Food and Environment Research Agency

A Hampton Implementation Review Report

December 2009

BIS Department for Business Innovation & Skills

BRE BETTER REGULATION EXECUTIVE

Food and Environment Research Agency

This review is one of a series of reviews of regulatory bodies focusing on the assessment of regulatory performance against the Hampton principles and Macrory characteristics of effective inspection and enforcement. It was carried out by a review team drawn from the Better Regulation Executive, the National Measurement Office and the Gangmasters Licensing Authority, in July 2009.

Further information about the reviews can be found at:
http://www.berr.gov.uk/whatwedo/bre/inspection-inforcement/implementingprinciples/reviewing-regulators/page44054.html

EXECUTIVE SUMMARY AND CONCLUSIONS

Key findings from the review:

The review team found that the Food and Environment Research Agency (Fera) demonstrates good compliance with the Hampton criteria in several areas, and has examples of recent good practice in strengthening its performance. Its recent creation provides further opportunities to improve its approach, for example how it shares information and requests data from business.

Key findings are:

- Fera is largely risk-based in its approach. For example GM audits are focused on certain home-grown seeds and all imported seeds which are known, based on scientific evidence, to be more at risk of adventitious GM presence.
- Good progress has been made on reducing the number of forms, especially on the seeds side. Fera also makes good use of both the online seed certification system and web based online forms.
- There were good examples of Fera working with business to develop practical approaches to implementation of European regulations. For example, as a result of industry feedback, Fera ensured flexibility with early movement of seed before certification processes are complete.
- Inspectors were valued for their expertise. They were keen to work with industry to correct and remedy problems rather than resorting to sanctions.
- There has been a licensing regime in place for the past 20 years in the seeds area. Fera licenses individuals to carry out crop inspection, seed sampling and seed testing work. Fera then samples and monitors this work to ensure it is up to standard. Having the licensing regime in place minimises the number of inspections required and is a good example of Hampton principles at work

Main issues for follow-up identified

The key follow-up issues identified are:

- Fera should consider greater involvement of

during the review: inspectors and stakeholders when developing the UK negotiating position during the initial phases of the EU policy making process. Impact Assessments should be used at the earliest appropriate stage in policy development.

- Advice and guidance should be reviewed to ensure it is accessible to the hardest to reach groups and new entrants as some of it is very specialist, particularly in the plant health areas. Fera should consider new and innovative ways of providing this advice and guidance and communicating it to stakeholders.

- Fera should review its risk model for seeds inspections to ensure that it is effective and that regularly compliant businesses are not unnecessarily overburdened with inspections simply due to the high volume of seed processed.

- It was not always clear to business, in the plant health and seeds areas, how and why inspections were conducted. Fera should revisit its communication strategy to raise awareness.

- Fera should use its intelligence on levels of compliance across seeds and plant health to evaluate whether the sanctions it currently has are sufficient, whether more are required, and whether they should seek access to expanded sanctioning powers under the Regulatory Enforcement and Sanctions Act (Macrory sanctions) in consultation with policy and enforcement staff and the regulated businesses.

- Fera is a new organisation and as such we recognise that it is still in the process of developing its strategy for inspection and regulatory affairs. It has published a Strategic Direction and Corporation Plan setting out ministerial targets and the business plan. The agency should work to ensure Fera's staff and external stakeholders recognise the outcomes it is trying to achieve.

INTRODUCTION

Introductory background information about the regulator such as the rationale for establishing it:	The Food and Environment Research Agency (Fera) was launched as an executive agency of the Department for Environment, Food and Rural Affairs (Defra) on 1 April 2009. Fera brings together the Central Science Laboratory (CSL), the UK Government Decontamination Service (GDS), the Plant Health and Seeds Inspectorate (PHSI), the Plant Varieties and Seeds Division (PVS) and the Plant Health Division (PHD). The regulatory work of Fera forms a relatively small but very important part of its remit. Only the areas for which Fera has regulatory responsibility, more specifically the work of PHSI, seeds and GM regulatory areas, were in scope in this Hampton Review.
The legislation establishing the regulator:	Fera is an organisation established by the Secretary of State for Environment, Food and Rural Affairs and supplies goods and services to Defra, other government departments, and the private sector. Section 1 of the Agriculture Act 1986 enables the Minister to provide goods and services connected with agriculture, food and the countryside. The Secretary of State has overall responsibility for Fera and is accountable to Parliament for all matters concerning the Agency. The Secretary of State for Environment, Food and Rural Affairs is responsible for the overall policy and financial framework within which Fera operates. In addition, the Secretary of State chairs the Ministerial Board overseeing the Government Decontamination Service. In practice the Secretary of State may empower the Minister to act on his/her behalf on all ownership matters related to the Agency. In 2009 Fera is included in the portfolio of the Parliamentary Under Secretary of State - Lord (Bryan) Davies of Oldham. The Chief Executive of Fera is Adrian Belton. A significant amount of Fera's work is UK-based. However, there are some devolved areas: • In the area of plant health, Fera, together with the devolved administrations and the Forestry Commission (FC), forms the UK Plant Health Service and works with other EC Member States

