff in Wales or Northern Ireland. It also does not include staff in Food Standards Scotland.

Source: National Audit Office analysis of Food Standards Agency staffing data

Risk analysis

2.8 To fulfil its new risk analysis responsibilities, FSA has expanded its Science, Evidence and Research Division from around 59 FTE posts in July 2018 to around 128 FTE in January 2022, a 115% increase. Within this division, the Risk Assessment Unit has grown significantly from around 10 FTE in March 2018, to around 61 in February 2022. It continues to recruit and expects to have reached 90 FTE by October 2022. FSA told us it has been challenging to recruit appropriately skilled toxicologists, and that it has had to deliver more training as a result.

Regulated products authorisations

2.9 FSA has received significantly more applications for regulated product authorisations than planned for. Its planning assumption was that it would receive around 150 applications per year (half of EFSA's applications for new regulated products). However, by the end of 2021, its first year, it had received 1,392 contacts and was progressing 428 applications. This increase is partly due to the growth in the UK's market for cannabidiol (CBD) products and requirements for CBD food products already on the market to go through the regulated products authorisation process.

2.10 In response to the unexpected volume and complexity of this work, FSA re-prioritised its workload and temporarily stopped some policy work to divert resources to work on regulated products. It is concerned that this will not be sustainable in the longer term and that delays to product authorisations could inhibit industry innovation. Agricultural industry representatives told us they have concerns over the time it is taking FSA to approve applications for GMO food and feed products that have already been authorised in the EU. FSA is tracking product authorisations individually and can identify whether it is meeting statutory deadlines on a case-by-case basis, but currently does not collate or report information on how long applications spend at each stage in the system. This includes the validation stage where FSA can 'stop the clock' on statutory deadlines if awaiting information. It is still developing performance measures it intends to track in the future.

2.11 FSA expects the number of CBD applications to remain high and is also expecting a considerable increase in work relating to GMO and genome-edited products due to a proposed change in definitions. In response it is investing in improving its IT system and recruiting a further 21 staff to build its risk assessment capacity. It is also currently looking for opportunities to simplify and streamline the legislative requirements set out in retained EU law.

Trade and import

2.12 FSA has established a new team to undertake imported food and feed public health risk assessments on behalf of the UK Office for Sanitary and Phytosanitary Trade Assurance (the UK Office).[4] FSA is responsible for providing food and feed safety advice to the UK Office when the latter is considering applications for new market access to import food and feed. FSA will also advise on proposed amendments to controls on imported food and feed. In the first year after transition, the UK Office has received more than 30 market access requests, which was a higher volume of requests than FSA had expected. FSA told us that it has the capacity to complete five complex import risk assessments per year, and in 2021 six had been identified as requiring substantial input from FSA. Although it will not take the lead on assessing the other market access requests, FSA told us it still expects to provide public health risk assessment and risk management advice for the majority of the market access requests that the UK Office receives.

2.13 FSA is now responsible for ensuring that an appropriate level of controls on imported foods are in place.[5] In preparation, FSA increased its support to local authorities and port health authorities, delivering additional training on imported food safety, surveillance sampling of imported food and developing new data and systems. FSA will need to manage the increase in controls on EU goods planned from the end of 2023, and any divergence in controls and policy between the EU and the UK. FSA will need to use the increased levels of data and intelligence produced by port health authorities and local authorities effectively to update its food safety border controls in response to changes in food safety risks. To ensure it has the capacity to deliver this work, it has recruited two additional staff in 2022 and plans to add up to three more FTE to its Imports Delivery Team over the next three years.

National Food Crime Unit (NFCU)

2.14 In 2019 we reported that NFCU had received additional resources to tackle food fraud but lacked the investigative powers it needed to operate independently without police support.[6] FSA is still seeking these powers, and provisions have been made in the Police, Crime, Sentencing and Courts Act, to allow for these powers to be conferred via secondary legislation in the future. FSA told us it hopes to seek ministerial consent for these additional powers following a public consultation planned for this spring. NFCU has received specific funding to strengthen its capacity and investigative capability post-EU Exit, to protect the reputation and integrity of the UK's food system, and has grown to 76 FTEs this year.

4 The UK Office for Sanitary and Phytosanitary Trade Assurance was set up in Defra in January 2021. It was established to oversee market access for imports of animals and animal products to the UK. This includes managing requests for new market access, coordinating safeguarding measures, and reviewing import restrictions.
5 In Scotland FSS has taken on similar responsibilities.
6 Comptroller and Auditor General, *Ensuring food safety and standards*, HC 2217, June 2019

Official controls

2.15 FSA has ongoing challenges with a shortage of veterinarians to deliver its official controls work. It considers these challenges have been exacerbated by a previous reliance on EU veterinarians who were eligible for mutual recognition of professional qualifications before EU Exit. FSA has found that the professional registration requirements for overseas vets, particularly English language requirements, that now also apply to vets who are recruited from the EU, are challenging to achieve for vets not currently working in the UK. The demand on veterinarians who can certify exports has also increased now this is a requirement to export to the EU. In response to short-term pressures in 2021 FSA told us it moved qualified staff from back-office roles to provide statutory services. FSA plans to bring a significant number of official veterinarian posts in-house, around 25% in the next year, and with ambitions to extend this to up to 50% in future. It is also looking at broader changes to how official veterinarian and meat hygiene inspector roles work.

Cooperation and data sharing with the European Union

2.16 At the end of the transition period, FSA lost access to EU networks and data-sharing systems. These included: the Trade Control and Expert System (TRACES), which provides information on imports; parts of the Rapid Alert System for Food and Feed (RASFF), which provides information on food safety incidents and their management; and the Alert and Cooperation Network, which allows for exchanges of intelligence and requests for assistance on food fraud issues between EU member states.

2.17 FSA has put in place alternative mechanisms for identifying and escalating risks and for sharing data and information including, for example, a system for monitoring open-source data for potential risks to food safety and standards in the UK. These alternative mechanisms operate differently from the previous systems, and in some instances may be more resource-intensive to implement. FSA's initial estimate indicates it requires around 65% more FTE resource to deliver the same international information exchange on food safety incidents now than it did using RASFF. FSA told us that it has access to data in the UK's replacement to TRACES (known as IPAFFS) and agreed a data-sharing arrangement in December 2021 with HM Revenue & Customs to use customs data to increase its intelligence on imports from the EU of high-risk food and feed. In time, it expects these new data sources to enhance its ability to identify food safety risks, but it is at an early stage in embedding their use. The NFCU told us that now the EU is no longer required to share intelligence with the UK, there is a risk that it may have less information about food fraud risks, but that this is mitigated to some extent by the alternative mechanisms FSA has put in place.

Longer-term strategic development

2.18 Plans for a longer-term strategy for the UK's food regulation system outside the EU are still being developed. In March 2022 FSA published a new five-year strategy running from 2022 to 2027 covering its roles in England, Wales and Northern Ireland. This set out FSA's intention to work with other parts of government to deliver reform in line with the government's January 2022 *Benefits of Brexit* policy paper. The policy paper identified the opportunity to review the UK's novel foods regulatory framework, including FSA's process for approving novel foods, to support innovation. No further detail on how or when regulation may change in practice has yet been made public. FSA has also contributed to the Cabinet Office's review of retained EU law. Industry stakeholders told us that they would like to know more about FSA's future strategy to enable them to plan effectively, including, for example, how and if FSA plans to diverge from EU approaches in key areas including risk assessment and the approval of regulated products.

2.19 Food safety is a devolved competence and there is scope for the regulatory approaches of the four nations of the UK to diverge. FSA is party to three common frameworks: the Food and Feed Safety and Hygiene Framework led by FSA, the Nutrition-related Labelling, Composition and Standards Framework and the Food Compositional Standards and Labelling Framework. A Memorandum of Understanding between FSA and FSS was updated in 2020 to reflect new ways of working following EU Exit. FSS told us that it had good working relationships with FSA and development of the common frameworks had been a collaborative process, although any issues of divergence and subsequent dispute resolution mechanisms have not yet been tested.

2.20 The Northern Ireland Protocol (the Protocol) has had significant implications for the work of FSA. Food and feed placed on the Northern Ireland market must adhere to EU rules. FSA in Northern Ireland is the authority responsible for fulfilling obligations outlined in these regulations. FSA told us that its engagement with the EU on regulations applicable to Northern Ireland has been limited and that it has put in place new processes to monitor EU regulatory changes because of the limited notice it has received direct from the EU. It also told us that its capacity to communicate regulatory changes to enforcement partners and industry across the UK was initially stretched, but it now has systems in place. FSA has provided guidance and financial support to enforcement partners responsible for ensuring public health checks on food and feed moving from Great Britain to Northern Ireland. FSA has put in place arrangements with the EU to manage food incidents in Northern Ireland and regular reviews have been agreed with the EU so that improvements can be sought if needed. Negotiations are ongoing between the UK and the EU on the future operation of the Protocol, which could have implications for the delivery of FSA's work. FSA is providing technical input into the development of agri-food proposals.

2.21 FSA currently has limited engagement with EU institutions such as EFSA. In the long term, FSA considers that an agreement with EFSA could facilitate scientific cooperation, but this is not actively being discussed between the EU and UK. At the end of 2021, the UK was asked to leave the Heads of Food Safety Agencies (a group of European food safety management bodies that meet to encourage mutual cooperation and share good practice). In its formal request for the UK to leave, the group stated that it felt that UK membership was no longer appropriate given the focus of the group on EU food policy and the enforcement of EU food law. The UK left the group with effect from February 2022. FSA had previously been involved in many of the working groups, including as co-chair of the working group on food fraud.

