PARLIAMENTARY DEBATES

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OFFICIAL REPORT

Ninth Delegated Legislation Committee

DRAFT BIOCIDAL PRODUCTS (HEALTH AND SAFETY) (AMENDMENT) REGULATIONS 2022

Wednesday 23 November 2022

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not later than

Sunday 27 November 2022

The Committee consisted of the following Members:

Chair: Mr Laurence Robertson

† Ali, Tahir *(Birmingham, Hall Green)* (Lab)
† Berry, Sir Jake *(Rossendale and Darwen)* (Con)
† Bridgen, Andrew *(North West Leicestershire)* (Con)
† Churchill, Jo *(Vice-Chamberlain of His Majesty's Household)*
† Davies, Mims *(Parliamentary Under-Secretary of State for Work and Pensions)*
† Edwards, Ruth *(Rushcliffe)* (Con)
† Foxcroft, Vicky *(Lewisham, Deptford)* (Lab)
† Gullis, Jonathan *(Stoke-on-Trent North)* (Con)
Hollern, Kate *(Blackburn)* (Lab)
† Lord, Mr Jonathan *(Woking)* (Con)
† McCartney, Jason *(Colne Valley)* (Con)
† McDonald, Andy *(Middlesbrough)* (Lab)
† Mishra, Navendu *(Stockport)* (Lab)
† Robinson, Mary *(Cheadle)* (Con)
Stephens, Chris *(Glasgow South West)* (SNP)
† Wild, James *(North West Norfolk)* (Con)
† Yasin, Mohammad *(Bedford)* (Lab)

Bradley Albrow, *Committee Clerk*

† attended the Committee

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[Mr Laurence Robertson *in the Chair*]

Draft Biocidal Products (Health and Safety) (Amendment) Regulations 2022

2.30 pm

The Parliamentary Under-Secretary of State for Work and Pensions (Mims Davies): I beg to move,

That the Committee has considered the draft Biocidal Products (Health and Safety) (Amendment) Regulations 2022.

It is a pleasure to serve under your chairmanship, Mr Robertson. This draft statutory instrument was laid before Parliament on 18 October. It is a technical change only, and there are no policy changes. It relates to biocidal products, which are used to control harmful organisms and include disinfectants, insecticides and rodenticides. These products have important roles in protecting human health and critical infrastructure, and it is therefore essential to society that their legal supply is not disrupted.

Although biocidal products are critical to society, they can pose risks to human health, animal health and the environment if used incorrectly. Therefore, to allow a biocidal product on the GB market, a two-step authorisation process is in place. First, the active substances used in biocidal products must be approved. Approval involves a rigorous scientific evaluation to ensure safety and efficacy—a process that takes one to two years and costs approximately £180,000. If an active substance is approved, applications can be made to authorise biocidal products containing that active substance. This evaluation looks at the safety and efficacy of the formulation—a process that takes about a year and costs approximately £25,000. As Members will understand, the applications are large dossiers of scientific data, and require complex evaluation and assessment by a range of specialist scientific disciplines to ensure that there is no danger to human health, animal health or the environment. The Health and Safety Executive operates a cost recovery model, so applicants bear the full cost of processing applications.

Biocidal products are regulated under the Great Britain biocidal products regulation—GB BPR—which was retained following EU exit. The authorisation process in Great Britain is similar to the EU, except where references to EU arrangements were replaced by domestic arrangements. Also retained in the legislation were legal deadlines by which applications should be processed. Those legal deadlines were in place to ensure consistency across the EU in how long was given to process applications and to provide transparency to applicants. While the UK was still in the EU, a steady stream of applications was processed across EU member states, though even at that time, deadlines were often missed.

In preparation to meet our ambition for the HSE to become a world-class stand-alone chemicals regulator following the UK's departure from the EU, significant investment has been made to increase the HSE's capacity and capability, and to embed new processes and procedures. Through a major transformation programme, the HSE's headcount for its chemicals regulation division has increased by around 40%, with ongoing significant investment in both people and IT.

As part of EU exit preparations, transitional arrangements were put in place to ensure a smooth transition for businesses to the new domestic systems. Those arrangements required businesses that had applications in process at the end of the implementation period to re-submit them to the HSE by deadlines in 2021 if they wanted to retain access to the GB market. Under the arrangements, biocidal products already on the GB market could continue to be made available until their application was processed. It was unknown at the time how many re-submissions would be made by applicants to access the GB market until those deadlines passed.