and the European Commission to agree appropriate plant health rules for Europe and to co-ordinate their implementation.

- In the area of GM inspection, Fera's responsibilities apply to England only.

- In the area of seed certification, Fera is the certifying authority for England and acts on behalf of the Welsh Assembly Government as the certifying authority for Wales (there are separate certifying authorities for NI and Scotland).

- The Plant Health Act 1967 makes the Forestry Commissioners responsible for plant health in relation to forest trees, and the Agriculture Departments in relation to other plants. Forest trees are not defined, and in the case of amenity trees, or pests of both forest trees and other plants, close co-operation between the two authorities is necessary.

This review focused predominantly on the work of Fera in England and did not cover bee health as this was subject to another recent review by the National Audit Office (NAO).

The regulator's statutory remit or objectives:

Fera's overarching purpose is to "support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks".

Key themes of the Agency are:
- plant and crop protection;
- food chain safety;
- environmental risk assessment and crises response; and
- promoting better integration between policy development, scientific evidence and inspection services.

Scope of Fera's activities include the following:

Regulatory activities (with which this Review is concerned)

Fera's regulatory activity is carried out within the scope of the Plant Varieties and Seeds Act 1964, the Plant Varieties Act 1997, the Plant Health Act 1967 and the Bees Act 1980. Fera has the UK lead responsibility for

the transposition of EU legislation, and implementation of obligations under international treaties and conventions, through a number of Statutory Instruments made under these Acts.

Research and Assurance Activities:

Fera also provides science and research services to underpin national policy, inspection and response functions. Fera supports the food, water, environment and plant health industries in meeting consumer protection legal requirements, by operating a number of Proficiency Testing Schemes that provide assessments of technical performance of their own analytical laboratories. Fera's aim is to be a respected provider of innovative and purposeful science support and advice.

Fera's national laboratory is also a contract laboratory and service provider to government customers and the commercial sector. Through this service provision, Fera supports UK and international business. Fera aims to encourage exploitation of these commercial opportunities and the generation of additional income in order to help underpin the infrastructure of the Agency.

Response and Recovery activities:

Fera incorporates the Government Decontamination Service (GDS) which provides an essential element of the nation's capability to respond to, and recover from, emergency situations, including the deliberate (CBRN) or accidental (HazMat) release of chemical, biological, radiological or nuclear materials.

The GDS provides advice, guidance and support to those responsible for dealing with the consequences of an accidental or deliberate release of hazardous materials. It also facilitates quick access to an assured Framework of specialist suppliers able to offer appropriate decontamination and related services in response to a CBRN or major HazMat incident.

The regulator's budget:

Fera is required to recover the full costs of its services. This includes the cost of internal programmes to ensure Fera's scientific expertise, and investment to maintain and develop appropriate infrastructure and capability.

	The Agency has a planned income and expenditure of some £72 million for 2009/10, and the Agency expects this to rise to £73 and £74 million in the next two years.
Number of staff (including breakdown of policy and frontline staff):	Fera has a starting complement of about 900 staff. The majority of the staff and activities are based at Sand Hutton near York; however there are also significant outstations at Cambridge, Woodchester Park, Stafford and Heathrow. In addition it has about 150 inspection staff based either at home or at nearly 40 offices throughout England and Wales.
The sectors and number of businesses regulated either directly or indirectly:	Fera has over 40,000 customers and 1,000 collaboration partners spread over some 102 countries. This stakeholder base is made up from Government, academia, industry and commerce and, whilst a significant proportion of Fera's work is UK based, it has global reach across the EU and more widely in over 100 countries.

