Home Office

ASRU Change Programme

Questions and Answers

Animals in Science Regulation Unit (ASRU)

Updated May 29, 2021

Contents

Introduction to Change Programme

What are the drivers for Change?

We have benchmarked our regulatory performance against the regulators code and best practice regulation and identified numerous areas for improvement.

Additional inputs which have assisted us in identifying the areas for improvement are:

- The Critical to Quality Report

Critical to Quality Report.pdf

- Review of the risks of regulatory failure

Risk Management of Regulatory Failure.ppt

- Concerns raised by the Animals in Science Committee and the Minister/Chief Scientific Advisor

Although the Change Programme started in advance of the 'One Home Office' initiative it is well aligned to and will complement that activity.

Some opportunities (in particular being able to assess the benefits and challenges with remote activities to assess the compliance of the regulated community) have arisen through the ways of working adopted during COVID 19

Although Brexit has not had a significant impact on our regulatory delivery there are potential opportunities especially the ability to independently move policy forwards in a political environment that supports clarity of policy and innovation.

What in particular have these inputs identified as areas for improvement?

Our benchmarking against good practice regulatory delivery has identified the following areas for improvement (all of which were confirmed by the critical to quality report):

- As a regulator we should more clearly differentiate our role to reduce confusion between our role, the responsibilities of the regulated community and those of other stakeholders.
- We should improve the consistent application of clear standards and processes to all aspects of our regulatory delivery.
- We could provide better training and career pathways aligned to regulatory practice to support and develop our staff.
- To enable the regulated community understand what they need to do to comply with ASPA and their licences, we should improve the quality, especially the clarity, user friendliness and extent of the regulatory guidance we provide.
- We should focus on the unique role we play in licensing of the regulated community to focus on integration of data, regulatory requirement and ensuring applicants for licenses meet the legal requirements and are best positioned to comply with ASPA.
- We should integrate and use evidence from a wide variety of compliance assurance activities to focus on areas of highest risk and demonstrate measurable decrease in risk.
- We should improve our regulatory delivery model. Currently with inspectors assigned to establishments there is the perception and/or reality of a high risk of regulatory capture. In addition, changing this model improves the degree to which work can be allocated flexibly according to changes in demand and/or business needs.
- We should improve and target the relationship management/customer service model we utilise with the regulated community more effectively to ensure it meets best practice and is clearly separated from regulated delivery and decision making.
- We should be proactive in horizon scanning so we can proactively develop and implement strategic policy.
- We should be more transparent in and add more value to the information and insight we provide publicly.

- We should improve our own internal systems to collect and use information, data, and insights.
- We should strive to be consistent across the whole of our regulatory delivery and interactions to drive clarity for the regulated community in how they can achieve and maintain compliance with ASPA.

These opportunities are summarised in the 10 strategic shifts which are driving our Change Programme.

ASRU Strategic Shifts FINAL January 2021.d

What other drivers for change are there? Is there a drive to save money or a response to a regulatory failure behind this?

The drivers are the ones we have described above. There is no drive to save money or reduce headcount and we are not responding to any specific incident or issue.

What is the scope of the ASRU Change Programme?

The programme team needs to deliver an **integrated solution covering all ASRU activities** including:

- Mapped processes.
- Procedural documents including policies, standard operating procedures, standards, and templates; and
- Job specific competencies, task grouping, job descriptions and organisational design.

The only area which is out of scope at this point is changes to primary legislation.

The team also has responsibilities to deliver an **integrated change plan** for ASRU, the regulated community and stakeholder groups which include:

- A communications plan for ASRU staff, the regulated community and stakeholder groups.
- Regulatory advice linked to the new ways of working; and training for ASRU staff and members of the regulated community

Change Programme scope.docx

Who Sponsors the ASRU Change Programme?

- The Ministerial Sponsor is Baroness Williams
- The Executive Sponsors are Jennifer Rubin, Home Officer Chief Scientific Advisor and Jenny Stewart, Director Home Office Science
- The Unit Sponsor is Will Reynolds, Head of ASRU

Who authorised the ASRU Change Programme?

Baroness Williams authorised the ASRU Change Programme based on review of the business case. The Minister will authorise changes to the business case as needed as new information becomes available and the Change Programme progresses.

Business Case for Change Programme.d

How are the Sponsors engaged in the Change Programme?