I am pleased to report that more than 70% of the biocides applications seeking access to the UK market under the previous EU system have been resubmitted to GB. That clearly shows that the industry has faith in the GB market and in the HSE as the regulator, but it also generates a greater workload than was originally anticipated. As a result, it is not possible to process the large one-off influx of biocidal product authorisation applications within the legal deadlines in place.

The HSE has been hindered by its loss of access to EU databases that hold historical reports containing scientific information relevant to the processing of applications. However, a resolution should be in place by the time the information is required to process the applications. The HSE will also consider what future digital solutions may be required once a resolution has been implemented. Nevertheless, we must recognise that the issue has caused some further delays in the processing of applications.

Following EU exit, the legal deadlines in the Great Britain biocidal products regulation amount to deficiencies in current retained EU law; therefore, the appropriate course of action available to the HSE is to make technical amendments through this statutory instrument under the powers in the European Union (Withdrawal) Act 2018 to remedy deficiencies in the current legal framework. The technical changes proposed by the statutory instrument are straightforward: the legal deadlines in place to process biocidal product authorisation applications will be temporarily extended for an additional five years.

The period of five years is derived from resource modelling from the transformation programme to which I referred earlier. It represents the amount of time that the HSE forecasts it will take to address the backlog and return to a position in which applications can be processed within the original legal deadlines. I trust it is understood that the processing of applications is not simply a rubber-stamping exercise and that it requires highly trained staff who cannot simply be brought in in large numbers at short notice.

To clarify, the amendment to the legal deadlines should have no impact on businesses. An extension of the deadlines does not cause any additional cost to the applicant; instead, this statutory instrument provides legal certainty that when biocidal products are on the GB market awaiting the outcome of their application, they can remain there. That may not otherwise have

been the case had the legal deadlines been missed. In turn, that ensures that there is no disruption to the legal supply of essential biocidal products while the applications are cleared.

The statutory instrument will affect a small number of new biocidal product authorisation applications. However, those applications will be prioritised to ensure that where businesses are waiting for authorisations before they can supply their products, they will not experience any delays.

Finally, this statutory instrument also adds an additional transitional measure—an oversight in the previous EU exit statutory instruments—that allows a type of biocidal product authorisation application called "same product applications" to transition to the GB market and be treated in the same way as other applications. This, too, has no impact on businesses. It is a technical correction to ensure that the biocide regime is fully functioning as intended.

I hope it is helpful for the Committee to know that this statutory instrument was robustly debated in the other place and passed without challenge. I can confirm that consent to make the statutory instrument has been obtained from Ministers in Scottish and Welsh Governments, in line with the normal conventions. The regulation of biocides in Northern Ireland follows separate arrangements under the Northern Ireland protocol and is not affected by this instrument. I hope colleagues of all parties will join me in supporting the draft regulations, which I commend to the Committee.

2.40 pm

Vicky Foxcroft (Lewisham, Deptford) (Lab): It is a pleasure to serve under your chairpersonship, Mr Robertson. I thank the Minister for presenting the statutory instrument. We do not consider it controversial, but I have a few questions for her.

This is one of the many statutory instruments being introduced by the Government as part of the return of powers from the European Union. This particular instrument aims to

"extend the legal deadlines in place for processing biocidal product authorisation applications by the Health and Safety Executive (HSE) acting as competent authority."

Importantly, the regulations will ensure that there is sufficient time to process applications and that biocidal products can remain legally on the market in Great Britain, as intended by the legislative framework. They will ultimately ensure business as usual—something the Labour party will always back. I do, however, have questions for the Minister.

What would the Minister say to businesses and the general public about the need for this SI? As I, the Minister and many Members here will know, following EU exit we no longer have access to the vital databases storing historical EU reports. These reports contain information concerning the evaluations that EU member states carried out to inform decisions on the approval of biocidal active substances and the authorisation of biocidal products. Although some of that information has been published, some aspects are confidential and not published at all. Many will worry that the consequences of EU exit have simply not been planned properly. How could the Government not prepare for this or see it coming? The scale of potential disruption caused by our exit from the EU sits firmly with successive Tory Governments.