THE HAMPTON VISION

Both the Hampton and Macrory reports are concerned with effective regulation – achieving regulatory outcomes in a way that minimises the burdens imposed on business. Key to this is the notion that regulators should be risk-based and proportionate in their decision-making, transparent and accountable for their actions and should recognise their role in encouraging economic progress.

Any findings relevant to whether the regulator is risk-based:	Fera is largely risk-based in its approach. For example audits for GMOs in seeds are focused on certain home-grown seeds and all imported seeds which are known, based on scientific evidence, to be more at risk of including adventitious GM presence. There was some concern expressed by stakeholders, particularly in relation to seed certification, that inspectors do not always appear to target 'poor' (non-compliant) companies instead of the 'good' (compliant) businesses.
Any findings relevant to whether the regulator is transparent and accountable:	Fera is currently subject to Defra's enforcement policy. More transparency is needed around inspection decisions and enforcement activities, specifically how they link to compliance.
Any findings relevant to whether the regulator encourages economic progress:	Fera successfully provides a regulatory framework that allows the industry to operate effectively. In light of the wealth of scientific expertise in GM crops it is important the GM Inspectorate input sufficiently into this debate, whilst recognising the ethical and political sensitivities. Fera should consider the potential barriers to entry that appear to exist in the seed and plant growing industries for which they have regulatory responsibility, and the impact of these on economic progress.

DESIGN OF REGULATIONS

Hampton principles

All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all parties should be consulted when they are being drafted.

When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.

Key findings on Design of Regulations:

- The policy framework for Fera's regulations in the seeds and plant health areas comes from Europe.
- Fera recognises the importance of getting involved in EU policy development early on – for example they recently gave up around 50% of Senior Executive Officer (SEO) time to the Commission on Phytosanitary Measures, which is the body which sets plant health standards under the SPS (Sanitary and Phytosanitary Agreement) agreement.
- Fera effectively gathers and uses stakeholders' ideas in the design of regulations, particularly at implementation stage, resulting in a practical approach to implementation of regulations. For example, as a result of industry feedback, Fera ensured flexibility with early movement of seed before certification processes are complete.
- The key representative groups have six-monthly meetings with Fera through which they feed into the design of policy, as well as contributing to formal consultations.
- Inspectors have been successfully involved in the development of policy and design of regulations. For example, inspectors suggested a modification to the proposed 50 meters separation between seed potato crops as this was simply not practical for growers, and they fed back a request from producers that sample sizes be increased from the proposed 25 tonnes to 30 tonnes – so that it would be in line with the current maximum lorry weight

capacity.

- Across regulatory areas, inspectors and stakeholders felt more involved in the design of the implementation aspects of regulations rather than the development of UK negotiating position during the development of EU legislation.

- It was not clear if Fera is always making the best use of Impact Assessments at the earliest possible stage in policy development.

- Fera is not responsible for the GM policy it enforces, but it has a lot of scientific and inspection expertise in this area. To influence the GM agenda Fera is linked in to a European network of GM inspectors that exchange ideas. Stakeholders raised some concerns that Fera may not be adequately involved in GM policy issues at the national level.

- One trade association said it was pleased to see Fera incorporating the policy/technical/enforcement capability within the new agency as they thought this would help policy-makers better understand the practicalities of the industry.

Background information such as the regulator's role in developing regulations:	Fera has the policy development responsibility for plant varieties, seeds, plant health and bee health in England and advises Defra Ministers on UK policy options in the plant, seed and bee sectors in consultation with the devolved administrations and other appropriate actors such as the Forestry Commission. Defra is the competent authority for GM policy and issues licences for GM trials. Plant and bee health policies are based on harmonised EU regimes. Similarly, plant variety and seeds policies are heavily influenced by EU legislation. In all cases the framework for policy is set at the EU level, while some interpretation is made at the national level.
Any examples of significant good regulatory practice:	Taking into account national factors when implementing EU Directives - The regulator amended the original "early movement" scheme proposals to allow seed processors to market seed to the customer while awaiting the official germination test results from the licensed testing station. This system is well-liked by

	the industry.
Review findings: The extent to which the review team believes the regulator is acting in line with the Hampton principles:	The policy framework is set at the EU level and in some cases, for example phytosanitary legislation, there is no scope for differences in implementation between countries. However, in other areas there is room for national interpretation. Fera is proportionate, taking into account industry needs when implementing these regulations. Fera has some good examples of getting involved early on to influence the design of EU policies so they are more proportionate. They have been pushing, at the EU level, for a review of this legislation against Better Regulation principles. Stakeholder and frontline staff views are sought prior to implementation. There are some areas that Fera can develop further. For example there seems to be wider scope for stakeholder and front line staff involvement at the negotiation stage of the design of EU regulations.

