

Regulation of Specified Animal Pathogens



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Current arrangements

- Defra and Devolved Governments have the policy lead and are the licensing authority
- HSE undertake regulatory functions under Agency Agreements and associated Memoranda of Understanding (MoU)
- Single set of regulations not currently possible but aiming for single regulatory approach



Defra, SG & WG are responsible for issuing, revoking and amending licenses

Development of proposed changes

HSE led review of current arrangements:

- legal constraints (non-legislative change)
- experience since 2008
- consulted licence holders
- lessons learned

Analysed options:

- cost-benefit analysis

Ministerial Approval to proceed:

- Approved by DWP (HSE), Defra, SG and WG Ministers



Key changes to SAPO

- SAPO licensing functions will transfer to HSE
 - Single point of contact
 - Licence conditions more risk based & goal setting
- Alignment with other biological agents regimes
 - Risk assessment pivotal
 - Management arrangements
 - Containment tables
- Revised guidance explaining how to comply



New SAPO licences

- Revised licence conditions –
 - less prescriptive and set goal to be achieved by means proportionate to risk
 - specific for containment of animal pathogens
 - replicate requirements of COSHH / GMO(CU)
 - use consistent terminology (eg suitable and sufficient)
 - More cohesive and integrated



Goal setting and risk based rather than prescriptive

New SAPO licence conditions



Conditions include -

- Management arrangements
- Training & competence
- Risk assessment
- Application of containment and control measures
- Procedures for waste, transport, emergencies
- Notifications (accident, dangerous occurrence, significant change, cessation)

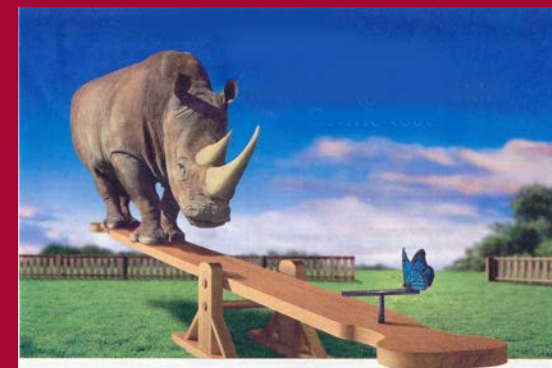
Licence conditions not required

- No requirement for transfer licence (importation requires separate licence (IAPO))
- No requirement to specify individual rooms (site address required)
- Certain containment measures (derogation can be obtained)
- No specific duties on Biosafety officer (competent advice required)



Impact of the changes

- Alignment with GMO/COSHH regimes (eg risk assessment, management)
- Adapt and integrate with existing arrangements
- Extent of arrangements commensurate with risk
- Enquiries to HSE



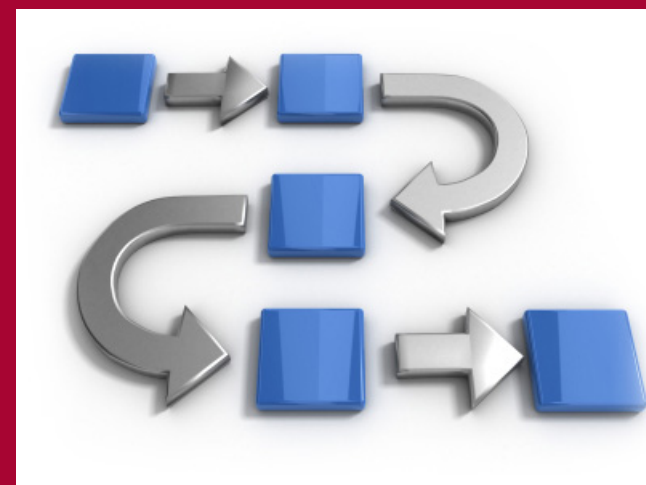
Implementation

- HSE is working with Defra/DGs to implement the proposal with effect from April 2015
- Guidance and licence conditions developed with significant input from core stakeholder working group
- Targeted consultation on revised guidance completed between 2-27 February 2015
- Application form – combined and stand alone



Transitional Arrangements

- Commence April 2015
- HSE will write to licence holders
 - Suggest date for transition
 - Agree feasibility (tailored)
 - Confirm new licence details
- Licence holders considers time and resource required to meet new licence conditions
- Licence holder confirms compliance
- Compliance inspection discretionary during transitional period



Transitional Arrangements

- New applications = 'new' licence conditions
- Expiring licences = 'new' licence conditions
- Amendments to existing licences = either amended existing licence or 'new' licence conditions
- Specific arrangements for SAPO4



SAPO applications in future

- Applications to HSE
- Compliance checked via:
 - SAPO2 – desk based assessment
 - SAPO3 – desk based assessment plus inspection on case by case basis or proactive inspection programme
 - SAPO4 – pre-licensing inspection & annual intervention plan
- Licences issued typically for 5 years
- Defra & DGs retain policy lead on SAPO



Further information

Draft revised SAPO Guidance

- HSE Microbiological Hazards Online Community
- Request copy by emailing microbiologicalhazardspolicy@hse.gsi.gov.uk



HSE web pages will be updated

- New arrangements
- New guidance
- Questions and answers



Existing guidance www.gov.uk website

Thanks

- SAPO stakeholder group consisting of 6 individuals from different organisations
- ISTR biosafety steering group & regional network
- Project Board & Team



Any questions?