2.22 FSA is developing a new international strategic plan, and it continues to engage with international fora for food and feed safety. FSA told us that before EU Exit it exerted international influence primarily through the EU, even where it took part as an individual organisation. In November 2021, FSA's Director of Global Affairs was elected chairperson of the Codex Alimentarius Commission, the international food standards-setting body. The UK has also taken on co-chair of the Codex working group on food fraud. FSA has also increased its involvement with the International Food Safety Authorities Network (INFOSAN), obtaining a seat on its advisory group and funding a secondment to the network.[7] Its aim is to work in partnership with INFOSAN and its members to establish best practice in food incident and crisis management processes. In March 2022, FSA established a new International and UK Affairs Directorate to take forward its international strategy, work on trade and the UK internal market.

7 The International Food Safety Authorities Network (INFOSAN) is a global voluntary network of national authorities with a role in food safety, coordinated by a joint Food and Agricultural Organization of the United Nations (FAO) and World Health Organization (WHO) secretariat.

Part Three

The Competition and Markets Authority (CMA)

3.1 Having an effective regulatory regime for competition and markets is important to protect consumers, to build the economy by providing a fair environment for businesses to operate in, and to encourage trust and investment in the UK economy.

3.2 CMA is a non-ministerial department with responsibility for promoting competition for the benefit of consumers, both within and outside the UK. It operates across the United Kingdom, and works closely with the Department for Business, Energy & Industrial Strategy (BEIS), which is responsible for the general framework of consumer protection and has overall policy responsibility for competition and subsidy control.

3.3 Before European Union (EU) Exit, CMA was responsible for enforcing competition law in cases which exclusively or predominantly affected the UK market, while the European Commission (EC) carried out competition investigations and mergers controls in cases with an EU-wide significance or which affected several member states. With the UK's departure from the EU, CMA has acquired jurisdiction over all competition investigations affecting the UK market, including the largest mergers.

3.4 CMA also investigates consumer protection issues that have market-wide impacts and enforces consumer protection legislation. As a member state of the EU, the UK's legal framework for consumer protection was based on EU regulations and directives designed to protect EU consumers and facilitate the single market. The UK was also party to the Consumer Protection Cooperation Regulation, which facilitates cross-border data sharing and consumer protection enforcement.

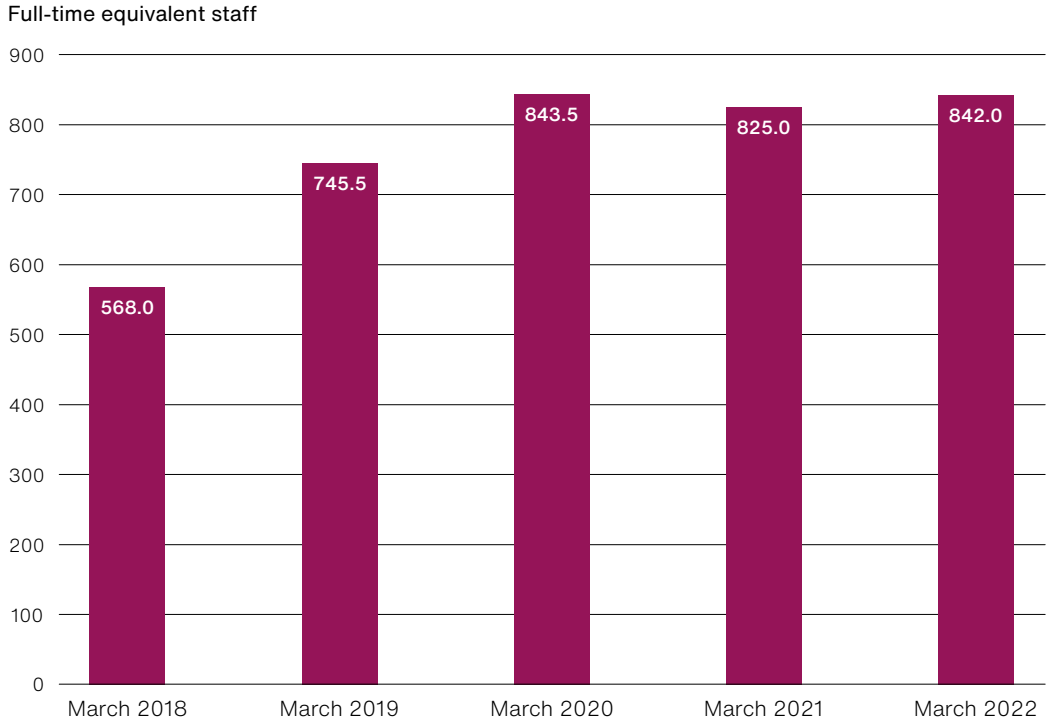
Preparations for Day 1

3.5 Outside the EU, CMA will investigate larger and more complex competition and merger cases, including large international competition law cases with a UK impact. CMA estimated that EU Exit would also increase the volume of its merger work by between 30 and 50 cases per year (approximately a 50% to 90% increase on its pre-EU Exit merger volumes). To build its capacity and prepare for EU Exit CMA was granted additional funds of £25.2 million for 2018-19 and £20.9 million in 2019-20 in 2021-22 prices (Figure 6). Since March 2018, it has built its capacity rapidly, growing by 48% by March 2022 from 568 to 842 staff (full-time equivalent, FTE) (**Figure 4**).

Figure 4

The Competition and Markets Authority's (CMA's) staffing levels between March 2018 and March 2022

CMA has grown by more than 270 full-time equivalent (FTE) staff since March 2018



Note

1 Figures do not include agency staff.

Source: National Audit Office analysis of Competition and Markets Authority staffing data

New functions

3.6 CMA has also taken on new functions following EU Exit, although there was uncertainty for some time as to what these would be, their timing and exact form (**Figure 5** overleaf).

- **State aid and subsidy advice.** In 2018-19 and 2019-20, CMA was awarded additional funding as part of its EU Exit settlement to develop a state aid function. However, preparations for this function were paused in 2020 as government changed its plans for delivering a state aid regime, and staff recruited for the work either left CMA or moved into other roles. In February 2021, the government consulted on a new subsidy regime, including the role of the independent body required by the Trade and Cooperation Agreement with the EU. It suggested CMA as one of a range of options for housing this independent unit. The unit would be responsible for providing advice to public authorities granting subsidies and reporting to government on the functioning of the subsidy control regime. This role is more limited than what the CMA was planning for in 2018-20, which also included enforcement powers. The Subsidy Control Act, which gives CMA this new responsibility, passed into law on 28 April 2022. The CMA has started recruiting staff for the new Subsidy Advice Unit and expects to be operational in autumn 2022.

- **The UK internal market.** The UK Internal Market Act 2020 created a new Office for the Internal Market within CMA to carry out independent advisory, monitoring and reporting functions to support the development and effective operation of the UK internal market. The Office for the Internal Market was launched in September 2021. BEIS announced the appointment of its chair in April 2022 and is leading the process to appoint its panel.

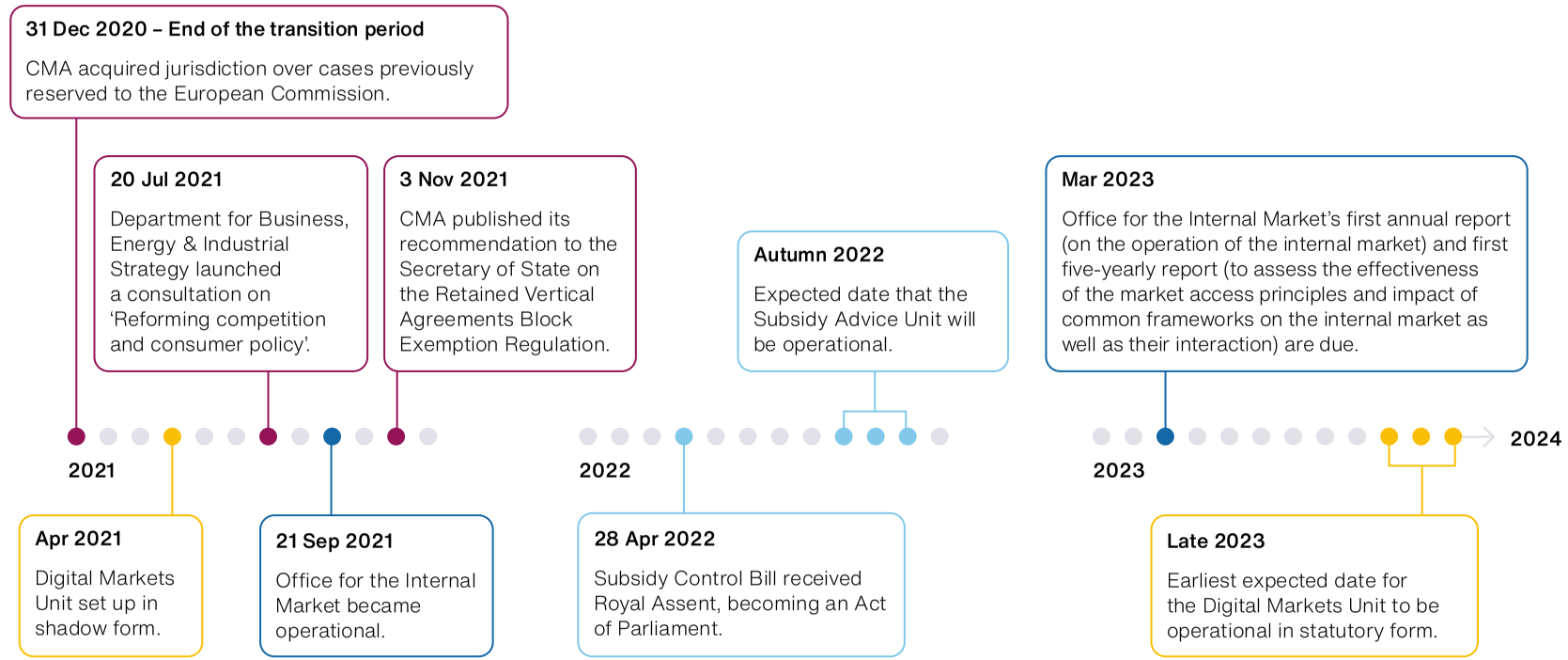
3.7 These functions are different from CMA's current roles to investigate and enforce regulations set by government. While these new functions will draw on CMA's existing legal and economic expertise, stakeholders have expressed concerns that it may be more challenging for CMA to maintain its independence from government when providing advice to it. CMA has also set up a Digital Markets Unit (DMU) to oversee a new regulatory regime for the most powerful digital firms, to promote greater competition and protect consumers.[8] While this is not a direct result of EU Exit, CMA considers that it could not have set up the DMU in its planned form while the UK was in the EU.