The Unit Sponsor has a formal update from the Programme Lead weekly and from the Programme Manager as required. He engages directly with the core Programme team approximately monthly.

The Unit Sponsor and Programme lead provide an update to the other Sponsors, the Chief Scientific Advisor and the Chair of the Animals in Science Committee on a monthly basis and as required.

Who provides input to the Sponsors?

- A Steering Committee is in the process of being established and will have its first meeting in May 2021
- The primary function of the Steering Committee is to provide strategic direction to the Change Programme in alignment with the purpose of ASRU and the Home Office to optimise delivery of benefits from the Programme.
- The Committee will achieve this through participating in the planning and oversight of the ASRU Change Programme and advising the Unit Sponsor.
- The Steering Committee will provide a stabilising influence so organisational concepts and directions are established and maintained, according to leading practice.
- The Steering Committee will monitor and review the project status, as well as provide suggestions on any future plans.

- Members of the Steering Committee ensure Programme objectives are being adequately addressed and the project remains under control.

Steering team Charter Final March 2

Who will be on the Steering Committee?

The Steering Committee will consist of the following members:

1. ASRU Head of Unit (Chair)
2. Frances Rawle (Ex-Director of Policy, Ethics and Governance, MRC):
3. Peter Holland (Chief Inspector, Crown Premises Fire Safety Inspectorate, Home Office):
4. Suzanne McCarthy (Ex-immigration services commissioner, Ex-CEO of the HFEA and Ex-CEO of the FSCS):
5. Professor Martin Lodge (Lecturer, London School of Economics):
6. Martin Vinell (PEL holder, Cambridge University):
7. Vicky Robinson (CEO NC3Rs):
8. Chris Sherwood (CEO RSPCA)

Who will be involved in the ASRU Change Programme?

- All of ASRU will be involved in different aspects of the ASRU Change Programme to different degrees depending on their interests and skills.
- Finn Lonsdale leads the programme and is accountable to the Sponsors for all deliverables and for the programme structure and coordination.
- Sree Pillai (supported by Farai Dangarembizi) is the programme manager and is responsible for all project management activities including programme planning, reporting and risk management.

How will we assess the impact of any changes on the regulated community?

A Regulated Community Change team has been established and met first on May 7, 2021.

The primary purposes of the Regulated Community Change Team are to provide input and guidance to the ASRU Change Programme through its Unit Sponsor, lead, and Change Team by:

- Providing feedback on the impact and deliverability of proposed changes on the regulated community
- Providing input into the development of change management plans for the Change Programme
- Assessing the robustness of the change management plan
- Monitoring the delivery and effectiveness of the change management plan
- Acting as champions for the change within the Regulated Community


Regulated
Community Change Te

Who are the members of the Regulated Community Change Team (RCCT)?

The following are members of the Regulated Community Change Team**.**
They have been specifically chosen to represent best possible diversity of named roles, establishment types and geography.

Please note any discussions with these members about the Change Programme must only be through the RCCT structure.

- John Hogan (PEL Newcastle)
- Steve Street (PEL Covance
- Gill Aitken (PEL Oxford)
- Miles Carroll (PEL PHE)
- Caroline Wilkinson (PEL CRUK Manchester)
- Lucy Whitfield (Agenda Vets)
- Richard Thomas (NVS Manchester/Birmingham/Keele)
- Linda Horan (NACWO, Unit Manager Strathclyde)
- Lynn McLaughlin (NACWO, Unit Manager Liverpool)
- Dominic Wells (RVC and UK Biosciences Consortium co-chair)
- Joanne Storey (GSK and UK Biosciences Consortium co-chair)

Bridging Ways of Working

Why is there a need for bridging ways of working?

The Change Programme were tasked to provide a recommendation for a change in ways of working for regulatory delivery (provision of regulatory advice, licensing, and assessment of compliance with ASPA) by April 2021

The primary reason for this is to free up resources to focus on further solution design tasks

The secondary reason for this is to start the process of aligning processes to the strategic shifts and obtain early feedback as part of a piloting mechanism.

What are the key components of the bridging ways of working?

1. Employing flexible multidisciplinary teams to deliver different aspects of regulatory activity to everyone in the regulated community as opposed to allocating inspectors and licensing staff to specific Establishments.

