HOUSE OF LORDS

Science and Technology Committee

Corrected oral evidence: Engineering biology

Tuesday 7 May 2024

10.15 am

Watch the meeting

Members present: Baroness Brown of Cambridge (The Chair); Lord Borwick; Lord Drayson; Lord Lucas; Baroness Neuberger; Baroness Neville-Jones; Baroness Northover; Lord Rees of Ludlow; Viscount Stansgate; Lord Strasburger; Lord Wei; Baroness Willis of Summertown; Baroness Young of Old Scone.

Evidence Session No. 6 Heard in Public Questions 60 - 70

Witnesses

I: Dr Michael Adeogun, Head of Strategy—Life Sciences and Health, National Physical Laboratory; Professor Robin May, Chief Scientific Adviser, Food Standards Agency; Professor Isabel Oliver, Director-General of Science and Research and Chief Scientific Officer, UK Health Security Agency.

USE OF THE TRANSCRIPT

1. This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Examination of witnesses

Dr Michael Adeogun, Professor Robin May and Professor Isabel Oliver.

The Chair: I would like to welcome our witnesses, all joining us by Zoom today, to the committee's sixth evidence session in its inquiry into engineering biology. We will be hearing from Michael Adeogun, head of strategy for life sciences and health at the National Physical Laboratory, and we thank him particularly because he is joining us from the United States. It is the middle of the night for him, so we really appreciate that. We have Professor Robin May, chief scientific adviser at the Food Standards Agency, and Professor Isabel Oliver, director-general of science and research, and chief scientific officer, at the UK Health Security Agency. Thank you very much to our witnesses. Let me hand over to Lord Wei to ask the first question.

Q60 **Lord Wei:** Could you each briefly introduce yourselves, your organisations and the roles that you play as either regulators or public bodies in the engineering biology field?

Dr Michael Adeogun: The National Physical Laboratory, which I will refer to from now on as NPL, is a Department for Science, Innovation and Technology-owned national laboratory. We have around 1,000 staff situated across the UK, predominantly at our Teddington site. We are a multidisciplinary laboratory comprising physicists, chemists, engineers, biologists and data scientists.

We are a public sector research establishment and, as for our role within the UK science and engineering ecosystem, we are the UK's national metrology institute. We form a large part of the Government's national measurement system alongside our sister laboratories at LGC, the National Institute for Biological Standards and Control, which is now part of MHRA, and NEL. As a community and as part of the national measurement system, we also form the bulk of the UK quality infrastructure alongside the accreditation service UKAS and the British Standards Institute.

As a collective, NPL is an asset base of facilities, skills and knowledge that provides the means to ensure that measurements and standards are internationally comparable and consistent across all market sectors. We cover all market sectors, whether health, energy, environment, defence, advanced manufacturing or digital, and put in place a measurement infrastructure that cuts across all technology readiness levels.

We do not work in isolation. We pride ourselves on the fact that we work with industry, government, the healthcare system, academia

and centres of excellence, as well as other national measurement institutes and designated institutes across the world.

I will just leave it there and say that measurements and standards are the invisible currency that underpin trade and regulatory systems, but also help accelerate innovation and adoption of new technologies such as engineering biology. That confidence in measurement is critical for trade and for innovation. The physicist Lord Kelvin once said, "If you can't measure it, you can't improve it".

Professor Robin May: I am professor of infectious diseases at the University of Birmingham, Gresham Professor of Physic, and chief scientific adviser at the Food Standards Agency. It is in that latter capacity that I am appearing in front of you today.

The Food Standards Agency is a non-ministerial government department that is charged with the safety and authenticity of all food in the United Kingdom. That includes the enforcement of activities in food businesses—abattoirs, packing plants, food production facilities and catering.

In the context of engineering biology, our role is in authorising regulated products. Those are all products that enter the food system that are either new—those not consumed in the United Kingdom prior to 1997—or are in a number of regulated classes, which includes diverse products such as additives, some enzymes, and genetically modified foods. That is the major area where engineering biology is likely to impact on the food system in the coming decades.

Professor Isabel Oliver: Good morning. I am the director-general of science and research, and chief scientific officer, at the UK Health Security Agency. The UK Health Security Agency is the government agency responsible for protecting health from infectious diseases, radiation, chemical and other environmental threats to health. We do this by preventing, detecting, monitoring, understanding and controlling these risks to public health.