8 The Digital Markets Unit was set up in shadow form in April 2021 in anticipation of CMA taking on powers to implement and enforce the new pro-competition regime for digital markets. The government intends to bring legislation to Parliament to provide CMA with these powers but no timetable has yet been set.

Figure 5

Timeline of the Competition and Markets Authority's (CMA's) key EU Exit activities and introduction of new functions

The Subsidy Advice Unit and Digital Markets Unit are not yet operational



- Key dates relating to competition and consumer protection policy
- Key dates relating to the Subsidy Advice Unit
- Key dates relating to the Office for the Internal Market
- Key dates relating to the Digital Markets Unit

Notes

1 The date for the Digital Markets Unit to become operational depends on the passage of legislation.

2 The vertical agreement block exemption is an exemption from competition prohibitions under certain conditions for sales or distribution agreements between businesses operating at different levels of the supply chain, for example wholesalers and retailers.

Source: National Audit Office analysis of Competition and Markets Authority documentation

Transitional arrangements

3.8 CMA's main challenge in ensuring continuity for Day 1 was to identify and plan how European Commission-led cases affecting UK consumers that were under way at the end of the transition period would be taken forward. It worked with the Commission to ensure that there was a plan for all cases.

- On mergers, a cut-off was applied based on whether a formal notification of a case opening had occurred by the end of 2020. Since 1 January 2021, CMA has opened 19 'additional' merger cases (in parallel with EC proceedings) where the relevant markets or customers are UK-based.
- On other areas of competition enforcement, at the end of the transition period there were 17 ongoing EU cases with relevance to UK markets. CMA assessed the significance of the UK aspects of each case against its priorities to decide what action, if any, it wished to take.
- On consumer protection, 10 cross-border cases facilitated by the Consumer Protection Cooperation (CPC) regulation were under way when the transition period ended. In four cases, CMA sought and obtained agreement from the EC to retain information relating to them after the end of the transition period.

Building operational capability

Capacity and capability

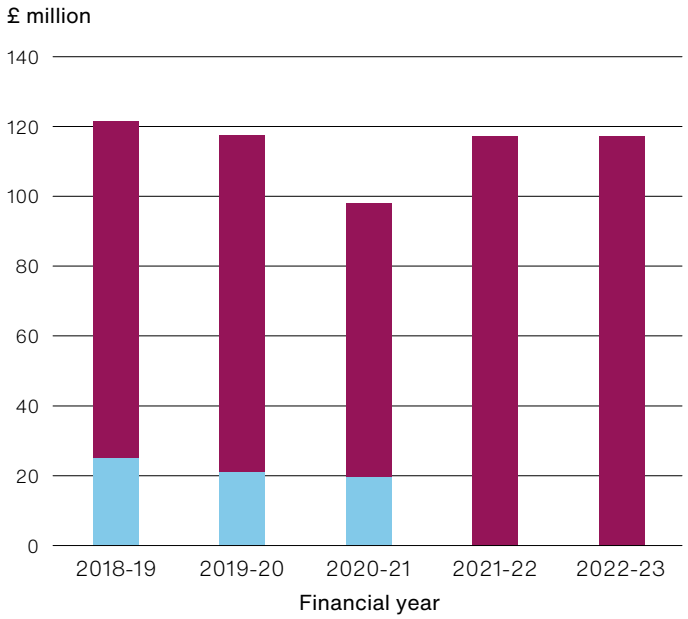
3.9 CMA has used its previous additional EU Exit funding as an indicator for future resource needs to support its new responsibilities and workload after EU Exit (**Figure 6** overleaf). It is expecting to add 37 roles to the Subsidy Advice Unit in 2022-23 as it becomes operational and is also building its capability to tackle digital issues through the new Digital Markets Unit. CMA has been broadly successful in securing the resources it asked for up to 2024-25 and is confident that the additional resourcing it plans to bring in, in particular for the Digital Markets Unit, will allow it to meet its expected workload.

3.10 CMA's work requires specialist skills, in particular legal and economics skills, and increasingly a need for experience of complex, multi-national business operations and digital skills. CMA considers it has long-standing difficulties in competing with the private sector when recruiting and retaining sufficient staff of the required quality, in particular for its competition and mergers work. Vacancy rates vary across CMA and by grade but are high in a number of key areas. As at the end of March 2022, CMA had 51 vacancies in its legal services profession (25% of total posts), and 28 in its economics profession (21% of total posts) (**Figure 7** on page 35). In its mergers and competition work, CMA has experienced particular challenges in recruiting at more senior grades.

Figure 6

The Competition and Markets Authority's (CMA's) annual budget between 2018-19 and 2022-23

CMA was allocated ring-fenced funding to support its EU Exit planning in 2018-19, 2019-20 and 2020-21 and its business-as-usual budget has been increased in response to its additional responsibilities after EU Exit



	2018-19	2019-20	2020-21	2021-22	2022-23
Business-as-usual budget (£m)	96.4	96.5	78.3	117.1	117.3
EU Exit budget (£m)	25.2	20.9	19.7		
Total budget (£m)	**121.6**	**117.4**	**98.0**	**117.1**	**117.3**

Notes

1 No funding was ring-fenced for EU Exit-related work in CMA's 2021-22 or 2022-23 settlements, however, budget allocations reflected the need to provide resources for CMA's new responsibilities at similar levels to its preparations for EU Exit.

2 The budgets include resource departmental expenditure limits (RDEL), capital departmental expenditure limits (CDEL) and exclude depreciation.

3 CMA received additional capital (CDEL) budget in 2018-19 and 2019-20 to relocate its London premises from Holborn to Canary Wharf. This is included in the business-as-usual budget above.

4 Figures are stated in 2021-22 prices.

Source: National Audit Office analysis of Competition and Markets Authority data

Figure 7

The Competition and Markets Authority's (CMA's) vacancies in March 2022

In March 2022, a quarter of legal services roles (25%) were vacant

Notes

1 Vacancies as at the end of March 2022.

2 Filled posts include roles at pre-employment stage.

3 Corporate services includes administrative support across the business.

Source: National Audit Office analysis of Competition and Markets Authority staffing data

3.11 CMA is using pay flexibility and the high-profile nature of its work to try to mitigate problems in recruiting and retaining staff. CMA considers that there are significant disparities between the pay CMA can offer and rates in the private sector, particularly for in-demand legal skills. For the past five years, CMA has been involved in HM Treasury's pay bill control pilot scheme, which provides some flexibility to pay more than is generally allowed under public sector terms. This has helped the CMA by increasing the minimum salaries it can offer, but CMA considers it has only partially mitigated the issue. CMA also uses the potential significance, diversity and scale of its work as a means to attract and recruit staff. In past years CMA has recruited staff with specialist economics skills from the European Commission. CMA considers that it may be harder to do so in future, but that it may be able to attract recruits from other international competition agencies.

Future workload

3.12 Following EU Exit, there is a risk that the increased scale and complexity of CMA's merger and competition work may put pressure on CMA's capacity and limit what enforcement action it can take in other areas, including consumer protection. The UK mergers control regime involves statutory deadlines that CMA and merging parties must meet. There are also legal deadlines to meet on appeals against its competition decisions, regulatory and market investigations. CMA has no control on how many of these cases it will work on, or when they occur. It has greater discretion over its competition and consumer enforcement work and can therefore deprioritise it if there are pressures elsewhere. CMA is aware of these risks and the challenges of balancing its work programme. Since 2021, it has increased its reporting to its board on progress against its annual plan to enable the board to assess the overall balance of work and provide a strategic steer on case selection.

3.13 The economic impact of the COVID-19 pandemic means CMA has no reliable baseline for merger activity post-EU Exit. In the previous five years to 2019-20, CMA had opened around 60 initial assessment cases annually. In 2020-21, the number fell to 38. The number of full investigations following on from these initial assessments was less affected by the pandemic and, at 10 investigations, was in line with the number of cases in the previous five years. The number of merger cases has started to increase again – in 2021-22 CMA carried out 55 initial assessments and eight full investigations.

3.14 CMA anticipated that each year around 30–50 additional cases previously reserved to the EC would require investigation by CMA. In the first 12 months after the end of the transition period, it had opened 19 initial assessment merger cases that would have been reserved to the EC prior to EU Exit. In planning this work, CMA is considering the timing of its actions, as aligning timelines with other jurisdictions including the EU, can minimise the disruption and cost to merging parties.

