

NHM ABS Training:
3. The UK Statutory Instrument:
The Nagoya Protocol (Compliance)
Regulations 2015

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EU and UK legislation on ABS

- Puts in place measures to implement:
 - the EU Regulation;
 - the Commission's Implementing Regulation;
 - elements of the Nagoya Protocol not covered by the EU Regulation.
- Does not include Access requirements
- Applies to the whole UK
- Despite Brexit, applies until we are told otherwise!

UK Actors

- **Policy Lead:** Defra (National Focal Point)
- **Competent National Authority (& Checkpoint):**
National Measurement and Regulation Office
(NMRO) – part of Regulatory Delivery (BIS)

<https://www.gov.uk/guidance/abs>

Due diligence obligations of EU Regulation which are subject to civil sanctions

Civil sanctions may be imposed in relation to a failure to comply with:

- Article 4(1) of the EU Regulation (obligation to exercise due diligence);
 - Article 4(3) of the EU Regulation (obligation to seek, keep and transfer information and documentation to subsequent users);
 - Article 7(2) of the EU Regulation (obligation to make a declaration of due diligence).
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- There is no failure to comply with the provisions referred to in paragraph the user has shown that they have effectively implemented best practice recognised under Article 8(2) of the EU Regulation.

Due diligence obligations of EU Regulation which are subject to civil sanctions

Note:

- No civil sanctions if we do not make a declaration of due diligence under Art 7(1)
- No civil sanctions if we implement a a recognised Best Practice
 - The CETAF Best Practice has been submitted for Recognition

Inspection

The Regulator has powers of entry if it is believed there is an offence

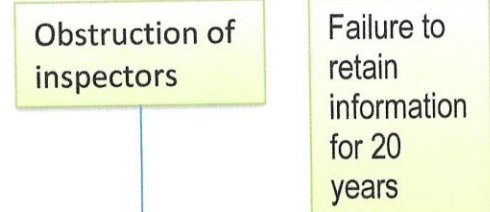
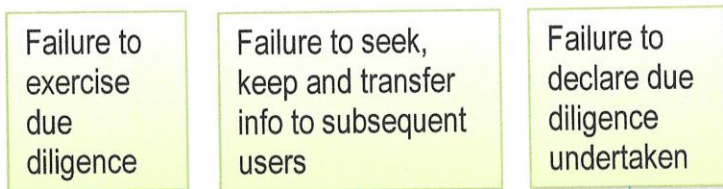
- We do not anticipate this will be an issue for us
- And we will invite NMRO to inspect our implementation

Offences

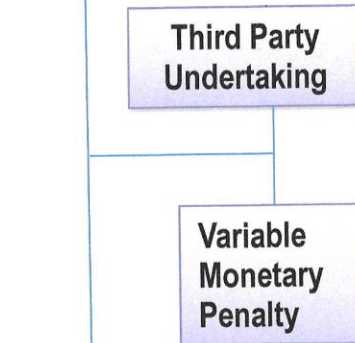
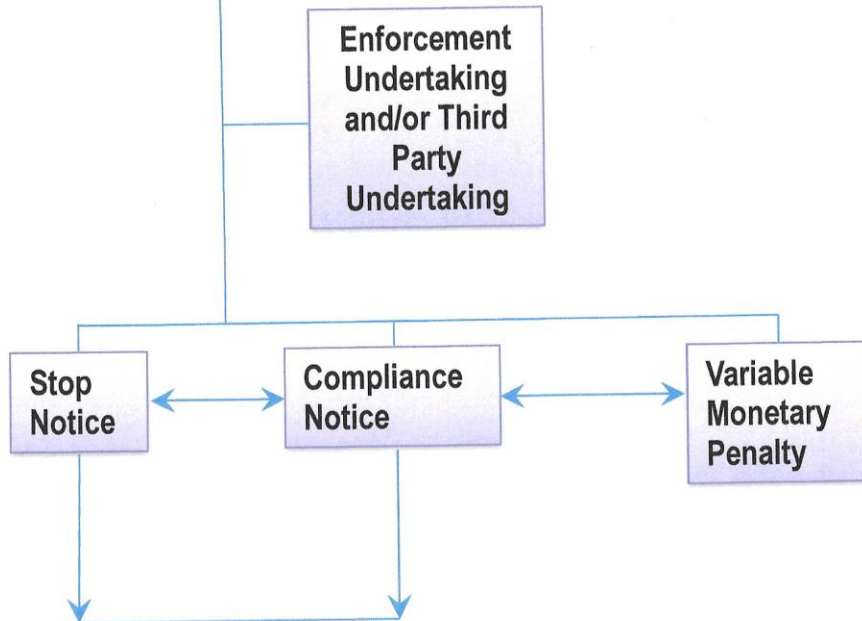
comply with—

- (a) a compliance notice;
- (b) a stop notice within the time limit specified in the notice;
- (c) Article 4(6) of the EU Regulation (obligation to keep information for 20 years after utilisation).

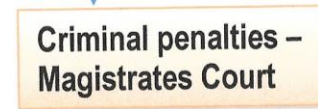
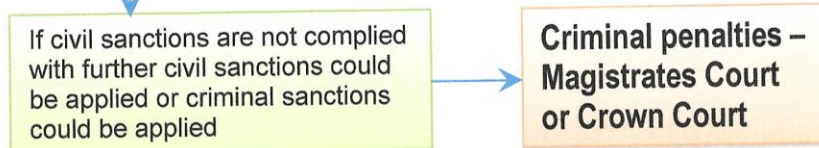
Offences:



Civil sanctions:
(Used individually or in any combination as appropriate)



Criminal penalties:



Our compliance actions

- Under Art 7(1) we may be requested to make a declaration of due diligence for utilization supported by a grant
- Although there are no penalties for not doing this, it would appear negative if we did not

Our compliance actions

- The cost could be considerable (1FTE!)
- So we will put in an argument for exemption
- But would commit to report if the grant-funded research:
 - includes discovery of properties of genes;
 - includes discovery properties of derivatives;
 - has intended commercial implications, or such implications emerge during conduct of the research;
 - Has a commercial body is a research partner;
 - involves use of aTK to identify properties of GR
 - Or the providing country makes such a declaration a condition under PIC and MAT

Our compliance actions

- The Commission is developing an on-line system, **DECLARE**
- This will allow us to make declarations directly from the database
- To be discussed when we come to data management

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**NATURAL
HISTORY
MUSEUM**