Our role in this area is in detecting, understanding, monitoring and controlling biological threats to health. We also work very closely with the Cabinet Office, the Department of Health and Social Care and other parts of government in the implementation of the national biological security strategy.

Q61 **Baroness Willis of Summertown:** Good morning, Professor May. This question is mainly for you. I am sorry that I am not there in person. What we are trying to get to our heads around is that,

when new products come to market, regulators are responsible for assessing the safety of these products. What challenges would you say come with that role in assessing and reviewing novel foods? In particular, how do you determine which ones to assess? I would imagine that it is obvious with new meats, for example, but there are so many sorts of things coming into foods now, so I would be interested to hear about that.

Professor Robin May: The FSA is the responsible body for authorising all regulated products. Perhaps to start at the end of your question, in terms of deciding what gets authorised, there are set down in law a number of categories of foods that must always be assessed. That includes genetically modified foods, additives and any novel food. In this context, novel food is something that was not widely consumed in the UK prior to 1997. Anything that enters those categories must, by law, come to us for assessment, unless it is, in essence, identical to something that is already on the market and approved. That is the first part.

Since we exited the European Union, the assessment process has been done entirely by the FSA, working quite closely with FSS—Food Standards Scotland—our equivalent in Scotland. Essentially, the way that that works is that an applicant will apply to us with a product that they think needs authorisation. It will be initially triaged to make sure, for example, that it is a food and not something else. It will then enter our risk assessment process, where our team of scientists, working particularly with our independently appointed scientific advisory committees and sometimes with outside experts, will scrutinise the information provided by the applicant and make an initial science assessment.

The nature of the information that an applicant provides depends very much on the food that they are authorising, but it will normally include quite detailed toxicology assessments; for example, is this product likely to cause DNA damage in any way that might trigger cancer? Might it bioaccumulate in a way that is toxic? Might it have an effect on your liver or your kidneys? All of that information is in the dossier that is considered by our scientific team.

They will then pass it on at the end of that process to the risk management team, who will issue a suggestion to Ministers about whether this food should be authorised, sometimes with additional constraints around it. We might say, for example, that it is broadly safe, but it should be advertised as not suitable for children or for pregnant women.

Baroness Willis of Summertown: With a lot of the new

foodstuffs coming through from the trade Act, who does the analysis work? Is that done in the UK by your teams or overseas?

Professor Robin May: If it is intended to be sold in the UK, it is done by us, but I should point out that science is of course very international. The data that we are using comes from all around the world. We have in excess of 100 independent experts on our scientific advisory committees. They are not employed by the FSA. They give up their time and are remunerated for it. They are drawn from all over the world, and we have many international members. Of course, we have very good links with other regulators in other countries, particularly those that have systems similar to ours, and do a lot of exchange of information about it.

We are agnostic as to where the science comes from; it can come from anywhere. The risk management suggestion is very dependent on the UK. There are things that concern UK consumers but do not concern consumers elsewhere. The decision on what you do with the science might be different, but the science itself is the same.

Baroness Willis of Summertown: You want to strike the balance between encouraging innovation and ensuring safety. How do you do that?

Professor Robin May: You are absolutely right. It is really key that we do not unduly stifle innovation in any sector, including engineering biology. The key thing really is about being proportionate in terms of the risks. At some times that is easier than at others. For a food that is largely similar to something already out there, such as food colouring, there is an enormous wealth of science about other food colourings and similar chemical structures that we can draw on. It is much harder for foods that are very novel.

In the context of engineering biology, one main challenge is that it encompasses a huge range of potential products. At one end, you have things that might be, for example, a recombinant enzyme. It is a single protein produced in a large vat, perhaps in a liquid. It is relatively straightforward to assess the toxicity and the long-term implications of that, because that is the process that we already use for many enzymes.

At the other extreme, you might have a 3D-printed, multiple cell layer artificial tissue which, in essence, is something that has never been in the human diet before anywhere. We cannot phone a friend in another country and ask, “What did you do with this?” because no one has done it before.

The key to balancing that innovation and regulation is having as much early sight of the technology and international collaboration as are possible in terms of assessing the science. One thing that is still a challenge for the system is how to balance commercial sensitivities and intellectual property with sharing that information as early as possible, so that the regulator can be ready to regulate the product when it comes to market.

Q62 **Baroness Young of Old Scone:** Good morning. Again for Professor May, the procedures that you have in place at the moment are, I assume, to try to prevent engineered organisms in the food system spreading beyond where they should be and any wider unintended consequences. How wide does that go and how do you carry out that task? I am particularly interested in whether Natural England is a natural colleague of yours because of the impact on ecosystems of some of the created products that you may be regulating. Do you see yourself having a role in that? How do you carry out that wider environment role?