ADVICE AND GUIDANCE

Hampton principle

Regulators should provide authoritative, accessible advice easily and cheaply.

Key findings on Advice and Guidance:

- Fera makes good use of online resources.
- Fera also delivers advice and guidance through inspections, with stakeholders highlighting that their inspectors are a valuable and respected resource.
- Businesses seem confident to approach Fera for advice and guidance. In general, stakeholders felt the advice and guidance available "is fairly well developed" and they appreciated the mix of published guidance and face-to-face contact during inspections.
- However it was noted that it could be improved:
  - so that it is easier for new entrants to the market to find – although it was noted that there are not many new entrants to the market.
  - by being more innovative in the way the data is presented to users – the current data "is bland and factual – dry".
  - by including some extra useful information, for example one trade association was concerned about the inconsistency of seed potato rules between England and Scotland and suggested Fera consider putting the Scottish requirements on their website to make it easier for the business to 'export'.
  - so that it is clearer what Fera's enforcement policy is. Currently Fera does not publish its own enforcement policy – it refers to the Defra enforcement policy.
  - by using more user-friendly language - "garden centres are not scientists".

Background information such as the means by which

Fera provides a large amount of advice and guidance, some of which is for very highly specialised stakeholders. These stakeholders range from hobby

the regulator provides advice and guidance:	farmers through to multinational food producers. This advice and guidance is provided on Fera's website, which is clear and easy to use. Stakeholders also receive a lot of advice and guidance directly from Fera, either by ringing up the organisation, via publications such as the Varieties and Seeds Gazette, or from inspectors when they were carrying out inspections.
Any examples of significant good regulatory practice:	Inspectors perform an important advice and guidance role alongside their traditional inspection tasks. Stakeholders valued the availability of experts whose contact details are listed in Fera's monthly Varieties and Seeds Gazette.
Review findings: The extent to which the review team believes the regulator is acting in line with the Hampton principle:	Business appreciated the mix of published guidance and face-to-face contact during inspections. They felt comfortable to go to the Fera website or contact Fera directly to access advice and guidance. Inspectors emphasised the importance of advice and guidance in securing compliance. Fera needs to ensure that its guidance and advice is accessible to the hardest to reach groups and new entrants as some of it is very specialist, particularly in the plant health areas. There was some concern that the technical nature of the industry, in the absence of easily accessible advice and guidance, could prove a barrier to entry. Fera should consider new and innovative ways of providing and communicating such advice and guidance to stakeholders.

DATA REQUESTS

Hampton principle

Businesses should not have to give unnecessary information or give the same piece of information twice.

Key findings on Data Requests:

- Fera requires a lot of information from business. However stakeholders were generally content with the volume and method of requesting this information.
- There were some suggestions from external stakeholders around how to further improve the coordination of this information and reduce duplication. Some of these suggestions may require action in Europe, for example reviewing the official seed certification labels process to minimise the need for double printing. Other suggestions could be reviewed domestically, such as better communication between Plant Health and the Forestry Commission, e.g. the Forestry Commission had banned the Oak Processionary Moth but PHSI were not aware of this.
- Fera has made good progress on reducing the number of forms, especially on the seeds side. They also make good use of online forms. Fera should explore ways to reduce/ rationalise forms further.
- Fera is looking at lifting barriers to information sharing with other Government departments and agencies to help coordinate Fera's work. There may also be some opportunities for Fera to rationalise databases, as a result of the recent merger, to allow for better access to information.

Background information such as the data required by the regulator; the means by which

Fera places a number of direct data requests on businesses under the seed certification, plant passporting and GM audit and inspection regimes. In most instances there are both electronic and paper

business can return data, etc:

based means of returning this data.

Seed certification:

- A company or person who wants to market seed covered by the seed marketing regulations must be registered with Fera. This registration is a one-off process and can be completed online or on paper.

- A registered person is required to maintain proper records of all their transactions in seed, testing and other operations undertaken in relation to seed.