2. A regulatory delivery model for the highest risk Establishments (in special measures), which is more intense, structured with greater oversight than for other Establishments

3. The implementation of a focused relationship management model for Establishments

What teams will there be in the bridging ways of working?

The following teams will be configured:

Regulatory Advice Team

- This team will have oversight of all requests and answers from the regulated community for advice related to the interpretation of ASPA and the answers provided.

- Other than the lead, there will be 4 other inspectors forming the core regulatory advice team. Each of the total of 5 inspectors will be `on call` for queries on one day of the working week.

- The entire core team will also participate in the review of data, metrics and trends emerging from the team and using this data to help further develop and refine processes and standards within the Regulatory Advice Change Programme workstream.

Licensing Team.

- This team will be led by the Solution Design lead for Licensing and be supported by an Executive Officer who will be the administrative lead for the team. Core members of this team will be the Administrative Officers who will maintain responsibility for processing of licences with a focus on personal licences.

- All inspectors will be members of this team.

- The Lead will oversee a quality control programme for project licenses and will collect and review data, metrics and trends emerging from the team which will be used to help further develop and refine processes and standards within the Licensing Change Programme workstream.

Compliance Assurance Team.

- This team will be led by the Solution Design Lead for Compliance.

- This team will have oversight of all compliance assurance activities. The core team will deliver all compliance assurance activities.

- The compliance assurance activities will include:

    - Provision of facility, systems, and thematic audits

    - Monitoring of action plans for those establishments which are assessed as being of high risk of non-compliance (in special measures)

    - Enforcement activities through investigation and management of potential cases of non-compliance

    - Reviewing reports submitted which are part of compliance assurance (e.g. SC 18 reports, retrospective assessments)

- Each Establishment in special measures will be subject to enhanced and integrated oversight by an inspector from this team who will be responsible for overseeing all regulatory deliverables for that Establishment (including provision of regulatory advice, licensing, and assessment of compliance). This inspector will usually perform most of the regulatory deliverables themselves but will be assisted where needed by other members of the team.

- The entire core team will also participate in the review of emergent data, metrics and trends and the use of this data to continually develop and refine processes and standards within the Compliance Assurance Change Programme workstream.

Licensing

How will the assessment of project and establishment applications /amendments be conducted, and licenses issued/amended?

- All project and establishment applications and requests for amendments will continue to be submitted through ASPeL.
- Inspectors are decision makers for project licences. Permission settings in ASPeL will be changed so that inspectors will directly issue or amend project and establishment licences, and these will not require the involvement of the licensing staff.
- The oversight of project licences from those establishments in special measures will be by an Inspector assigned to that establishment within the Compliance Assurance Team. Depending on the establishment and the action plan the Lead Inspector may perform these assessments themselves or release them to the licensing team.
- Otherwise project licences will be assessed by all inspectors on a `taxi rank` basis. This means that as each inspector becomes available to perform review and assessment activities, they will be allocated the project licence which is next in the queue based on date of submission.
- They will complete these activities in the time when they are not dedicated to team-based activities.
- Once an inspector has performed an assessment of the first draft of a PPL that licence will be redirected back to them to review the changes made to the comments sent by them.

How will assessment and issuing/amending personal licences be conducted?

- This will continue to be the responsibility of the administrative officers.
- When personal licences are referred for decision making to an inspector the inspector will issue/amend the personal licence directly.

How will the knowledge that the assigned inspector currently has about establishments now be available when assessing license applications?

- It is important that any information that is taken into consideration in assessing licence application is objective and documented to ensure objectivity and fairness.

- Every establishment will have an established profile available to all ASRU staff which will be commenced by the currently assigned inspector and will be updated based on objective documented evidence from regulatory activities.

- We will also aim to make this profile available to the establishment.

- This will ensure that any decisions made for any particular licence application is based on all available documented objective information ASRU holds relevant to that licence application.

The `taxi` rank system sound quite rigid. How will urgent amendments (e.g. following unexpected results where severity is exceeded) be managed?

- Although most routine applications will be managed in the order they are received there will be processes to expedite licences assessment in some circumstances such as the one described above.

How will you ensure that the ability to expedite assessments is not misused for routine applications?

- Although there will be a transitional period, we do not intend that this system unduly benefits project licence holders who fail to submit routine applications in a timely manner.

- In such cases licence applications will continue to be assessed in the order in which they are received.