Professor Robin May: The remit of the Food Standards Agency is very much about the safety of food for the human consumer. The wider impact on the environment is largely a responsibility of Defra in England and of equivalent bodies elsewhere in the UK. The best paradigm for this is a novel food crop or a GM crop, for example, where ACRE, which is the scientific advisory committee that Defra oversees, will make decisions about how likely this organism is to escape and cause environmental damage. If we were to receive an engineering biology application where we felt that the organism involved had potential environmental risks, we would refer that back to Defra and ACRE to look at.

There is the wider question here about regulatory join-up across departments. The one that is probably most relevant to this is the Health and Safety Executive, which regulates laboratory containment. There is very good working between us on that. For example, most genetically modified engineering biology applications will have started as a lab project that will have had authorisation through the HSE. When it comes to the FSA for market approval, we will be able to draw on all the scientific evidence that the HSE used in appraising its safety and its containment within the lab.

Baroness Young of Old Scone: Is that wider environment role properly represented on the Engineering Biology Regulators' Network?

Professor Robin May: The Engineering Biology Regulators' Network is very new. It has met four times. It has FSA

representation, although that is not me, so I am not immediately aware of who else is on there. I know that there are about 10 or 12 government departments. We can check the list and perhaps write you afterwards with that. The organisation that we have had the most links with is the HSE.

Thus far, that network has been very good in terms of people sharing early information and their approach. What we do not quite have yet from them is a single unifying document that sets out the different regulatory landscape for the UK. In the fullness of time, it would be really good if the department were able to create something that clearly demonstrated where these different responsibilities fall. Your question points out one that is clearly somewhere between the gaps at the moment, and it would be good to really bottom that out.

Baroness Young of Old Scone: Thank you. It would be useful if you could write in. I have one last point, which is on Frankenstein foods. Do you have a role in public-facing activity to try to persuade the great British public that this stuff is safe when it is approved and that they should relax and eat it?

Professor Robin May: I like to think of us as not trying to persuade anybody of anything particularly, but you are absolutely right that the FSA has a critical responsibility in terms of consumer awareness. That is front and centre in our remit. We do lots of consumer messaging around all sorts of things, such as foodborne outbreaks and novel foods. There is a big role here for the FSA in explaining what these are. Terms such as "engineering biology" are not ones that most consumers are familiar with. There is a huge amount of mystique around lab-grown meat, et cetera.

My view—and the organisation would stand four-square behind it—is that our key role here is to tell the truth and to be absolutely clear. It is not about persuading people to eat more—or less—lab-grown meat. It is just about explaining what it is, how the safety risks have been appraised and, if it is on the market, why it is safe to eat. It is then up to individual consumers to decide whether they wish to eat that particular product.

Q63 **Lord Lucas:** This is a question for Dr Adeogun. We have heard from industry that one barrier to scaling up is a lack of standards, such as the ISO standards. Is this correct? Can you set out what role NPL can play in helping the industry to develop standards? Could you also set out some of the work that the new Centre for Engineering Biology, Metrology and Standards with NPL is doing to help in this area? I have observed what damage we have done ourselves by not keeping up with standards and standard essential

patents in, for instance, telecommunications. How will we avoid that in engineering biology?

Dr Michael Adeogun: The short answer is that there is a lack of standards. As part of our stakeholder engagement across the national measurement system, this has been borne out. Hence the *National Vision for Engineering Biology* also talked about this, as did the Council for Science and Technology report. The latter talked about the lack of standards and lack of metrology.

You are absolutely right. If you look at any successful market sectors, what they all have in common is a robust measurement and standardisation infrastructure and, in some shape or form, the five critical technologies that have been highlighted, of which engineering biology is one. There is activity around standardisation and, to some larger or lesser degree, that is ongoing.

There are two elements around standards, of which there are many different types. You have documentary standards that people agree on in terms of a classification, a guide or some form of terminology or specification. Then you have measurement standards, which are critical for QA and QC. These can be physical materials, reference materials or calibrants. It includes vetted data, which is going to be important for engineering biology as we see the increased use of AI and machine learning tools, for example. That validation of algorithms and data standardisation formats and protocols will be extremely important.