- There are a variety of forms which need to be completed in relation to making an entry for certification of a crop or seed lot. The application forms are all sent to the National Institute of Agricultural Botany (NIAB) who deal with all technical aspects of seed certification. These can be completed on paper or online. In 2004 Fera set up an online seed certification database (ESP) for businesses to use to submit these forms. Around 70% of businesses now use the ESP system.

- Seed testing stations, seed samplers and crop inspectors are required to be licensed. A candidate must pass an official examination before s/he is licensed.

The key steps in Plant passporting are as follows:

- Registration with the Plant Health and Seeds Inspectorate (PHSI). This is a one-off paper-based process.

- Application to be authorised to issue plant passports. This is an annual process – licences must be renewed each year.

- Production of a plant passport for high risk plants and plant products within the EU, and all plants or plant products imported from non-EU countries. These need to be produced or applied for as part of the importing process. Plant passports can be completed online through the Government Gateway which is linked to the information required by HM Revenue and Customs (HMRC).

GM Inspectorate:

- Details pertaining to all GMO deliberate release trial

sites are requested and the management procedures of organisations involved in GMO field trials are audited to ensure compliance with specified conditions set down by Defra when agreeing trial. Data can be submitted by email and in hard copy at audits.

- Voluntary audits of seed companies - data is gathered on all imported seed and home-grown at-risk seed annually. This is done through an excel spreadsheet which can be returned as a hard copy or electronically.

Any examples of significant good regulatory practice:	Fera has rationalised the number of seed certification forms; from 45 forms seven years ago to 16 forms today. (Note in some categories there is a form for each of the five species because the technical requirements differ). Fera recently introduced a new integrated import system in partnership with the Rural Payments Agency and HMRC to streamline the importing process. Although there were some hiccups when this was initially introduced, business are now pleased with the system.
Review findings: The extent to which the review team believes the regulator is acting in line with the Hampton principle:	There is a clear purpose for the information that is collected and processes are in place to make it as easy as possible for businesses to complete. Data-sharing with other organisations has been explored although those interviewed felt there is scope for further work in this area; especially in light of the recent merger. External stakeholders also suggested some other ways for minimising data request burdens further. Fera should explore these suggestions to see if they are feasible. Fera has introduced new IT systems to help streamline data submissions.

INSPECTIONS

Hampton principle

No inspection should take place without a reason.

Key findings on Inspections:

- Across regulatory areas stakeholders valued the expertise of inspectors and the inspections did not seem burdensome for the industry. For example, in the seeds area one business stated they thought it would be a “disaster” if the regulations were removed – the standards keep the quality of crops high and the traceability of crops is assured.

- However, it was not always clear to business, in the Seeds and Plant Health areas, how and why inspections are conducted, and whether the current approach was the most effective:

    - Stakeholders noted that the seeds ‘industry’ is sometimes self-policing as businesses are quick to point out non-conforming (competitor) businesses to inspectors.

    - One stakeholder noted thought that “there were not too many inspections but maybe need more inspections at ports”.

- There has been a licensing regime in the seeds industry for the past 20 years. Having the licensing regime means that the number of inspections undertaken by officials is greatly reduced. Stakeholders stated that the licensed inspector scheme cost them approximately £250 per year over a 5 year cycle.

- In plant passporting Fera are required to achieve full economic cost of inspections. There were some concerns expressed that this could incentivise more inspections. For example reducing the number of inspections could reduce the amount of inspection fees which could mean a reduced number of inspectors to maintain full cost recovery.

- The GM inspectorate said it would like the statutory power to test seeds for the presence of GMOs. The current system relies largely on "self policing", which may not always work. For enforcement to be

effective legal thresholds for allowable levels of GM contaminants are needed.

- In the plant health area inspectors use ‘standard operating procedures’ to determine frequency and duration of inspections. These appear to limit taking further risk-based judgements over inspection frequency because inspection frequency has been pre-determined by managers, apparently removing discretion from in-the-field inspectors.

Any relevant background information such as the number of inspections and the number of businesses inspected; the regulator’s risk model etc

To a high degree, Fera has to carry out inspections to meet the requirements of international and EU level agreements. This Review focuses on the inspection activities covering plant health, seeds, and GM crops.

Seeds industry:

- The market is generally mature with few if any new entrants. For example there are just 100 seed companies entering seed for certification in England. However, 769 companies are registered to undertake some form of seed industry activity.