I hope the Minister can also provide clarification on the extra workload. The Minister will know that the transitional arrangements requiring the resubmission of applications to the HSE have resulted in a one-off influx of simultaneous applications around transitional deadlines, and this has caused a temporary backlog of applications. One of the main reasons for this SI, as the Minister outlined, is that the HSE will not be able to meet the legal deadlines for processing authorisations set out in GB BPR. Why is the Minister asking the HSE to do more with less? In 2010, Government funding to the HSE stood at £231 million; 12 years later, it stands at £178 million. That is a cut of £53 million. It is simply baffling to ask the HSE to take on more following the EU exit. Will the Minister clarify what extra support is being put in place to support the increased workload?

I hope the Minister will remember that this SI covers material that must be handled with care. The HSE deserves the proper support to manage the increased workload. Not doing so would leave the public at risk, and that is something I am sure we can agree no one wants. I appreciate the Minister laying this SI before Parliament. As I said, it is one that we will support, but it would be helpful if the Minister could answer a few of those questions.

2.43 pm

Tahir Ali (Birmingham, Hall Green) (Lab): I have some questions for the Minister. The first concerns the resubmission rate of 70%. What are the actual numbers? If this instrument is to be extended for five years, what are we looking at 70% of? My next question is about the data that was lost because of EU withdrawal. That will now mean that a lot of work has to be done again from scratch, which will involve some intense resources and support for HSE, as my hon. Friend the Member for Lewisham, Deptford mentioned. How much extra resource will be put into the HSE? In five years, there will be the 70% of re-submitted applications, as well as the submissions that would normally come in. Will we be in a position in five years' time where we have another backlog and have to look at another extension?

2.45 pm

Mims Davies: I have many notes. I thank the hon. Member for Lewisham, Deptford for her questions and the spirit of them—I am being passed even more notes, so I feel pretty sure that I can answer most of her questions.

Let us start with the most important issue: resourcing and funding. The HSE has already increased the number of staff working on chemicals regulation by around 40% from 256 in March 2020 to 355 in March 2022, with further significant recruitment planned over the next two to three years, which I hope answers the question raised by the hon. Member for Birmingham, Hall Green. That reflects the need for increased resources for the HSE's post-EU exit responsibilities.

Likewise, the total budget for the HSE's chemicals regulation division has grown by 39% from £22.4 million to £31.2 million between 2018-19 and 2022-23. It was always anticipated that it would take several years to reach full operating capacity following Brexit, due to the need to recruit and train large numbers of new staff in specialist disciplines required for chemicals regulation.

[Mims Davies]

It is an honour to be the Minister responsible for the HSE. The depth of work it does across covid and all sectors is a joy to behold and learn from, with its cost recovery scheme and the way that it works. One of its recruitment plans is to grow and progress more of its own people, which I very much welcome.

Andy McDonald (Middlesbrough) (Lab): Given what the Minister just said, does she see it as a matter of regret that we have lost over 400 HSE inspectors since 2010? During the covid crisis, their roles had to be adopted by debt collectors, who were performing their functions by inspecting premises and carrying out tick-box exercises in their stead.

Mims Davies: I thank the hon. Gentleman for that point. In the time that I have been working with the HSE as a Minister, whether on visits to Derbyshire or to Bootle, I have been really impressed with its ingenuity and the way it has got people to come into the sector, grown its local workforce and given people opportunities. It is brilliant at bringing people in and training them. If he is saying that we welcome people from all walks of life to come into this growing sector, we are on the same page.

Sir Jake Berry (Rossendale and Darwen) (Con): Will the Minister confirm that, as part of this welcome recruitment drive, the ministerial head of the HSE will insist that all new employees have to work from an office base, rather than working from home? We are talking about deep scientific research, a key part of which is collaboration. I understand that the Government cannot do much about civil servants who had their terms and conditions altered during covid, but will she confirm that, on an ongoing basis, the civil servants she is recruiting into the HSE will have to work from an office, rather than from home?

Mims Davies: My right hon. Friend is right to talk about learning and development within the business, which is really important. In my engagement with and visits to the HSE, it has been very clear about that, but it also has many people in the field and around the country who balance working from home with working from the base where they deliver their processes. It is a mixed picture, but I am happy to look at that point and raise it with management.

The HSE's chemicals regulation division has reached full capacity and will be in a position to meet the usual timescales set out in the legislation, but it is important to bring this measure to the House, to give us the time to achieve this recruitment and, ultimately, make sure that this area is safe and works. I hope that reassures hon. Members.