There is also a need for standard methods. Both documentary and complementary measurement standards are going to be needed to improve reproducibility and comparability, because, at the end of the day, all stakeholders and developers want is to be able to benchmark the physical and digital performance attributes of their biological processes or the products that they are producing. That would allow developers to measure, compare and reproduce in a shared and common language. That is definitely the key and the drive forward in engineering biology.

From an NPL perspective, we have decades of experience of establishing and developing measurement standards, as well as inputting into documentary standards, across the variety of market sectors that I alluded to earlier. Many of our scientists sit on various ISO, IEC and other international standards committees, as well as national ones through BSI.

It is a challenge. It is a recognised problem, but one that the national measurement system and NPL are looking to give ourselves up to and to offer our services in addressing.

Q64 **Baroness Neville-Jones:** Is part of the issue that engineering biology is more complex than engineering, and so setting standards and measuring things is inherently more complicated? How do regulators deal with that if that is the case?

Dr Michael Adeogun: In 2017-18, we created a virtual centre in partnership with Imperial College London's SynbiCITE, with Professors Freemont and Kitney, and also with our colleagues at LGC and the National Institute for Biological Standards and Control. Our initial foray, from an NPL perspective, was to start engaging with industry and to establish a cryogenic electron microscopy facility and enhance our biophysical characterisation for testing systems and components.

The key thing for us was that engagement with industry to understand and support those needs, and what came out was that complexity. We have worked with more than 30 companies in the past several years to address problems around batch-to-batch variations and scale-up, physicochemical and morphological problems, impurity, intracellular delivery efficiency, and data analytics.

What comes through is the fact that biological systems, in themselves, are inherently complex. You are dealing with different length scales and the need to understand the operating context of your engineering biology systems, which can be adversely affected by temperature or pH. A change within the living cell, for example, if you are doing gene editing, might perturb other aspects of the cell. All these interactions need to be understood.

On top of that, you might have human variations and errors—although automation and robotics are starting to address those problems—as well as the biological situation and sensitivity. All these factors make it difficult to reproduce activities at a larger scale. This reproducibility and comparability crisis is recognised in the life sciences sector, and so it is challenging to put in place the necessary measurement infrastructure and the standards to go alongside that.

We are looking to create new multimodal, multiscale, interoperable measurement techniques and, therefore, the standards alongside them to look at the whole of the system, but it is still, in some respects, early days as we move forward. If you cannot reproduce something, that is problematic. You see the retraction of publications. You see false product development starts. In many cases, you see wasted time and resources because people cannot reproduce what others have attempted. It is a real challenge for us.

Baroness Neville-Jones: That sounds very complex. In the end, people do not know whether it is the product or the inability to measure accurately. Is that where you end up?

Dr Michael Adeogun: Yes, sometimes. You have to ask yourself what you want to measure and why, and what you need to standardise and why. You might look at it from the process side of things and ensure that you have control and a full understanding of your process, or you might say, "I'm interested not so much in the process but the end product. Can I verify, validate and test the performance attributes of that end product?" It is about getting that balance, and it all depends on the application and the regulatory requirements, which determine where you would look and what attributes you need to focus on.

Baroness Neville-Jones: Can I add another element of complexity to this? Engineering biology priorities often seem to be proprietary. The intellectual property rules might need to evolve in order to reflect the nature of the technology. Do you reckon that changes or updates are needed to regulatory procedures?

Dr Michael Adeogun: I may not be the best person to answer this, but I certainly feel that there are lessons to learn from other sectors. One that springs to mind is nanotechnology, in its early days. Some of the comments that have come out were also talked about in nanotech. There were changes in the IP rules around certain situations.

I would posit that, with engineering biology-based products, you might want to build on existing regulations that are already in place for non-engineering biology-built systems and processes. Any additionality or changes will be based on the fact that you might have some form of biological byproduct within your end result. It is more about the processes that may require new regulations and, therefore, a bit more thinking around the IP side of things.

Baroness Neville-Jones: Does the regulatory network help in the discussion of these problems?

Dr Michael Adeogun: I fully endorse the creation of the Engineering Biology Regulators' Network. NPL recently hosted a meeting of the Regulatory Horizons Council on engineering biology regulations. NPL, LGC and others were there alongside the regulators. Bringing together these groups is extremely important, so I fully endorse the creation of that network.

Q65 **Baroness Neuberger:** Professor Oliver, we had a session last week on biosecurity and the possible implications if engineering

biology were to result in new biosecurity threats. How does UKHSA engage with this area and keep tabs on any scientific developments that might result in new biosecurity threats?