- Applicants who have protected animals maintained under expiring licence authorities where it is unlikely new authorities will be granted prior to the expiry of existing authorities will receive a time limited maintenance licence only until their full application is reviewed. This will prevent unnecessary duplication of use of animals due to expiration of licence authorisation. Please note that the failure to ensure adequate licence authorisation is always present for protected animals may be investigated as a case of potential non- compliance.

- We continue to recommend that any routine applications (not amendments) are received by ASRU 6 months before they are required and no later than 3 months before they are required.

How will applications for specialised project licences (e.g. those for regulatory toxicology, primate neuroscience or work in the wild) be assessed?

At the start of the bridging ways of working these will be assessed by a smaller group of inspectors with experience in the assessment of these licence applications. As the bridging

ways of working become establishments and standards for the assessment of these licence applications are in place we will assess if this approach is still necessary.

What does assessing the suitability of licence holders mean? Will this involve interviews?

The principle underlying this shift is that ASRU has primary responsibility for the licensing of people and has unique responsibilities to ensure they are suitable to hold such licences.

It is recognised that the modular training is only a preliminary training which permits the start of more specific training and competency assessment.

It is also recognised in feedback from non-compliance cases that there is often very poor understanding of the standard conditions for licence holders and that there can be substantial challenges in managing licence holders who have attitudes which are incongruent with the principles of ASPA.

We will explore all of the following areas:

- The optimum mechanism for all licence holders (PIL, PPL, PEL) to be trained and assessed both prior to granting of licences and any requirements for licences to be maintained. This could involve conducting interviews for applicants, but all mechanisms will be assessed.
- This can include solutions which replace current modular training system and/or have ASRU more involved in that system including delivering of training.
- Role for more detailed individual assessment of licence holder applicants by ASRU
- Role of requirements for ongoing training/development by licence holders and/or reassessment of knowledge/competence.
- Staged licences based on increased levels of training/competency.
- Standards for the assessment of attitude, knowledge and competency by project licence holders and establishment systems (including named persons and AWERBs)

What are the issues involving assessing applications for `service` or multiple generic licences?

- There are a range of different circumstances where PPL holders provide a service for other researchers by providing products or data
- These have in the past all been generally referred to as `service licences` and there has been variability in approaches to these.

- These may range from generation of GAA animals to regulatory toxicology and wide-ranging licenses offering oncology or infectious disease models or imaging.
- The key issue with these types of licenses is that the harms accrue to the PPL in question, but scientific benefit usually accrues to another party. This makes harm benefit assessment more complex.
- For both these types of license a key criterion is ensuring the presence of robust governance systems
- There are two main types of applications which have been considered within this description:
    - Those which provide products or data using repeated highly standardised protocols e.g. GAA production, antibody production, surgically prepared animal production, regulatory toxicology/ADME These meet the definitions of multiple generic projects and going forward these will be referred to in that manner.
        - With these applications the aim should be minimise regulatory burden in accordance with the risk.
        - For some of these applications it will be possible to generate standard criteria
    - Those which provide data using variable protocols usually as part of pre-regulatory drug development e.g. projects offering a range of disease models for use in compound screening for efficacy or safety. These often occur within academic institutions as well as within Contract Research Organisations or Pharmaceutical Companies.
        - We aim to develop a different approach to these applications based on the associated risk and variability.

Regulatory Advice

How will you ensure the response time to queries for advice does not increase?

Our pilot activities indicate that having dedicated staff who can answer regulatory queries will make the timelines for receiving answers for regulatory advice shorter. However, we will also monitor these timelines and reassign resources if the timelines for answering these questions lengthens.

How will applicants be able to obtain early guidance as to how to structure their project licences? This has been very valuable in the past.

We plan to provide far clearer guidance to applicants and named persons to enable a higher level of capability within establishments to address some of these questions. However, where this type of advice is needed it can be obtained via the regulatory advice team.

Compliance Assurance

This sounds like it is all just focusing on non-compliance. Why is that?

- Actually, this an approach focusing on compliance rather than non-compliance.
- This is different in that it aims to assess the systems in place to ensure compliance and as such is far broader than merely managing non-compliance. It is preventative rather than reactive and supportive rather than punitive.
- Through assessing compliance, we can understand how best to clarify expectations and support licence holders to develop and implement systems which reduce the risk of non-compliance.
- Of course, this approach does incorporate the management of cases of potential non-compliance but only as one strand of overall activity.