The hon. Member for Lewisham, Deptford asked why we have to do this and whether we envisaged the timetables. The changes will ensure that regulatory deadlines provide sufficient time for the HSE to clear the backlog of applications, and will give legal certainty to the affected businesses, whose products, vitally, will be able to remain on the market while their applications are, rightfully, assessed.

The active substances will be reviewed by the HSE, and the legislation allowing flexibility and timeliness should be welcome. I reassure hon. Members that the work to review the programme is in development. The HSE will continue to communicate and engage with stakeholders on its work in due course. It has already started work on evaluating the active substance applications, which fall outside the formal review programme.

There was a question about how the businesses will be notified about applications. Businesses have been notified and have submitted more than 400 biocidal product applications. That includes new applications, changes to existing authorisations and renewals, while 250 are complex new applications, which require the most resources. Compared with the EU workload, that represents about 70% more than anticipated, but I strongly believe that the HSE can withstand that. I thank the hon. Member for Lewisham, Deptford for making those points.

I have covered the staffing measures. On the long-standing transition arrangements that allow the biocidal products to stay on the market until their applications are assessed, most affected products have previously been on the market for many years, and in most cases in the EU as well. I reassure colleagues that this is nothing for us to worry about. The HSE has the experts, and the draft regulations will allow it to do its work and to monitor as it can and should.

The HSE has a process for monitoring international scientific information of relevance to UK active substances and products, including the EU assessments. Should new evidence emerge, the HSE will again work with any relevant regulatory agencies and take any suitable action as a result.

Andy McDonald: The Minister is being generous in giving way. Given the commitments she has made this afternoon, is she able to give any indication to the Committee as to the increase in the HSE's budget following the autumn statement? It has an awful lot more work to do.

Mims Davies: I am happy to write to the hon. Gentleman about the budget. I have information about the staffing that I can give him, but I point to the cost recovery in this area. The HSE is exemplary on that. I am happy to write to him with more detail, if that is helpful.

I want to cover data; forgive me, I have so many notes here, I cannot find the bit on data. Here we go—so many bits of paper! I hope hon. Members appreciate that this is a technical instrument and it is important that we get it right. I would rather give more detail and data than less.

The HSE's assessment of biocidal products remains based primarily on the data submitted by the businesses. They have to act for the authorisation in place for their products on the market. The businesses can continue to do that without access to the EU databases. That is not under threat. The risks of loss of access to the EU databases are being considered as part of HSE's work to manage biocide authorisations taking into account the loss of access to EU databases, but HSE's long-term objective is to develop solutions that will allow the authorisation processes to work without disruption, so that no risks materialise.

I hope that I have covered most of the questions put to me. I welcome the Committee considering the draft regulations. I reiterate that the statutory instrument is a technical change only and that there are no policy changes. It relates to biocidal products that are used to control harmful organisms, including disinfectants, insecticides and rodenticides—products that have important roles in protecting human health and critical infrastructure. The instrument will therefore allow us to ensure that the legal supply of such products is not impacted in the long term.

The draft instrument provides important additional time for the HSE to complete biocide authorisations while applications are addressed, and extends the relevant deadlines by a one-off period—I stress the "one-off"—of five years after the regulations come into force, by which time the HSE forecasts that the authorisations will have been cleared. After that, it will return to the normal processing times set out in legislation.

I remind the Committee that no cost to businesses arises from the changes made in this draft statutory instrument. Importantly, it provides legal certainty that, where biocidal products are already on market in Great Britain waiting for an authorisation decision, they can continue to be used and supplied. That will ensure that suppliers of biocides are treated fairly and that there is no disruption to the legal supply of essential biocidal products while the backlog of applications is cleared.

The draft regulations provide a transitional measure to supplement the existing Great Britain biocidal products regulation or GB BPR, bringing over the last elements of pre-EU exit regulation. That change ensures that a certain type of biocidal product authorisation application, namely same product applications, can be treated in an identical way to other applications. Again, that has no impact on businesses and is a technical correction to ensure the biocide regime is now fully functioning as intended.

To conclude, the draft instrument will provide the necessary extension to the legal deadlines to enable HSE to process affected biocidal product authorisation applications. That will provide legal certainty to businesses that biocidal products on the market awaiting their application to be processed can remain there. In turn, biocidal products essential to the functioning of society can continue to be made available and used appropriately.

Question put and agreed to.

2.57 pm

Committee rose.