Data sharing and cooperation with the European Union

3.15 Outside the EU, CMA no longer has access to EU data-sharing and cooperation networks, which it considers may constrain its capability in competition enforcement and consumer protection where cases involve the EU. CMA is no longer part of the European Competition Network, which provides for investigative assistance and sharing of confidential information on competition investigations. Outside this mechanism, CMA has pursued confidentiality waivers from businesses and third parties to enable sharing of information across competition regulators if and when this is appropriate. CMA is confident that on its merger cases most parties will agree to such waivers as they have commercial incentives to provide CMA with information for its review or investigation of the merger. However, there is a risk that parties involved in enforcement activity may be less cooperative. CMA sees the competition agreement provided for in the Trade and Cooperation Agreement with the EU (see paragraph 1.3) as the best route to share information and provide assistance with the EU and member states in the future.

3.16 The UK also no longer has a legal gateway to share confidential data with the EU and member states on consumer protection cases. This means that, for example, a French consumer enforcement agency that is taking forward a case that has affected UK consumers no longer has the legal means to share details of its investigation with CMA. CMA does not yet have a clear solution for how it can gain information on the progress and outcomes of such cases.

Longer-term strategic development

Future competition and consumer protection strategy

3.17 The government has proposed improvements aimed at ensuring a swifter, stronger and more flexible competition and consumer protection regime in the UK. BEIS issued a consultation on reforming competition and consumer policy in July 2021. CMA's response welcomed many of the proposals in the consultation and signalled its readiness to assist in developing the government's proposals for reform. The government's formal response to the results of the consultation was published in April 2022. Alongside wider government policies to increase consumer protections in specific areas, the response sets out plans to adjust merger controls and to enhance CMA's powers in enforcing competition policy and consumer protection. The response emphasises that many of the reforms it sets out will require legislation to implement, and that this will happen as Parliamentary time and priorities allow.

3.18 As part of preparing for EU Exit, the government enacted a new provision to the UK's Competition Act, which from 31 December 2020 allows CMA (and the other UK competition authorities) greater scope to diverge from EU competition law where they consider it appropriate in the light of differences between UK and EU markets.

3.19 CMA's view is that any UK divergence from EU competition law is likely to be at the margins as there is generally international consensus on the core substance of competition law. To date, CMA's main area of differentiation from the EC has been in the changes recommended following its review of vertical agreement block exemption.[9] CMA told us that the broad approach it has adopted so far is to recognise the advantages to business of consistency between the UK and EU while taking the view that such advantages should not outweigh the need to protect UK consumers and the UK economy from harmful anti-competitive practices.

CMA's role in the UK internal market

3.20 Through the Office for the Internal Market, CMA will have a new role in overseeing the operation of the UK market. The role of the Office for the Internal Market is to assist the governments of the four nations of the UK and other key stakeholders in understanding how effectively companies can sell their products and services across the four nations of the UK, and the impact of regulatory provisions on this, including the impact on competition and consumer choice.

3.21 The UK Internal Market Act sets out a requirement for the Office for the Internal Market to report on the operation of the internal market annually. It must also report every five years on any interaction between the operation of the market access principles of mutual recognition and non-discrimination across the four nations of the UK and the common framework agreements. This includes reporting on exclusions from and exemptions to the market access principles. The first of both these annual and five-yearly reports are due by March 2023 and must be laid before the legislatures in each UK nation. In March 2022, CMA published its first official analysis of the UK's internal market ahead of its statutory reports. As at April 2022, the Office for the Internal Market had not yet received any formal requests for advice.

9 The vertical agreement block exemption is an exemption from competition prohibitions under certain conditions for sales or distribution agreements between businesses operating at different levels of the supply chain, for example wholesalers and retailers. There are other block exemptions retained in UK law – for example, those relating to research & development agreements and technology licensing agreements.

International influence

3.22 CMA is working to develop more broad international engagement, both to improve the effectiveness of its operational work and to develop further influence internationally. CMA told us that before EU Exit the European Commission often took the lead, particularly as it handled more multinational cases. CMA continues to work through and contribute to international fora focused on competition and consumer issues such as the International Competition Network and International Consumer Protection and Enforcement Network. CMA has well-established working relationships with the European Commission and with competition authorities in member states, which it is seeking to maintain. It told us that it has also found that collaboration with a smaller number of similar-minded authorities can progress joint approaches effectively and efficiently. In September 2020 CMA signed a Multilateral Mutual Assistance and Cooperation Framework with its counterparts in Australia, Canada, New Zealand and the US with the aim of strengthening cooperation on multi-jurisdictional investigations through information sharing and mutual investigative assistance. In February 2022 the competition authorities in the framework launched a working group looking at collusion in the global supply chain.

Part Four

The Health and Safety Executive's (HSE's) responsibility for chemicals regulation

4.1 Chemicals are important for many aspects of daily life, with uses in agriculture and food production, manufacturing and many products used in homes and gardens. They can also present hazards, and chemicals regulation is essential for ensuring these risks are managed and action is taken to protect the health of people and the environment.

4.2 The Health and Safety Executive's Chemicals Regulation Division (CRD) is responsible for regulating chemicals (including pesticides) to protect the health of people and the environment. HSE is an executive non-departmental public body, sponsored by the Department for Work & Pensions (DWP). In England, policy responsibility for chemicals regulation is primarily split between the Department for Environment, Food & Rural Affairs (Defra) and HSE, while the Welsh and Scottish governments have policy responsibility in matters relating to areas of devolved competence, for example environmental protections.[10,11] Under the Northern Ireland Protocol (the Protocol), European Union (EU) chemicals regulations continue to apply in Northern Ireland. As set out in Appendix Two, this report focuses on regulation in England.

10 The Department for Business, Energy & Industrial Strategy (BEIS) has policy responsibility for some chemicals regulations, such as cosmetics.
11 In practice, chemicals regulation can be complex and may cover both reserved and devolved competencies.

4.3 HSE is the main regulator for chemicals in the UK and has taken on significant new responsibilities as well as increased volumes of work as a result of EU Exit. Its roles have expanded across a number of different regimes by which chemicals are regulated. It is carrying out responsibilities which in the EU are carried out by the European Chemicals Agency, the European Food Safety Authority, and the European Commission, with member states sharing the workload. **Figure 8** overleaf summarises HSE's role in the new regimes in Great Britain. These include:

- implementing UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), which regulates chemicals in Great Britain (GB) to protect human health and the environment;
- implementing a GB-wide plant protection product regulatory regime, which includes authorising pesticides for the GB market; and
- implementing a GB-wide biocides regulatory regime, which regulates the use of biocidal products for the GB market.

Preparations for Day 1

4.4 Defra and HSE prepared for EU Exit in a context of considerable uncertainty. As well as wider uncertainty about the form of EU Exit (Part One), there was specific uncertainty around how chemicals regulation would be affected:

- **Northern Ireland**

  Preparations were initially made with the expectation that the new chemical regulatory regime would be UK-wide. Legislation passed in 2019 to prepare for the UK-wide regime was amended in 2020 to take account of the fact that Northern Ireland would remain part of the EU regulatory regime. HSE had to put in place measures to support the operation of both regulatory regimes.

- **Demand for the new GB regulatory regime**

  Manufacturers and importers of chemicals wishing to access the GB market must comply with the new regulatory regimes. It was not clear until after the end of the transition period, when companies began to register for the GB regimes, what level of demand there would be.

Figure 8

How chemicals regulation operates in Great Britain since 31 December 2020 as a result of EU Exit

The Health and Safety Executive (HSE) has expanded its role and taken on new responsibilities in chemicals regulation, and responsibilities are different for each regulated area

Regulated area	Purpose	Great Britain (GB) regime	Governance
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Regulates chemicals to protect human health and the environment.	HSE implements REACH regulations under a new UK REACH regime. This includes developing regulatory opinions to inform decisions on authorisations and restrictions. These decisions are made on a GB-wide basis by the Department for Environment, Food & Rural Affairs (Defra) Secretary of State with the consent of Welsh and Scottish ministers on matters of devolved competence. The Environment Agency has a statutory role as environmental adviser to HSE on UK REACH, and HSE must seek its advice on relevant environmental issues.	Defra has policy responsibility, except where Welsh and Scottish governments have devolved competence. HSE is the agency for UK REACH. It is responsible for implementation across all three nations and provides support to the Northern Ireland government to fulfil its duties under EU regulations.
Plant Protection Product Regulation (PPPR)	Regulates the use of pesticides including the authorisation of products on the market and maximum residue levels permitted in food and feed.	HSE implements Plant Protection Product Regulation under a new GB regime (GB PPPR). HSE is responsible for exercising regulatory functions and taking regulatory decisions on active substances, maximum residue levels and product authorisations. Decisions are made on a GB-wide basis on behalf of the Defra Secretary of State, Welsh and Scottish ministers (although ministers/devolved administrations have the ability to exercise functions directly if they wish). The Environment Agency provides support on environmental matters where appropriate at the request of HSE.	Defra has policy responsibility, except where Welsh and Scottish governments have devolved competence. HSE is the competent authority responsible for implementation under agency agreements for all three nations, and provides support to the Northern Ireland government to fulfil its duties under EU regulations.
Biocidal Products Regulation (BPR)	Regulates the use of biocidal products, including the authorisation of products for the market.	HSE implements Biocidal Product Regulation (BPR) under a new GB regime (GB BPR). HSE is responsible for providing regulatory opinions on active substances and product authorisations. Decisions are made on a GB-wide basis by the Department for Work & Pensions (DWP) Secretary of State with consent of Welsh and Scottish ministers on matters of devolved competence. The Environment Agency provides support on environmental matters where appropriate at the request of HSE.	HSE has policy responsibility, except where Welsh and Scottish governments have devolved competence. HSE is the competent authority responsible for implementation across all three nations under agency agreements for Scotland and Wales. It also acts as the competent authority in Northern Ireland, delivering the EU biocide regime under an agency agreement with the Northern Ireland government.