Why are you starting to use the word `audit `instead of `inspection`?

There is some confusion currently with some groups/individuals thinking inspection refers only to activities conducted `on site`. An audit is a process which verifies conformance to standards through review of objective evidence. Thus, this word which incorporates the purpose of these activities in a better way than the word `inspection` does which focuses only on the activity itself.

What do the different types of audit mean?

- A **facility audit** is based on the facility itself to ensure it meets code of practice and other standards
- A **systems audit** looks at governance systems within an establishment or a project to understand how robust they are at maintaining compliance
- A **thematic audit** looks at one particular area of compliance across the regulated community to assess the overall approach to maintaining compliance in this area.

Have you looked at learnings from other regulators which operate audit regimes?

Yes, we have looked at learnings from other regulators operating regulatory regimens. In particular our integration of systems, facility, and thematic audits with other sources of information to make an overall assessment of compliance is, we believe, a more robust and risk-based approach than some other audit-based regimens. In addition, we intend to maintain a supportive approach to audits which will reduce the risk of decreased transparency from the regulated community.

How will the on-site visit programme be organised and managed?

An onsite visit programme will be planned and adjusted based on risk.

On-site visits will be prioritised as follows:

- For the investigation of any potential non- compliance which is likely to have a remedy exceeding inspector advice. This investigation should serve as an opportunity to perform a holistic audit of the establishments governance system.
- To any establishment which houses special species which has not received an audit for any other reason in the last year.
- For any focused reason which cannot be performed remotely (e.g. approval of facilities where this cannot be done satisfactorily by remote means)
- Any establishment which has not received an on-site assessment within the past 3 years.

What is meant by thematic audit?

Every quarter a remote activity will be held which assesses a particular area of compliance. These areas will be selected based on emerging evidence on areas of risk.

Examples of these types of activities could be:

- Review of procedures in place in establishments to prevent unauthorised procedures
- Assessment of understanding of Named Veterinary Surgeons of PPL Standard Condition 18
- Mechanisms for PPL holders holding neuroscience primate PPLs to ensure they are conducting procedures in the most refined way
- Commissioning of work on service licences
- Review of AWERB functioning
- Review of particular training and competency records

Each of these activities will be led by one individual to ensure consistency. This individual will be different each quarter and may not be a member of the core Compliance Assurance Team to ensure all inspectors are involved over time in compliance assurance activities.

Will you be transparent about the standards and processes you will be using for audit?

Yes, we will be transparent about all standards and processes we will use. We will also operate a feedback system which ensures we can refine any of these as we move forwards.

Why are you using the word `enforcement`?

- Again, this is linked to some confusion about the words we currently used. For example, our current `Compliance Policy` is actually a policy for managing potential cases of non-compliance.

- We have tried internally to shift the language to using the term `non-compliance` but this still causes confusion.

- Most regulatory bodies use the word enforcement to describe the process of managing cases of non-compliance and so we have decided to use this word to clarify the position and align to commonly used regulatory terminology.

This approach will decrease the openness that establishments currently have with their inspector and it is likely to result in licence holders hiding things and therefore decrease the impact of the regulator. How will you deal with that?

- The primary purpose of our compliance assurance activities is supportive and not punitive. We know that most members of the regulated community want to comply, and we aim to support them in that by improving the clarity of our guidance and consistency of the advice we give.

- The way in which we conduct audits will still be collaborative and supportive and although there will no longer be a relationship with 1-2 inspectors we expect there to be a supportive and meaningful engagement with a larger variety of inspectors who will be engaging with you.

- Given that nearly all potential cases of non-compliance are currently self-reported by the regulated community we do not expect that this will change significantly. However, we do believe that this more consistent and targeted approach will provide more clarity and support to detect risks to compliance and address them before non-compliance occurs.

Why are PPL Standard Condition 18 reports reviewed by the Compliance Assurance team? They are not about non-compliance?

As mentioned above the compliance team is assuring compliance by reviewing evidence which demonstrates compliance not merely managing potential non-compliance. PPL Standard Condition 18 reports are part of the evidence which demonstrate compliance.

We know there is some confusion about PPL Standard Condition 18, and we are in the process of updating regulatory advice on this subject which we will implement in the summer.

Why have you decided that special measures will only be applied to establishments? What about project or personal licence risk?