- Inspection visits are timed to coincide with the growing season wherever possible. In terms of duration of an inspection, one trade association stakeholder said that the duration of a typical inspection was 2 to 3 hours and the quality of visits was “generally very good, but can be variable.”

- There is a licensing regime. Fera licenses individuals to carry out crop inspection, seed sampling and seed testing work. As part of its enforcement responsibilities Fera undertakes check inspections of crops and samples a small percentage of the seed certified to ensure compliance with standards. There are 369 licensed seed samplers, 505 licensed crop inspectors and 29 seed testing stations.

Plant health:

- Quarantine inspections are not chargeable to the industry.

- For plant passporting, Fera is required to achieve full economic cost of inspections. There are between 2 and 4 chargeable visits per year, with

the duration generally depending on the expertise and experience of growers.

GM Inspectorate:

- GMO field trials - Responsible for ensuring consent holders (those authorised by Defra to release a GMO for research and development) are complying with the strict conditions they have agreed to adhere to when conducting and managing the GMO release. GM inspectors visit the consent holder and the deliberate release sites to ensure consent, such as size and location and monitoring requirements etc are being adhered to.

- Seed audits – Carry out seed audits to manage the risk of adventitious GM presence appearing in the UK. The audits are voluntary and focused on most at risk crops.

Any examples of significant good regulatory practice:

The agency is attempting to reduce the number of inspection visits by multi-skilling the inspectorate so that a single inspector can check compliance with several regulatory requirements on a single visit. PHSI has reduced the number of inspectors on seeds work. But, because of the need to maintain expertise in this area, particularly crop inspections, they have become experts in all aspects of seeds work.

Inspectors provide free booklets and posters to commercial growers so that they can identify - and thus take preventative action against - potential pests.

One inspector we spoke to gave free lectures on plant heath and preventative measures to a local agricultural college.

Review findings: The extent to which the review team believes the regulator is acting in line with the Hampton principle:

Fera recognises that a risk-based approach to inspections is essential and business appreciate that the inspections are important to protect seeds, crops and horticulture and value the high quality advice and guidance provided by inspectors as part of them.

Fera should review its risk model for seeds inspections to ensure that it is effective and that regularly compliant businesses are not unnecessarily overburdened with inspections simply due to the high volume of seed processed.

It was not always clear to business, in the plant health and seeds areas, how and why inspections were

conducted. Fera should revisit its communication strategy to raise awareness, as some businesses were concerned that inspections may not targeted and risk-based.

Fera should consider reviewing its process for collating intelligence, from both internal and external sources, to maximise its effectiveness.

SANCTIONS

Hampton & Macrory principles

The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.

Regulators should be transparent in the way in which they apply and determine administrative penalties.

Regulators should avoid perverse incentives that might influence the choice of sanctioning response.

Regulators should follow up enforcement actions where appropriate.

Key findings on Sanctions:

- Staff and stakeholders appreciate the flexibility and discretion inspectors have (across the areas) to assess a situation on its merits.
- Inspectors in the plant health and seeds areas are willing to work with industry to correct and remedy problems. The ultimate threat of withdrawing authorisation, destroying a crop, making a company write to customers, or undertake a product recall is generally sufficient.
- Some concerns were expressed, in the seeds and plant health areas, that information on repeat offenders may not be captured and so they may not be effectively targeted.
- Inspectors were currently not aware of the proposed plan to apply for expanded sanctioning powers under the Regulatory Enforcement and Sanctions Act 2008 ('Macrory' sanctions) and were not convinced it would help enforcement outcomes – indeed one thought it may hinder this. Seeds workshops are to be held later in 2009 to explain the role of sanctions in enforcement of the seeds legislation to the seed trade and PHSI staff.