Note

1 HSE also has policy responsibility for the Classification, Labelling and Packaging Regulation and Prior Informed Consent Regulation in Great Britain. Decisions on these regulations are made on a GB-wide basis by the DWP Secretary of State with the consent of Welsh and Scottish ministers on matters of devolved competence.

Source: National Audit Office review of publicly available data

Interim operating capability

4.5 HSE and Defra prioritised continuity and a smooth transition for Day 1 and worked towards having an 'interim operating capability' in place, in line with government intentions for there to be no major policy changes at the point of exit.

IT systems

4.6 On leaving the EU, HSE lost access to a number of IT systems, including those used to support REACH and biocide regulations. Defra as policy lead led the development of 'Comply with REACH', a major IT system designed to support the registration of chemicals for the GB market, including submission of safety data. A minimum viable product went live on 1 January 2021 and Defra has continued to develop the system since then. By the end of 2021-22 it had cost £32.3 million. HSE also developed interim IT systems to replace the EU's biocide IT system and databases for the plant protection product and classification, labelling and packaging regimes.

Transitional arrangements

4.7 Arrangements were put in place to support a smooth transition to the new GB regimes to enable companies to comply with the regulations and continue to access the GB market. These included extending deadlines for some regulatory processes.

- **UK REACH**

  GB-based EU REACH registrations were transferred automatically and without a fee into UK REACH to ensure continued access to the GB market. Companies then had to supply initial information to support these registrations by 30 April 2021. As at November 2021, information had been supplied supporting 9,200 registrations.

  In general, GB importers of chemicals from the EU (known as downstream users) are now required to register under UK REACH to continue to access the GB market. They were given until 27 October 2021 to submit a notification to UK REACH, and a further two to six years to deliver their full obligations depending on the volume and hazard profile of the chemicals concerned. As at November 2021, 5,400 downstream user notifications had been made to UK REACH.

  Defra has carried out some initial analysis to assess the number of substances covered by registrations transferred into UK REACH and told us it believes the process to have been broadly successful. It is carrying out further work to review the substances notified by downstream users, to provide a clearer indication of the full range of substances in circulation in Great Britain.

- **Biocides**

  Active substance approvals and UK product authorisations approved under the EU regulations remain valid in the new GB regime. Companies that were part-way through an application to the EU regime were required to re-submit these applications to HSE if they wished to continue accessing the GB market. As at September 2021, 341 applications for active substance approval have been re-submitted to the GB regime (74% of the ongoing applications in the EU regime). HSE told us that although it had not identified any major gaps in coverage that would limit the choice of products on the market, it was continuing to work with industry to assess where loss of an active substance not re-submitted to the GB regime might cause concern. Where issues have been identified, critical use permits have been put in place.

- **Plant protection products**

  Existing active substance approvals, plant protection product authorisations, and maximum residue levels (MRLs) approved under the EU regime remained valid in the new GB regime. Defra has extended the expiry dates for active substances due for renewal before 1 January 2024 by three years, with the earliest new expiry date set for January 2024. As at February 2022, HSE had received 156 applications for renewals of active substances in this group.

- **Guidance to stakeholders**

  Guidance for duty holders on the new regimes was in place for Day 1, with some further work needed, for example, updates to non-critical webpages, amendments to reflect the Protocol and improved accessibility.

Building operational capability

4.8 It will be some years before HSE's new regulatory regimes are fully operational. Many of the regulatory functions it has taken on from the EU were designed to be shared between its member states and supported by the European Chemicals Agency and the European Food Safety Authority. HSE considers that the transition of these regimes to a GB-only model will require a significant increase in its capacity, alongside investment in new systems and processes to move from an initial operating capability to full operating capability.

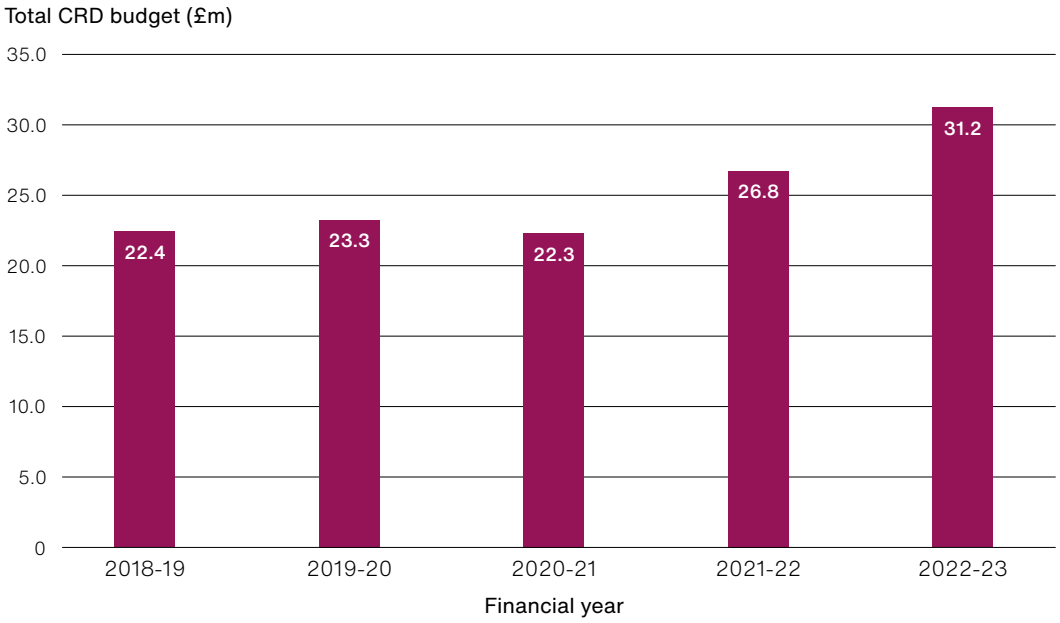
Capacity and capability

4.9 The Chemicals Regulation Division (CRD) total budget has grown by 39% from £22.4 million to £31.2 million between 2018-19 and 2022-23 (in 2021-22 prices) (**Figure 9**). This funding will be from a combination of increased government funding and increased industry fee income from the additional regulatory work it is undertaking.

Figure 9

The Health and Safety Executive's (HSE's) Chemicals Regulation Division (CRD) budgets between 2018-19 and 2022-23

CRD total budget has increased by 39% between 2018-19 and 2022-23 from £22.4 million to £31.2 million (in 2021-22 prices)



Notes

1 CRD is funded through a combination of government funding and industry fees and levies.

2 Figures are in 2021-22 prices.

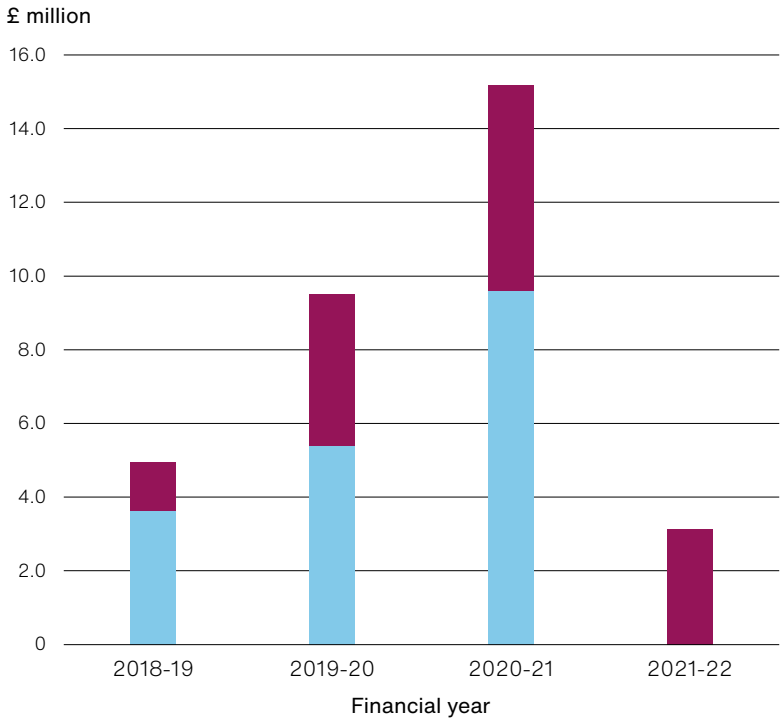
Source: National Audit Office review of Health and Safety Executive funding data

4.10 Between 2018-19 and 2021-22 HSE budgets included £32.8 million in 2021-22 prices for its chemical regulatory regimes for EU Exit (**Figure 10** overleaf). The majority of this funding was allocated to CRD, including a total of £18.6 million of EU Exit funding from Defra for the UK REACH and the Plant Protection Products regimes. The remaining EU Exit funding (£14.1 million) was allocated by DWP for other aspects of the chemical regulatory regimes.

Figure 10

The Health and Safety Executive's (HSE's) chemicals regulation EU Exit budgets for 2018-19 to 2021-22

Between 2018-19 and 2021-22 HSE was allocated a total of £32.8 million of EU Exit funding for its chemical regulatory regimes (in 2021-22 prices)



	2018-19	2019-20	2020-21	2021-22
DWP EU Exit funding (£m)	1.3	4.1	5.6	3.1
EU Exit funding on REACH and PPP (£m)	3.6	5.4	9.6	
Total EU Exit funding (£m)	**5.0**	**9.5**	**15.2**	**3.1**

Notes

1 PPP refers to Plant Protection Product regulations and REACH refers to Registration, Evaluation, Authorisation and Restriction of Chemicals regulations.