Professor Isabel Oliver: As I mentioned in my introduction, we are working with the rest of government on the implementation of the national biological security strategy. That means leading a range of programmes of work to deliver the outcomes within that strategy.

In addition, we do this through the delivery of our core functions, which include detecting threats. For example, today I am at our laboratories in Porton Down, where we have a rare and imported pathogens laboratory, which is responsible for detecting and diagnosing rare and new pathogens.

We do this by maintaining robust surveillance systems and applying our scientific skills and capabilities to understand threats once they are identified. For us to be successful in this mission, it is important to work in partnership, not just with government agencies but with industry and academia.

Baroness Neuberger: We also heard about routine screening of the population, which was of course a big deal during Covid and has been scaled back considerably. I know that you cannot say exactly what the strategy will be, but are you concerned about population health screening being scaled back?

Professor Isabel Oliver: I would differentiate between screening and surveillance. Normally, when we talk about screening, we do that in the context of the clinical management of patients. It is normally about making sure that we are able to detect, diagnose and treat disease, if there is an effective treatment, as rapidly as possible.

In terms of maintaining surveillance, you are absolutely right. It is essential not only that we maintain a robust basic level of surveillance, but that our surveillance continues to develop to be able to deal with new threats and challenges, and continues to strengthen in the context of the development of new technologies and other scientific advancements. That is absolutely critical for us to be able to detect new threats—

The Chair: We have lost the connection. Let us move on to Lord Drayson's question and come back to Professor Oliver, if we can.

Q66 **Lord Drayson:** We are aware that the work that you do as regulators is scientifically complex and resource-constrained. Could you comment on how easy you are finding it to recruit and retain

the scientifically competent people you need in this rapidly developing area?

Professor Robin May: You are right that, for us, access to scientifically skilled experts is absolutely critical. There are probably three challenges that we face. One of those is very much around the training pipeline. For example, not very many toxicologists are trained per year. Many organisations, including our own, need a steady supply of excellent toxicologists, as does industry, so there is a real challenge around ensuring that there are sufficient toxicologists and then competing in the market for those.

There is also a challenge around international collaboration. Science does not know borders; people move all the time between countries. It is really important to be visible in that international community, but that is quite tricky if you are in a regulatory area where some things are confidential, for example.

We have also struggled somewhat with data and data handling. We deal with a large volume of very large and complex data. That might be chemical data, or it might be trade data, for example, on sales. If you are a really good data analyst, that is a very exciting project, but there are also lots of exciting projects in industry where, to be perfectly frank, you can earn a lot more than you can in government.

There is a market competition challenge there with those three areas. As we move forward, particularly into more novel areas, it will be critical to think very hard about that training and visibility angle, particularly in multidisciplinary training, which Michael mentioned earlier. Increasingly, engineering biology is not just about being a biologist or a chemist, but someone who can couple together different skills and use them in a really versatile way.

It is a very exciting area of science, but it needs investment at an early stage in training, so that we have a steady stream of people at graduate and postgraduate level, and experienced scientists, who are able to enter that field and combine these different types of science in a way that enables us to appraise their safety quite rapidly.

Lord Drayson: Given that, with regulation, there is always a balance between the need to promote and allow innovation to deliver economic growth, and the need to ensure the safety and security of the population, we have had feedback from some companies that there is insufficient resourcing going into the regulatory agencies to enable innovation to flourish and commercialise in the way that they would like. Is that something

that you three see? If so, what could be done to resolve it?

Dr Michael Adeogun: I will build on Professor May's reply. There is a real opportunity for the UK to attract the best talent as regards engineering biology, as well as the other critical technologies. I really feel strongly about that, because we have a leadership position. To enable that to happen, however, we also need to attract the best talent into the infrastructure that will support that translation and that greater growth through commercialisation.

As Professor May stated, we are in competition with various organisations and sectors to attract some of the best. At NPL, for example, we sometimes struggle to attract data scientists to address our challenges. One approach that we have gone through on the training side of things is to have a postgraduate institute, where we look to train 250 or so PhDs.

Lord Drayson: I am sorry to interrupt you, Dr Adeogun, but my question really was whether you see that this shortage of resources—you have talked about the challenges in recruiting people—is currently, as we have heard from industry, a limitation on the ability to innovate and commercialise engineering biology in the UK. If it is, what do you suggest is done about it?

