National Audit Office

Regulating after EU Exit

Regulation

REPORT

by the Comptroller and Auditor General

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HC 61

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.**