2 EU Exit funding for REACH and PPP regulations was allocated by the Department for Environment, Food & Rural Affairs (Defra) as policy lead. The EU Exit funding provided by the Department for Work & Pensions (DWP) is for other aspects of the chemical regulatory regimes.

3 Because of the way EU Exit funding has been allocated, it is not possible to combine this funding with the Chemicals Regulation Division (CRD) budgets. The funding provided for REACH and PPP is included in CRD's total budgets. The EU Exit funding provided by DWP for chemicals regulation was allocated to CRD and other parts of HSE and it is not possible to distinguish what proportion was allocated to CRD.

4 From 2021-22, Defra no longer distinguished between funding for EU Exit and business as usual. Funding for the ongoing delivery of REACH and PPP continued as part of CRD's business-as-usual funding.

5 Figures may not sum due to rounding.

6 Figures in 2021-22 prices.

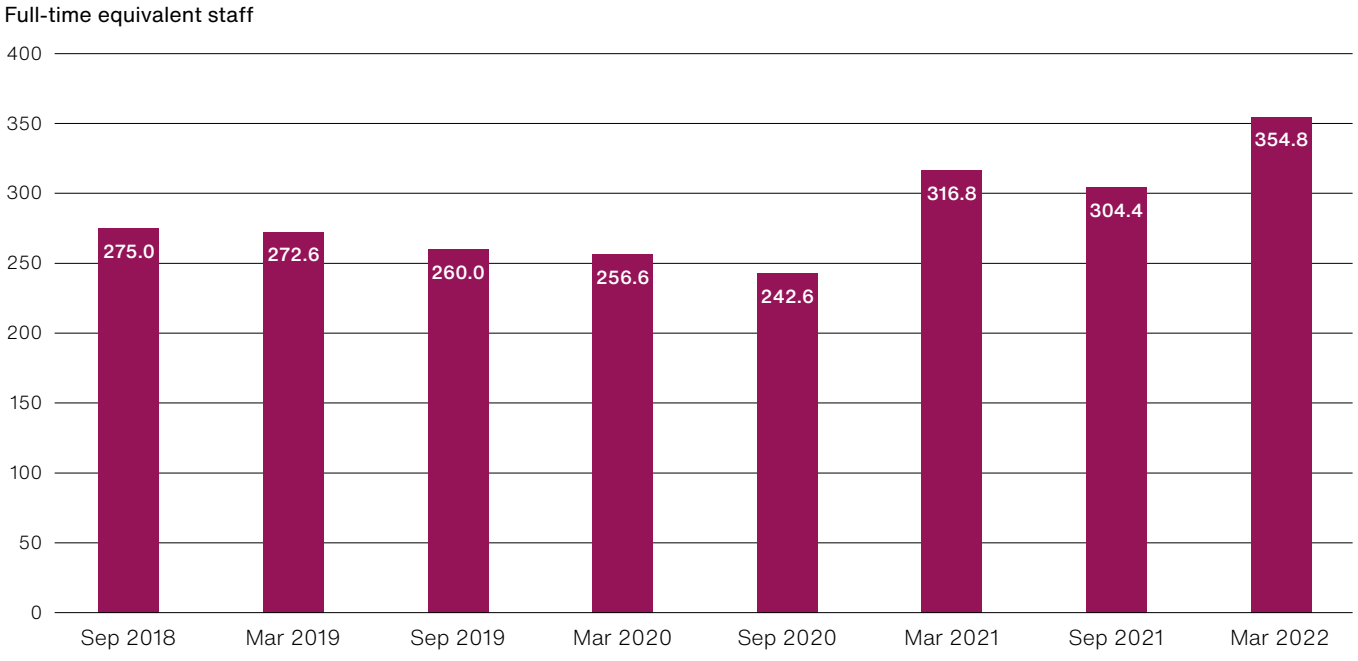
Source: National Audit Office review of Health and Safety Executive funding data

4.11 CRD has grown from around 243 full-time equivalent (FTE) staff in September 2020 to around 355 by March 2022, an increase of 46% (**Figure 11**). It has plans to grow further to 550 FTE by March 2024. The majority of its growth has been post-transition, with the largest intakes in January and October 2021. CRD has largely recruited at graduate entry-level grades, and consequently there is a significant training requirement to build their expertise. 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. In 2021-22, HSE reported that 25% of staff time in CRD was spent on training. HSE told us its capacity to train and support new staff was a limiting factor on the speed at which it could increase its capacity. It had also experienced some challenges in recruiting specialists, including experienced toxicologists. As at February 2022, CRD had 77 vacancies not yet filled. Since April 2018, Defra's chemicals policy teams has also grown from 39.5 to 74.8 FTE staff to reflect its expanded role.

Figure 11

Staffing within the Health and Safety Executive's (HSE's) Chemicals Regulation Division (CRD)

There has been net recruitment of more than 110 full-time equivalent staff in CRD since September 2020



Note

1 Figures represent an average for the month.

Source: National Audit Office review of Health and Safety Executive staffing data

Future workload

4.12 While HSE builds its capacity, Defra and HSE have taken steps to extend regulatory deadlines and pause regulatory activity in a number of areas (**Figure 12**), but keeping pace with demand remains challenging:

- **UK REACH substance evaluations**

  Under REACH, chemicals are evaluated to determine whether their use poses a risk to human health or the environment. HSE is developing risk-based criteria for its substance evaluation programme and no substance evaluations were carried out in 2021-22 while it developed its approach and submitted its draft plans to the Secretary of State for Environment, Food & Rural Affairs, and Welsh and Scottish ministers for comment. In spring 2022, it published its intention to evaluate two substances in 2022. It stated that in its approach it had sought to complement rather than replicate the evaluations carried out by other regulatory regimes including EU REACH, which has four substance evaluations planned for 2022, and a further 23 scheduled for 2023 and 2024. Because its processes are at an early stage of development HSE has not yet set out its plans for 2023 and 2024.

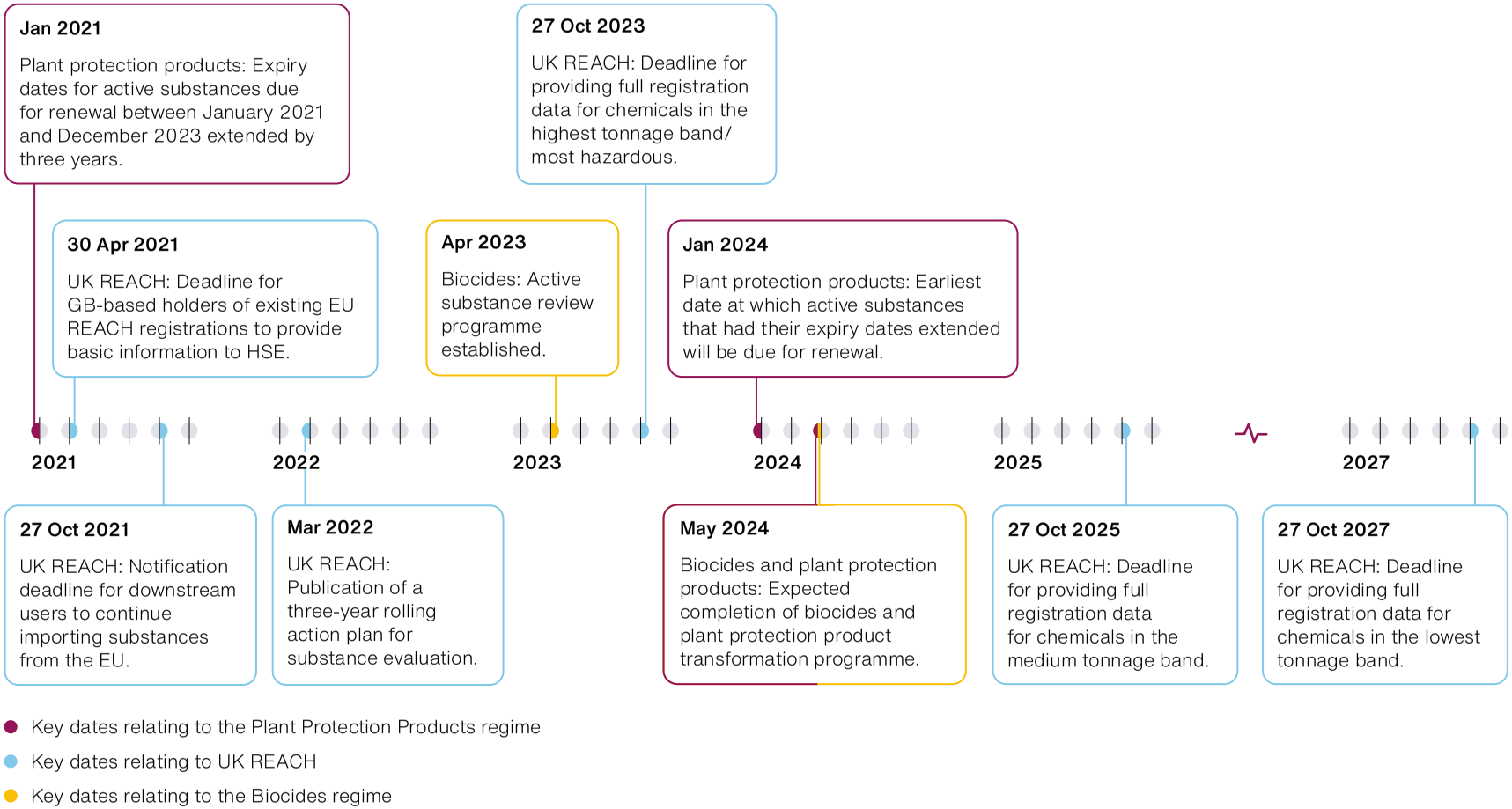
- **Biocidal Products Regulation**

  The EU has been carrying out a rolling review of all biocidal active substances that were on its market in May 2000 to assess their safety. This is a substantial programme of work shared across EU member states, which is expected to complete in 2024. At the end of the transition period, 297 of the 386 ongoing applications under this review were re-submitted to HSE for review under the GB regime. In addition, HSE is responsible for reviewing new active substance applications and renewing permissions for active substances that are due to expire.