Dr Michael Adeogun: It is. One way to address it is through funding streams. We are back in Horizon Europe, so that is a great opportunity to bring in and enable recruitment for those types of projects. I see that as one way, but it could also be through other funding streams or through government schemes such as Innovate UK or UKRI grants. We look to those to attract talent as well.

To me, it comes back to collaboration. You might not be able to get all the expertise and all the skill sets that you require internally, so looking for those opportunities to collaborate is key in moving forward.

The Chair: Thank you for that. Let us move back to Baroness Neuberger's question and pick up with Professor Oliver, if we can.

Q67 **Baroness Neuberger:** Professor Oliver, we lost you, so can we just go back to population health surveillance? You were saying that it was very important. Perhaps you could tell us what is under way at the moment. Also, one of the desired outcomes of the biosecurity strategy was a national biosurveillance network. Could you just tell us what that might look like?

Professor Isabel Oliver: Thank you very much and apologies for the disruption. In relation to your original question, you might have been referring to the metagenomics approach. A key thing that we

can do to strengthen surveillance is to maximise the benefits of genomic technologies. Still within a research framework, we are exploring the benefits of a metagenomic approach, which is a way of analysing genetic material from samples in the environment, for example soil or water, to help us understand the community of microorganisms present. That might provide some benefits for surveillance going forward.

You mentioned that one outcome of the biosecurity strategy is the development of a new biosurveillance network. The UK Health Security Agency is leading a pilot, working with Defra and other government departments, to bring together surveillance data from humans, animals and the environment to allow us to detect and understand threats to health more rapidly and effectively than we are able to do otherwise. This is currently a pilot and we are exploring the benefits of this, with the aim of informing future surveillance developments in the UK.

Baroness Neuberger: Thank you very much indeed. If you have some more material on that, it might be quite useful for us to have it, if you are able to send it to us.

Professor Isabel Oliver: Yes, of course. We would be very pleased to.

Q68 **Lord Rees of Ludlow:** About three years ago, the House of Lords did a so-called special inquiry into preparedness for extreme threats and risks, and I was on the committee. I would like to ask two questions that relate to the present discussion. First, to what extent are you happy with the way that the National Risk Register is prepared? Has it been improved recently? For instance, it famously mentioned the threat from influenza pandemics, but rather downplayed other kinds, so that needed improvement.

Secondly, it seemed that there was not really enough joined-up thinking to cope with pandemics; as we know, Covid-19 affected not merely the health service, but schools and supply chains. Has there been an improvement in the focus on preparedness in the joined-up sense?

Professor Isabel Oliver: Yes, there has. The Department of Health and Social Care leads the work on the national security risk from pandemics, and the UK Health Security Agency is supporting the Department of Health and Social Care.

There has been significant work to consider the range of possible pandemic threats, including the effects that climate and environmental change might pose, because that is the context in

which, for example, a new pandemic might arise and is an important driver of pandemic risk.

We are supporting the Department of Health and Social Care in its lead work in this area. It might also be worth mentioning that, as part of the implementation of the biosecurity strategy, the UK Health Security Agency has been working with partners to develop a list of priority pathogens to inform research and development to ensure that we are as well prepared as possible to deal with any threat that arises. That means advancing the development of diagnostics, vaccines and therapeutics.

Professor Robin May: As Isabel mentioned, the FSA is also quite closely involved with the National Biosurveillance Network. We have been working with other organisations, including UKHSA, on developing a system called PATH-SAFE, which is for pathogen surveillance in food, agriculture and antimicrobial resistance. That is aimed precisely at that challenge that you just highlighted about sharing data between organisations, for example enabling one to link an outbreak in a human consumer to a source in agriculture or further down the food chain. Those kinds of initiatives will be really critical in the future for all sectors, including engineering biology.

Lord Rees of Ludlow: There is also perhaps a need for more exercises. There was one called Cygnus some years ago. On our committee, we had two former Defence Secretaries, who made the point that you need to have exercises to check that things work, et cetera, in this area. I wonder if there will be more exercises like Cygnus.

Professor Isabel Oliver: I may be able to answer this. We work with the Department of Health and Social Care and NHS England to agree a programme of exercises. A revised programme is being developed and agreed at the moment. There will definitely be a whole range of exercises over the coming year at various levels.

Q69 **Lord Strasburger:** Good morning. I would like to ask you all two questions on the topic of communication and co-ordination between those involved in regulating engineering biology. There are many regulators, public bodies and government departments that have a stake in developments in engineering biology. First, how easy do you find it to co-ordinate efforts with other relevant bodies? Secondly, who, if anyone, has overall responsibility for regulating engineering biology? Is there a risk that some of it could drop into the gaps between you all?