- In this context establishing the `risk of non- compliance` within an establishment aggregates the risk from the establishment itself, the project licence holders and personal licence holders
- These three governance systems are so interlinked they cannot be separated.
- This assessment is not related only to the systems which are the accountability of the establishment licence holder but to all systems existing within the establishment and thus covers all activities occurring within the establishment.

How will Establishments be assessed as requiring special measures?

At the start of this bridging plan the proposed criteria for being considered in special measures will be:

- Establishment or any licensee within the establishment which has had a compliance notice, or any licence revoked/suspended in last 12 months (Article 13 or as remedy to NC case)
- Establishment which has had any noncompliance involving special species in the previous 12 months

These have been chosen as they represent the only objective criteria which are consistently applied.

Establishments who meet these criteria as of June 2021 will undergo a full systems audit between July and September 2021. On the basis of the results from these audits, together with the non-compliance history an initial decision will be made for the first establishments to enter Special Measures in October 2021.

As the way of working continues to be refined and compliance assurance data becomes more consistently documented and shared these criteria will be refined.

Why are you naming these establishments as being in `special measures`? This has negative connotations from for example OFSTED.

We have reviewed this question at some length. Discussion with legal advisors have confirmed that the term `special measures` should be used consistently across regulators where increased scrutiny and specific action plans are put in place to ensure risks of non-compliance are adequately addressed. This term implies that such establishments need increased support from the regulator in order to be able to comply and we will ensure the supportive element of this process is emphasized.

What will the implication be beyond ASRU for establishments in special measures?

ASRU will not publish or release the names of individual establishments which are in special measures. Any awareness therefore that an establishment is in special measures will only be if the processes within that establishment require that this is communicated elsewhere.

How will Establishment risk be monitored and assessed?

There will continue to be a quarterly risk management/compliance assurance review meeting for Establishments overseen by the Chief Inspector.

The main purpose of this meeting will be:

- To assess overall progress of those Establishments in special measures
- Determination if pre-set criteria for Establishments moving into and out of special measures have been met
- Review of themes of risk emerging from previous quarter and approving appropriate action plans
- Confirmation of theme for focused compliance assurance activity programme

Between risk meetings there will be a schedule of regular meetings covering the following business needs:

- A deep dive meeting for each Establishment in special measures to reassess the pan and progress against the plan
- Review of complex non-compliance cases to assess lessons learnt and ensure these are communicated and applied across the organisation
- Review of focused compliance assurance activity outputs to determine themes and actions needed

Overall Questions on Bridging Ways of Working

How will flexibility be achieved in these ways of working?

Although Inspectors and Executive Officers will be allocated to one team as core team members, they will also be allocated tasks from other teams through the Team Lead as required to meet business needs. Team Leads will work closely together to do this in an integrated way.

How will these ways of working free time for the Change Programme?

- Firstly, the time for all staff across the Unit to participate in the Change Programme will be ringfenced. The time commitment involved will vary for each individual and over time.
- Secondly there will be efficiency in the focused way of team working.
- In addition, some work will be redistributed between different staff types which will increase efficiency.
- Allocation of project licences on a `Taxi Rank` basis ensures an equitable distribution of work and will prevent the build-up of individual workloads due to demand fluctuations
- Compliance assurance activities will be more focused to optimise their impact.

When will the bridging ways of working be implemented?

- It is anticipated these will be implemented in July 2021.
- During May 2021 there will be targeted engagement (Steering Team, Regulated Community Change Team, and Animals in Science Committee).
- During June 2021 there will be broader communication with the regulated and stakeholder communities.
- During the next two months the ways of working will continue to be developed and refined and further communication/training will be rolled out to you.

How long will these ways of working be in place?

- Implementation of ways of working will provide input to the Change Programme to inform the best ways of working in the longer term.
- Exactly when and how these ways of working will transition or be refined will depend upon emerging evidence and review.
- However, it is not anticipated that these ways of working will be in place for less than a year although minor refinements will be made to optimise them.

Who will be accountable for implementing the bridging ways of working within establishments?

This will be the accountability of the Establishment Licence Holder/Named Person Responsible for Compliance.

Has a formal impact assessment been completed on the bridging ways of working? Is it possible these changes may make the research sector within Great Britain less competitive?

A formal governmental impact assessment on the bridging ways of working is not required nor planned. None of these changes are creating a new regulatory requirement or higher bars so we do not anticipate any negative impact on the competitiveness of the sector.