  HSE is aware it cannot match the resources of the EU or keep pace with its programme. It is in the process of developing a biocide active substance assessment programme tailored to the GB regime, but this will not be finalised until April 2023. In the meantime, 16 active substances due for renewal in 2021-22 had their approvals extended, with the earliest expiry date now 2023. Due to the transition to the GB regime, HSE has received a large volume of biocidal product approval applications. In 2021-22 it received 414 product applications and it has completed 39 evaluations.

Figure 12
Timeline of chemicals regulation

The Department for Environment, Food & Rural Affairs (Defra) and the Health and Safety Executive (HSE) have taken steps to extend regulatory deadlines and pause regulatory activity in a number of areas



Notes

1 UK REACH refers to UK Registration, Evaluation, Authorisation and Restriction of Chemicals.

2 In December 2021, the government announced it will consult on extending the deadlines (currently set for 2023 onwards) for providing the full registration data for UK REACH under transitional arrangements.

Source: National Audit Office review of Health and Safety Executive documents

- **Plant protection product regulations**

  Under the EU regime, the European Commission is responsible for active substance authorisations used in plant protection products, with support from member states. This role is now the responsibility of HSE, taking decisions on a GB-wide basis on behalf of the Secretary of State for Environment, Food & Rural Affairs, Welsh and Scottish ministers. HSE considers that it does not have the capacity to keep pace with the EU regime. As policy lead, Defra extended the expiry dates of active substances due for renewal around the time of the transition by three years, with the earliest new expiry date set for January 2024. This is to give time for the development of an active substance review programme tailored to the GB regime. In the meantime, the EC continues to evaluate active substances, including not renewing some because of safety concerns. Since the end of the transition period and in the absence of its own review programme, HSE has requested permission from Defra and the Scottish and Welsh governments to initiate six urgent reviews of active substances, five of which were undertaken in response to assessments made by the EU. In addition to the active substance reviews, HSE continues to process plant protection product authorisations. In 2021-22, it completed 76% of these authorisations within the statutory 365-day deadline.

4.13 HSE is planning to develop its biocide and plant protection product regimes and build on the interim operating capability it had in place at the end of the transition period. The transformation programme will include improvements to customer interfaces and new IT systems, as well as redesigns of operational and performance frameworks. HSE considers its interim and legacy systems are resource-intensive and without investment, over time, they increase risks of delays to regulatory decisions, poor customer experience and delays in products getting to market. The programme is expected to cost £19.8 million and take until May 2024 to complete. In the long term, HSE hopes to establish more streamlined authorisation processes by, for example, carrying out active substance evaluations and product authorisations in parallel.

4.14 Industry stakeholders told us they were concerned at the time it will take for HSE to build its capability. For example, a plant protection product industry body raised concerns that the government might further defer active substance renewals beyond the current three-year extension while HSE builds its capability, which would increase regulatory uncertainty in the industry.

Data sharing and co-operation with the European Union

4.15 While the Trade and Cooperation Agreement included broad commitments to facilitate the exchange of non-confidential information on chemicals between the EU and UK, it did not extend to full data-sharing arrangements.

- **EU REACH data**

  HSE no longer has access to the chemical safety data underpinning EU REACH. Companies that have already registered their chemicals under EU REACH are not necessarily able to access the data used for EU REACH to support their UK REACH registrations. The cost of replicating testing data has been estimated at up to £800 million by industry. To address these concerns, Defra extended the deadlines set in the initial transitional provisions for companies to meet the full data requirements to between October 2023 and October 2027.[12] However, industry concerns over the costs remained. In December 2021 Defra announced its intention to explore alternative arrangements for transitional registrations, with a greater focus on risk assessment (in terms of use and exposure) in a GB context. In parallel, while these alternatives are explored, Defra announced plans to consult on further extending the deadlines for full data requirements. These alternative arrangements are likely to require changes to the Comply with REACH IT system, although their nature and extent will depend on what alternative is agreed.

  HSE told us that it draws on a range of data sources in its evaluation of chemical safety and the lack of full registration data in UK REACH will not impact on its ability to evaluate or restrict chemicals of concern on a case-by-case basis.

- **EU biocide risk assessments**

  HSE has lost access to historical risk assessment reports that would support biocidal product authorisation renewals. It is currently exploring a range of options to mitigate this loss.

4.16 The UK government would like to establish a memorandum of understanding with the European Chemicals Agency (ECHA) to take forward cooperation on scientific and technical matters. However, as at March 2022, engagement between HSE and ECHA has been limited to issues related to HSE's role in chemicals regulation in Northern Ireland and implementation of the Protocol.

12 Deadlines for full data submissions vary by hazard profile and volumes, with the most hazardous chemicals in the largest volumes given the shortest deadlines.

Chemicals regulation in Northern Ireland

4.17 Under the Protocol, EU chemicals regulations continue to apply in Northern Ireland. HSE continues to act as the competent authority for biocide regulation under an agency agreement with the Northern Ireland government. It also provides support for the other regimes, including authorising plant protection products. To continue to deliver this role and to enable it to provide guidance to businesses in Northern Ireland as well as Great Britain, it has adapted its processes and systems, and invested in staff to monitor EU regulatory activity. It has also agreed a data-sharing agreement with ECHA to access EU biocide databases to facilitate its continued role as the competent authority in Northern Ireland. As the regulatory regimes diverge over time, HSE expects the administration of the regimes to increase. For example, currently HSE will issue plant protection product authorisations that apply across both Great Britain and Northern Ireland because the regimes are aligned. However, if over time there is divergence in requirements, separate authorisations will be required.

Longer-term strategic development

4.18 The longer-term strategic direction of chemicals regulation is not yet clear. In 2018, the government committed to publishing a Chemicals Strategy to set a strategic direction for regulation after EU Exit. However, Defra, lead department on the strategy, told us that preparing for EU Exit and the impact of the COVID-19 pandemic had delayed its progress. It expects engagement with stakeholders on the strategy to begin in spring 2022. In December 2020 Defra, working with the devolved administrations, opened a consultation on a UK National Action Plan for the Sustainable Use of Pesticides. The plan will set out a five-year strategy to increase the sustainability of pesticide use in the UK and includes a goal to ensure continued robust regulation to protect health and the environment. It was due to publish in spring 2022 but is now expected to be published later in 2022. HSE's strategy for the next 10 years is due to be published soon.

4.19 Wider stakeholders whom we spoke to, including industry groups and non-governmental organisations, told us they are concerned over a lack of clarity on the future direction of chemicals regulation. While views differed on what form stakeholders wanted the regime to take, they consistently told us they wanted greater transparency and engagement on when and how plans would be developed.

4.20 Outside the regulatory structures of the EU, there is potential for the regulation of chemicals to diverge between England, Scotland and Wales, particularly in areas of devolved competence such as environmental protections. In February 2022, Defra published the Chemicals and Pesticides Provisional Common Framework, which had received ministerial approval from all four governments of the UK. The framework establishes governance structures across the four nations with the aim of ensuring effective operation of the new chemical regimes, as well as putting in place processes for managing any proposed divergence between the four nations. These structures include the UK Chemicals Governance Group (UKCGG) and supporting delivery boards. Welsh and Scottish government officials told us that the process of developing the framework had been constructive and governance structures are in place. However, they are at an early stage of operation and dispute resolution mechanisms have not yet been tested.

4.21 While Defra leads on international chemicals policy, CRD has an objective to engage and influence global chemicals regimes and it is developing an international strategy to inform its approach. HSE told us that before EU Exit it had to exert international influence primarily through the EU. In 2021-22 its immediate priorities were to develop its longer-term strategy, establish new processes for supporting and prioritising international engagement and fully engage in the wider UK government trade agenda. Its plans for 2021-22 included developing negotiating positions with government on chemicals, in advance of trade negotiations with specific countries. HSE continues to participate in international fora for chemicals and pesticides, including representing the UK at the United Nations Globally Harmonised System of Classification and Labelling of Chemicals. Its staff also contribute to the Joint Meeting on Pesticide Residues, administered jointly by the UN Food and Agriculture Organization and the World Health Organization.