Professor Isabel Oliver: The UK Health Security Agency is not a regulator, but we work very closely with regulators. Our own

scientific work is of course reviewed and inspected. Co-ordination can always be improved. In the UK, we are probably better than in other countries, because there is a good level of joint working and perhaps fewer organisations with responsibilities in this area than there are in other countries. Nevertheless, as you say, it can still be complex.

To strengthen biosecurity and the biosecurity system, we need to act at all levels. It is not just about development, standards and regulation. We also need, for example, organisations that will accredit against those standards. We need the scientific community and the research funders to take action to strengthen the system. We need action at a range of levels.

Professor Robin May: That is absolutely right, not just for engineering biology but for many other topics. We are increasingly seeing these things fall between different departments. I would agree with Isabel that, in the UK, we have pretty good working-level relationships between regulators and departments in these areas, although there are a couple of problems that I would identify.

One is an infrastructure problem. It is not always easy to share the underlying data. Individual people in these different regulatory organisations talk, but then, if you want to share data between, for example, a clinical setting and a food setting, that is not always straightforward.

The second problem is that, in answer to the previous question about resource challenges, resource absolutely is always a challenge. That means that everyone has to focus on business as usual and the day job. These innovative, future-looking projects that fall between areas—such as engineering biology—are often pushed slightly further down the line, because, day to day, everyone is wrestling with what needs to be done tomorrow, rather than what needs to be done in six months. If one were to look at additional resource, a key area would be to give a bit of breathing space for those cross-disciplinary activities to really invest in the future.

As a last point on that, to your question about falling between pillar and post, or between regulators, there are areas where that is particularly likely. For example, we have had a number of conversations recently with MHRA about products that fall into the gap between being a health medicine and a food—one example being around health claims associated with microbiome modulation through food. The more of those conversations that we have, the better, but it is really about getting the right people in the room,

building time and capacity to share data, and thinking about how you might regulate something that does not sit entirely in a nice, neat legislative box.

Dr Michael Adeogun: I totally agree with the other two speakers. It is vital that we keep those communication channels open and use groups that already exist more effectively, as Professor May has alluded to. It is about making sure that the right organisations are linked and represented in the right forum.

Again, I would endorse the Engineering Biology Regulators' Network, which will help with that, alongside the Engineering Biology Steering Group, which has also been set up as part of the vision. I totally agree with the other two speakers.

Lord Strasburger: Can you give us more information on how the Engineering Biology Regulators' Network works? Does it meet regularly? Are there specific individuals within the regulators who are tasked with keeping track across members in the network? Professor May, I think that you are more involved in this.

Professor Robin May: As I mentioned earlier, I do not sit on that network, but other colleagues from the FSA do. There are about 10 or 12 government organisations on the network. It has met three or four times. It is chaired by the Department for Science, Innovation and Technology. It is early days to assess where it is going, but I would say that it is a very good initiative. It is a very good vehicle to get people talking together.

There are two challenges. One is partly around fluidity. This is a rapidly evolving field. The membership of that group might well evolve over time, depending on where we see the market going in engineering biology applications—will it be more directed towards medicine, foods or materials, for example?

The overall leadership sits with DSIT, primarily. I mentioned in an earlier answer that one thing that would be really useful to get out of that group in the coming months would be a landscape of the current regulatory structures, perhaps identifying grey areas that need more work ahead of time, rather than at the point at which an application comes in and everyone realises that it is not entirely within their remit to deal with.

Lord Strasburger: Does that need to be done at government level?

Professor Robin May: Yes. That is the most useful vehicle. You could imagine other scenarios, but it is a key government priority. It is in the science and technology framework. I do not think that

government has to do everything, but having that national vision about where the different remits lie and how you might co-ordinate them would fall within DSIT's purview.

The Chair: Could I just press you on that, Professor May? Would it be your perception, therefore, that DSIT has overall responsibility for the regulation of engineering biology in the UK?

Professor Robin May: I do not think that it has overall responsibility for the regulation. In terms of the innovative science and technology aspects of engineering biology, it would.

The Chair: Do we have somebody you would see as being responsible overall for the regulation of engineering biology. Is there a single organisation or point that we could identify?