However, we will closely monitor the effects of these changes on the regulated community and the Regulated Community Change team will be a critical mechanism to give feedback on unintended impacts.

Will the guidance on the Operation of ASPA be changed?

Yes, we intend to replace the current Guidance and replace it with a much smaller Guidance document that meets the statutory requirement for such Guidance as outlined in ASPA Section 21(1). Our intention is to create a web- based user friendly dynamically updated system of operational guidance for the regulated community which will replace the current advice notes and the operational content of the Guidance.

Assigned inspectors currently play a role in enabling members of the regulated community connecting with other researchers within Great Britain conducting similar research? In this model how will this be managed?

Researchers will have their own networks to contact researchers in other fields without needing the assistance of the regulator. However, where ASRU is aware of other researchers who have particular information or experience especially with interpreting or applying regulatory guidance they will continue to provide opportunities for researchers to make contact with each other.

How will inspectors be made aware of specialised areas such as drug discovery and development?

We will continue to ensure that all inspectors receive ongoing training on specialised areas which we regulate.

External Engagement Framework

Why have you developed an External Engagement framework?

- One of the key priorities of the Change Programme is to ensure that we are clear about our role as a regulator.
- Our review of our current way of external engagement is that it tends to be driven from outside ASRU with little clarity from within ASRU as to exactly what the purpose of the engagement should be.
- In addition, we have not clearly segmented the external engagement we do in order to interact differently with different stakeholders.
- The external engagement framework aims to address both of these challenges.

Is this all about less external engagement?

- We know that external engagement is an important part of our deliverables.
- This framework is about making sure we have value added and appropriate engagements based both on our needs as the regulator and the different needs of those we engage with.

How does the framework work?

The framework segments those we engage with into different groups so that we can be specific about the purpose and mechanism of engagement with each group.

There are three main groups identified:

- Other government departments
- Sectoral advisory bodies
- The public which is further subdivided into:
    - Advisory Group
    - Special interest Groups
    - The Regulated Community

What does inter-department engagement focus on?

- Engagement with other departments such as DEFRA and BEIS focuses on ensuring the accountability for policy ownership is clear and that we collaborate on areas which fall across more than one policy area.
- At a high level for example BEIS is accountable for the promotion of research, industry, and science whereas DEFRA is accountable for animal welfare whereas we are a regulator with a purpose to administer ASPA.

What are sectoral advisory groups?

- These are organisations which have an input into the research process or research governance
- This includes funding organisations, NC3Rs and modular training accreditation bodies
- As such they may set standards or policy which ASRU may mandate are met as part of their regulatory requirements
- From ASRU`s perspective the focus of the engagement with these bodies is to understand the process by which they develop policy and standards so ASRU can determine whether and how these policies/standards can be incorporated into the regulatory framework

How does ASRU see its engagement with the public?

- ASRU serves the public through administration of ASPA and engagement with the public (as our ultimate customer) is therefore important
- However, it is challenging due to the diversity of public opinion and information asymmetry
- The most knowledgeable amongst the public are represented by special interest groups and it is critical that these groups do not promote their own agenda in an unbalanced way with the regulator which could influence regulatory practice
- Although the regulated community are themselves part of the public there is a need for a different type of engagement with them due to the regulatory relationship

The three key mechanisms for true public engagement are:

- Through the website and published reports

  We aim for this to be more two way and there are opportunities to present material in a more engaging manner

- Through the Ipsos Mori poll

- Through integrated objective input from the Animals in Science Committee

What is the role of the Animals in Science Committee (ASC)?

- The ASC is the Independent Advisory Committee to the Minister/Department which is tasked with providing strategic policy advice in a balanced objective way on matters related to ASPA

- The ASC is thus the route by which an `informed` public has input into the nature and implementation of regulation

- Members of the committee are not representing the organisation or sector from which they belong but are working collaboratively to advise in a balanced way bringing information from their background.

- They are also not promoting their own or their organisation/sector agenda but fulfilling a duty to provide an evidence based holistic position to the Minister on behalf of the public as a whole.

What do you mean by Special Interest Groups?