Background information such as a summary of sanctions available

Fera is subject to Defra's "Enforcement Policy Statement", which sets out four principles of enforcement: i) Proportionality, ii) Consistency, iii) Transparency, iv) Targeting.

to the regulator and any data on sanctions imposed by the regulator:	Fera has a range of potential sanctions available: information notices, enforcement notices, prohibition notices – and ultimately the power to withdraw a trial or destroy a crop. The sanctioning approach varies across the relevant areas of Fera as shown in the following sections. <u>PHSI powers/ prosecutions</u> PHSI looks to apply a 'light touch' approach – the number of prosecutions it undertakes is quite low. Part 6 of the Plant Health (England) Order 2005 lists most of PHSI's powers. Key elements of this include: • Providing there are reasonable grounds for believing there is, or may be, a quarantine pest or disease or any otherwise prohibited material present, PHSI have (on production of their authority) the right to enter any premises (excluding premises used wholly or mainly as a dwelling) at any reasonable time. PHSI can take whoever they feel they need to take with them. PHSI can serve statutory notices on whoever they consider to have possession of the material at the time, even if they are not the legal owner, and require any actions they consider necessary to be taken, by the occupier or by contractors. PHSI can require any information they deem necessary, however stored and can inspect any material they consider necessary/appropriate. • There is no provision in the legislation for a right of appeal otherwise than by Judicial Review. • It is an offence to fail to comply with the requirements of a statutory notice or to obstruct an Inspector. A list of offences is at Part 10 of the Order. • If PHSI intercept quarantine pests or disease they can require destruction of the consignment or re-export of the consignment out of the UK/EU. Alternatively, PHSI can treat, or process the consignment as they consider appropriate. • If there is an outbreak of a quarantine pest or disease PHSI can require destruction of the crop, require or allow processing of the crop, place cropping restrictions on the land, undertake surveys

for spread of the organism, require lists of customers supplied with the same material, and follow up previous cropping and marketing. PHSI can put bans on the irrigation of certain crops from specified watercourses – all to prevent the spread of the organism.

However, PHSI aims to regulate in as light a manner as possible and operates a principle of increasingly strict actions against persistent offenders. PHSI starts off by explaining to firms and individuals what is required of them, including at times providing them with training. This is followed by encouragement when mistakes or errors are found by again explaining what is required and reinforcing to the trade what is required of them. This would initially be done verbally, and followed up in writing if mistakes continue. For persistent offenders this is followed by written warnings of the action that will be taken in future cases followed by that action.

Whilst there are some practical tools that can be employed against persistent offenders most of these are only withdrawing 'concessions'. With plant passporting, PHSI can withdraw the firm's authorisation to issue passports; for exports they can insist on the minimum amount of pre-notification of the export – but cannot refuse to issue a phytosanitary certificate. For seed potato certification PHSI can only refuse to certify a crop if it fails to meet the standards but they can refuse to issue certification labels or not supply labels for the producer to print if they fail to comply with marketing standards. For imports, PHSI can require the minimum amount of pre-notification as required by the legislation and can stop the automatic clearance and release after a certain amount of time has elapsed since the firm notified the PHSI of the availability of the consignment. This 'auto release' is not recognised or provided for in the legislation but is something PHSI has introduced due to lack of resource to do all the import inspections required of them.

Unfortunately the only real penalty PHSI can impose on someone who persistently fails to comply with the plant health legislation is to prosecute them through the courts. PHSI would welcome the opportunity to have powers to apply penalties without having to go down the route of prosecution through the courts.

The plant health policy team has shown some interest

in getting access to the powers created under the Regulatory Enforcement and Sanctions Act.

Seeds/ PVS

The power to withdraw certification, a licence or registration is a provision in seeds legislation, all are subject to appeal. The PVS Act has recently been included under the Regulatory Enforcement and Sanctions Act which means when the Seed Marketing legislation has been consolidated a system of sanction will be introduced; the aim for this is June 2010.

PVS is exploring the use of 'Macrory' sanctions because the current legislation makes it very difficult to prosecute, particularly as the allowed time frame is only six months.

GM crops

The GM inspectorate can use the enforcement powers available to it under part 6 of the Environmental Protection Act 1990.

GM inspectors have the power to issue information notices and prohibition notices. They are trained in the basic elements of PACE awareness. The GMI does not pursue prosecutions itself, but refers cases of non-compliance to Defra Investigations Branch and legal teams who determine if prosecutions will be pursued and which sanctions to apply. There was one prosecution around 7/8 years ago (before Fera had responsibility for this work[1]).

Review findings: The extent to which the review team believes the regulator is acting in line with the Hampton principles and Macrory characteristics:

Inspectors use a range of options to address non-compliance, including providing advice and guidance. In general the ultimate threat of destroying a crop or consignment of products is felt to be sufficient.

Fera should review its use of information management in targeting and understanding the prevalence of persistent offenders across the seeds and plant health areas.