Appendix One

Our audit approach

1 This report assesses how three regulators, the Competition and Markets Authority (CMA), the Food Standards Agency (FSA) and the Health and Safety Executive (HSE) in respect of chemicals regulation, are addressing the opportunities and challenges of EU Exit. Our report reviewed:

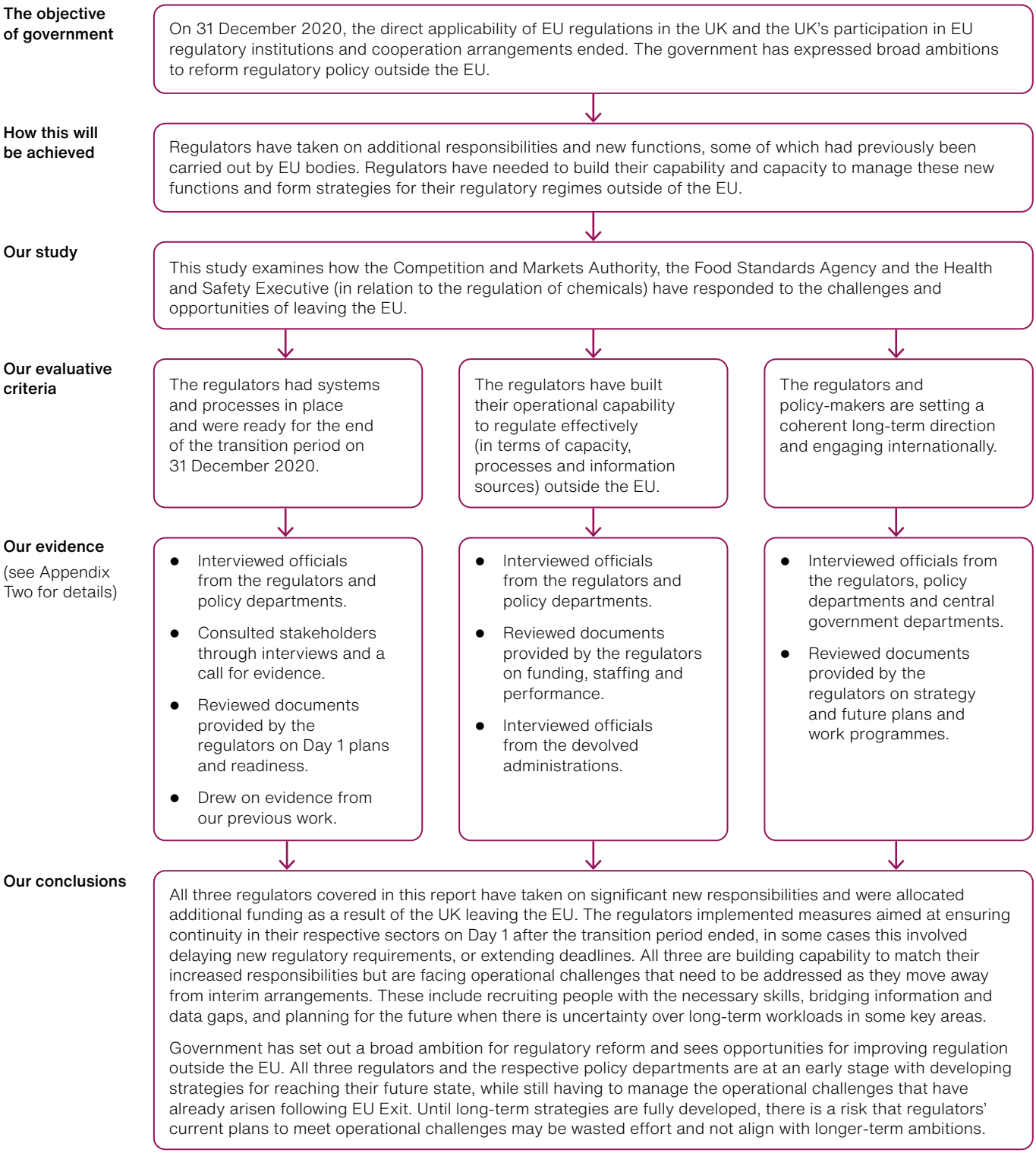
- the regulators' preparations and readiness for the end of the transition period;
- the operational effectiveness of the current regulatory regimes; and
- the regulators' long-term strategies for their regulatory regimes outside of the EU.

2 We chose to assess these three regulators because each of the regulators has responsibility for different areas of regulation, including competition, food safety and chemical safety, and they have all been substantively impacted by EU Exit, taking on new competencies as a result.

3 Our evaluation focused on how well the regulators managed the end of the transition period, how effectively they have been operating outside of the EU, and whether they are forming coherent long-term strategies for responding to the challenges and opportunities of EU Exit. Our assessments were based on our evaluative framework, which drew upon our good practice guidance on the *Principles of Effective Regulation*.

4 Our audit approach is summarised in **Figure 13**. Our evidence base is described in Appendix Two.

Figure 13
Our audit approach



Appendix Two

Our evidence base

1 We reached our independent conclusions, on how well the Competition and Markets Authority (CMA), the Food Standards Agency (FSA) and the Health and Safety Executive (HSE) (in relation to the regulation of chemicals) are responding to the challenges and opportunities of EU Exit, by analysing evidence collected between October 2021 and March 2022.

2 The focus of our report is regulation in England. Where regulatory processes are the same in Scotland, Wales and/or Northern Ireland, or where regulators operate in England and in one or more of the other nations of the UK, we set this out. We also explain how regulators across the UK are working together, including frameworks to manage the functioning of the internal market, to explore the impact this is having on the work of regulators in England.

3 We applied an analytical framework with evaluative criteria to our analysis, which considered whether the regulators have a strategy for responding to the risks and opportunities of EU Exit; have the data and intelligence to meet their regulatory objectives outside the EU; are intervening effectively in areas of new competence; and are cooperating effectively on the internal market and on international engagement. Our analytical framework and evaluative criteria drew upon our 2021 good practice guide, *Principles of Effective Regulation*.

4 We used a range of study methods to reach our conclusion, described below.

Document review

5 We reviewed a range of documentation across the three regulators. This included documents on strategy, capacity and capability, legislative and regulatory frameworks, international engagement, intelligence gathering and risk assessment, and governance and the UK internal market. We also reviewed programme documentation and performance reports on different areas of their regulatory functions. Where relevant, we analysed documentation from the regulators' policy departments.

6 We drew on evidence from our previous body of work on EU Exit and reports on:

- *Ensuring food safety and standards;*
- *Exiting the EU: Consumer protection, competition and state aid;* and
- *Department for Environment, Food & Rural Affairs: Progress in Implementing EU Exit.*

Data analysis

7 We analysed data on the regulators' funding, including specific EU Exit funding, to understand the resources at their disposal to meet their new responsibilities. We used data from the regulators' Spending Review submissions and settlements to understand how the regulators' overall budgets and EU Exit allocations have changed since 2018. We did not review actual spending over the period 2017-18 to 2019-20, because our previous work on the cost of EU Exit identified limitations in government's ability to identify all of its expenditure.

8 When comparing financial data over multiple years, we often present values in the prices of the current year (that is, we present the data in 'real terms'). This makes it easier to compare differences over time by removing the effects of inflation. To make this adjustment, we have applied HM Treasury's Gross Domestic Product (GDP) deflator as at 31 March 2022 and presented financial figures in 2021-22 prices. The COVID-19 pandemic's associated lockdowns and government spend resulted in atypical movement of the GDP deflator in 2020-21 and 2021-22. We found that this did not change the trends in the data or the conclusions we would have reached. Where not stated, we have presented figures in nominal prices rather than real terms.

9 To understand how the regulators have increased their capacity and capability in response to EU Exit, we analysed data on levels of staffing changes, recruitment and vacancies across the three regulators. Due to difficulties in separating EU Exit-specific recruitment, we report mainly on overall numbers of full-time equivalent (FTE) staff during the period 2016 to 2022.

10 We reviewed performance-related data across the three regulators to understand how effectively they have been operating in new areas of regulatory delivery since the end of the transition period, and whether they are meeting key deadlines such as statutory deadlines.

Interviews

11 We conducted 41 interviews with representatives from FSA, CMA and HSE to inform our audit. For each of the regulators we held interviews on different aspects of their regulatory delivery functions and on cross-cutting topics such as strategy and governance, resourcing and capability, stakeholder engagement, international influencing, intelligence gathering and risk assessment.

12 We conducted semi-structured interviews with other government departments.

- The Department for Environment, Food & Rural Affairs on its roles in chemicals and food regulation and how it works with FSA and HSE.
- The Environment Agency on its role in working with HSE on chemicals regulation.
- The Department for Business, Energy & Industrial Strategy on its roles in competition policy, consumer protection, subsidy control, the Office for the Internal Market and the Better Regulation Executive.
- The Cabinet Office on the Brexit Opportunities Unit.

13 We conducted semi-structured interviews with representatives from the devolved administrations in Scotland and Wales to understand their views on working with the regulators in a post-EU Exit environment, the development of the common frameworks and the operation of the internal market. We also spoke to Food Standards Scotland, the body responsible for the regulation of food safety in Scotland, about its working relationship with FSA, any changes as a result of EU Exit and common frameworks development. In the absence of a Northern Ireland Executive during March and April 2022, we did not carry out interviews with representatives from the Northern Ireland government departments.

Evidence from wider stakeholders

14 We collated the views and perspectives of a wide range of external stakeholders, including non-governmental organisations (NGOs), consumer organisations and industry bodies with interests and experiences in the regulation of chemicals, food and competition. We did this by:

- conducting interviews with external stakeholders. We asked them about their engagement with the regulators on EU Exit preparations, strategy and decision-making, the operational effectiveness of the regulatory regimes and future opportunities and challenges for post-EU Exit regulation;
- analysing stakeholder responses to the National Audit Office's February 2022 call for evidence on how the regulators have responded to the challenges and opportunities of EU Exit. The call for evidence asked for their views on how well the regulators have engaged with them on transition preparations; decision-making and future plans and strategy; how effectively the regulators have been managing their regulatory functions outside of the EU; and what the key opportunities and challenges for the regulators are following EU Exit. We contacted 15 organisations and received 6 written submissions in response; and
- analysing additional public information on stakeholder views such as written submissions to select committees and responses to consultations.

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