- These are special interest groups excluding those from within the regulated community

- They are primarily animal welfare and protection groups (e.g. RSPCA, CFI, PETA etc)

- Engagement with these groups is a way of increasing understanding of the way ASRU regulates and the outcome of those regulations

- These engagements must not be an opportunity for these groups to directly influence ASRU towards particular regulatory priorities or approaches as this would be unbalanced

- The views of these groups (as subgroups of the public) should be reflected in a balanced way by the objective evidence-based input from the ASC.

How do you see engagement with the regulated community?

Our primary engagement with the regulated community is by delivering regulatory services (provision of regulatory advice, assessment of licence applications and assessment of compliance.

This is supported however by three other activities:

- An opportunity for the regulated community to provide assessment of impact of ASRU changes through the Regulated Community Change Team
- Communication routes with the regulated community through a variety of mechanisms (newsletters, meetings, website)
- An operational level relationship management model

In addition, the regulated community is itself a subsection of the public and so their perspective must be included in balanced objective way as part of the overall ASC strategic policy advice to the Department and the Minister.

It is important this input on strategic direction is arm's length from the regulator itself to reduce the risk of regulatory capture at a policy level.

What principles guide your interaction with the regulated community?

With regard to the regulated community the regulators code advises how we should best interact with those we regulate.

- The Regulators should carry out their activities in a way that supports those they regulate to comply and grow
- Regulators should provide simple and straightforward ways to engage with those they regulate and hear their views
- Regulators should base their regulatory activities on risk
- Regulators should share information about compliance and risk
- Regulators should ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply
- Regulators should ensure that their approach to their regulatory activities is transparent

Based on this code we have developed our principles for engagement with the regulated community:

- **Regulatory independence**

There will be clear separation of relationship management from regulatory decision making both at a strategic(policy) level and tactical level (implementation of policy on a particular case)

- **Equal access**

All members of regulated community will have equal access to the regulator to create a regulatory playing field

- **Transparency**

ASRU will share what it does and how it does this with the regulated community in a meaningful way

- **Objectivity**

ASRU will conduct its regulatory activities in a way which is clearly documented against objective standards

- **Fairness**

ASRU will conduct its regulatory activities according to clear standards and criteria applied consistently to all within the regulated community

What do you mean by an operational relationship management model?

- Although it is important that the regulatory decisions we make are not directly influenced by our relationships with the regulated community it is important from a customer service perspective that we do manage our relationships with the community.

- From a customer service perspective, the regulated community expects that the regulatory services they receive are in line with the principles outlined above.

- In particular they expect that there will be clarity as to the timelines in which regulatory activities will be completed. We will be developing, jointly with the regulated community, service level agreements as to the levels of service which will be provided.

- We will be appointing an individual who will be responsible for operational relationship management for the regulated community. They will be assisted by others as needed.

The key activities this individual will perform will be:

- Conducting a quarterly meeting with the Home Office Liaison Contact (HOLC) at each establishment to understand if there are any issues or concerns about any aspect of regulatory delivery
- Overseeing the conduct of an annual regulated community survey (which will include all members of the community included project and personal licence holders)
- Overseeing communication mechanisms with the regulated community (i.e. newsletters, meetings, website updates)
- Measuring delivery against service level agreements
- Managing the formal complaints process.

This individual will not be involved in any regulatory delivery (i.e. dealing with a specific licence, audit, or regulatory advice question) but will work instead at the overall relationship management level.

What about engagement with the regulated community as a whole?

There is already an established mechanism for the regulated community to engage with ASRU which is the UK Bioscience Sector Coalition (UKBSC) and ASRU engagement will be primarily through the policy group of the UKBSC at the stakeholder meetings described below.

The chairs of the UKBSC are also members of the Regulated Community Change Team

How will stakeholder meetings occur?

We intend that ASRU will hold regular meetings (6 monthly or annually once the Change Programme is complete although this may be more frequent during the Change Programme) with all its key stakeholders together.

This means that all stakeholders hear all the same information together and receive the same answers to all questions and there is no risk that messages drift in different meetings with different stakeholders.

Invites to these meetings will be issued to.

- Animal protection and welfare group representatives
- The UKBSC policy team members representing the regulated community

- Representatives of the NC3Rs and Accreditation bodies.

In addition ASRU will accept invites on a case by case basis to present at meetings organised by individual members of the UKBSC(e.g. LAVA, LASA, IAT, HOLTIF) provided the purpose of the engagement is limited to communicating and clarifying the position , process and deliverables of the regulator.