Fera should use its intelligence on levels of compliance across seeds and plant health to evaluate, in consultation with policy and enforcement staff and the regulated businesses, whether the sanctions it

[1] At the time of the prosecution, the Central Science Laboratory had responsibility.

currently has are sufficient, whether more are required, and whether they should seek access to expanded sanctioning powers under the Regulatory Enforcement and Sanctions Act (‘Macrory’ sanctions).

FOCUS ON OUTCOMES

Hampton principle

Regulators should measure outcomes and not just outputs.

Key findings on Focus on Outcomes:

- Fera was recently created (April 2009). Staff and external stakeholders commented on its recent creation.
- Staff and some external stakeholders commented positively on the potential for synergies between the different organisations that now make up Fera, for example that fact that they cover similar businesses.
- Fera's stakeholders identified a lack of clarity over the outcomes FERA are working towards and how potential synergies would be utilised.

Background information such as the regulator's key objectives:

Fera's overarching purpose is to "support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks (Fera website)".

Fera lists 18 objectives in its 2009/10-2011/12 corporate plan (those linked to policy and regulation are in italics). These are:

- *Deliver more proportionate and evidence-based policy outcomes in the areas of Plant Health, Bee Health and Plant Varieties and Seeds.*
- Increase the breadth and impact of our scientific contribution to Defra and wider government in support of policy development.
- Develop and exploit horizon scanning to assess and protect society from future food security and environmental risks.
- *Develop and identify new work programmes, providing policy support and evidence in sustainable land use and addressing the consequences of climate change on food production and food security.*
- Improve our scientific innovation through comprehensive strategic relationships with the UK, EU and international research community. More

effectively develop and exploit scientific innovation.

- Exploit the broader scientific expertise within the organisation to better understand the underlying risks and to reduce the gap between known capability and likely service requirement.
- *Improve use of available knowledge and tools to underpin better policy making across government.*
- Add value across government and industry by exploiting and marketing leading edge capability in e.g. modelling and statistical expertise.
- Support and enhance our capability in emergency and contingency response and recovery.
- *Improve use of risk assessment based on sound evidence to support regulation and policy.*
- Expand and develop innovative risk assessment methodologies in an increasing range of fields, e.g. socio-economic sciences through partnership.
- Improve use of expert operational and scientific advice in contingency planning and in emergency response and recovery.
- *Develop and implement best practice in regulation to optimise the balance of desired outcomes and burden on industry.*
- Develop innovative solutions to support smarter regulation, reduce burden and increase quality of advice.
- Extend provision of strategic guidance to improve UK and International resilience against risks e.g. to support global trade.
- *Demonstrate and promote the value and relevance of both our and others' assets and resources.*
- Develop and exploit information and knowledge resources in partnership with stakeholders e.g. to facilitate knowledge transfer to industry and to inform future policy and science questions.
- Ensure Fera resource is recognised as part of wider UK and International expertise in order to improve response and recovery capacity and capability.

The extent to which the review team believes the regulator is acting in line with the Hampton principle:	Fera is a new organisation and as such we recognise that it is still in the process of developing its strategy for inspection and regulatory affairs. It has published a Strategic Direction and Corporation Plan setting out ministerial targets and the business plan. The agency should work to ensure Fera's staff and external stakeholders recognise the outcomes it is trying to achieve.

Appendix 1: Review team membership

Richard Sanders is a Director at the National Measurement Office, managing Weights & Measures and Hallmarking policy/legislation on behalf of BIS ministers, and the enforcement of some environmental protection legislation under contract from BIS. He is also the Agency's Better Regulation Champion. Previously, he worked at the National Physical Laboratory on high-energy electron and x-ray radiation dosimetry.

Siobhan Tuohy is an Assistant Director in the Better Regulation Executive (BRE). Prior to joining the BRE, Siobhan worked as a Project Manager at Surrey County Council responsible for piloting Self Directed Support and at the Institute for Employment Studies undertaking qualitative and quantitative research projects in the employment, unemployment and skills areas.

David Nix is the Head of policy and communications at the Gangmasters Licensing Authority, where he has worked since 2005. His previous post was as public policy advisor working on regional economic strategy for the East Midlands Development Agency. Prior to that he worked in the Cabinet Office's Regulatory Impact Unit, where he was responsible for promoting the Government's regulatory reform agenda, with particular responsibility for the Home Office and the Department of Health.

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