Professor Robin May: One challenge there, not just for engineering biology but for all sectors, is that it is quite hard to come up with an overarching body that regulates the entire thing. If we think about classical foods, for example, the FSA holds the regulatory remit for the consumer part of that—the things you eat—but the food system relies on agriculture, which is Defra's remit. It also relies on innovations such as crop breeding, which might come through DSIT or other organisations.

There is no single overarching regulator all the way through the existing food system, let alone the future engineering biology one. What I am saying is that, rather than a single responsible body, that convening power and that single overarching network vision are quite critical, even if individual regulators retain the remit for their particular sector.

The Chair: So there is nobody responsible for making sure that things do not fall through the gaps in terms of regulation.

Professor Robin May: In our existing legislation, it is quite hard for things to fall through the gaps, because the default is that it is not authorised. There are systems where, for example, the default is that you go to the market, unless it is blocked.

In the UK food system, it is the opposite. You cannot bring a food to market unless it is approved. For example, with a food that did not seem like a food and was not the FSA's remit, but did not seem like a medicine and was not MHRA's remit, the default would be that it just does not come to market, so there is quite a strong incentive to solve that problem as it stands.

The system does not fail in the sense of allowing things to slip through the gaps. It could, though, be much more efficient in terms

of joining up, particularly around products that are deliberately designed to fall in that gap between different areas.

The Chair: But you mentioned that things do fall into the gaps.

Professor Robin May: In terms of their regulation application, they do. Let me give you an example. We sometimes receive a food application that comes to the FSA for authorisation as a food. The dossier of material that is submitted with it includes a health claim. It might say, "Likely to help weight loss". We do not regulate health claims; that goes into DHSC and MHRA territory, so we would then pass that application to those regulators to look at it from a health claim aspect. They would look at the health claim and pass it back to us to look at the food system.

That works relatively well. None the less, it is an application that has fallen into the gap in the sense that it has come into one regulator but should have been looked at by both. If we think about engineering biology, one thing that you could do is to design a system up front that allowed all those regulators to sit in the room together at the outset to look at it, rather than playing tag as the process went along.

The Chair: That is very helpful to us.

Q70 **Baroness Northover:** Following on from that, we will be making policy conclusions and recommendations to government. My question is to ask what are your top three priorities for action across government to ensure that the UK is prepared to maximise the advantages and mitigate the risks from engineering biology?

Dr Michael Adeogun: My top three would be quite simple. If we are to invest in R&D and scale up translation, we must invest in the regulatory and public body infrastructure that goes alongside that. To me, that pro-innovation regulatory approach is imperative.

As we have already mentioned, it is vital that government help to convene and bring the right groups and organisations together, as Professor May eloquently articulated, to address those gaps. I have already mentioned the regulatory network and the steering group.

Last but not least, there is an element of importance around the safety and confidence from a public perspective in engineering biology-enabled products, services and solutions.

Professor Isabel Oliver: First, it is really important to maintain a robust and resilient health security system and to continue strengthening our surveillance.

The second component is the importance of strong relationships between government, scientific organisations, industry, academia and policymakers. This ongoing relationship and dialogue is critical.

Thirdly, we need to strengthen our biosecurity system at all levels. However, this needs to maintain the flexibility to allow us to respond to new technologies and threats, and needs to enable the realisation of the benefits from these technologies, which will be critical to having the tools that we need to protect health from the threats that we know we are going to face in the future.

Professor Robin May: The benefit of going last is that I sound a bit like a broken record. My top three points would be very similar to those. Absolutely number one is the training and skills pipeline that we talked about earlier. If you do not have the training pipeline, you cannot get the staff to design these things or to regulate them when they come on to the market, so that is key.

Secondly, I would echo Michael's point about regulation up front, particularly thinking about these areas that we just highlighted and that potentially fall between gaps, and designing that flexible regulatory framework.

My third would be the underpinning infrastructure that will facilitate engineering bio coming to market. Part of that is physical infrastructure—so big pieces of kit—but the key aspect for me is around data infrastructure. How can we share data, particularly commercially sensitive data, from industry at a very early stage, so that we, in regulating it, have the information that we need to do that up front rather than always running to catch up from behind?

The Chair: Thank you very much. We are about to conclude the session, so I say a very big thank you to our three speakers for joining us this morning. I need to remind you that there will be a full transcript of the session, which will be sent to you shortly after the session for you to make any minor amendments. If you think of anything that you would like to have said—in two cases, we have had offers to send us further information—we would very much appreciate if you could send that in. That will become part of the formal evidence for our inquiry. Thank you very much and, at this point, the formal session is now terminated.