

The Nagoya Protocol: will it impact your R&D and business development?

22 February 2018



Panel



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Department for
Business, Energy
& Industrial Strategy

Office for Product
Safety & Standards

The Nagoya Protocol on Access and Benefit Sharing

Simon Trevenna
22 February 2018

Office for Product Safety & Standards,
Department for Business, Energy & Industrial Strategy
(BEIS)

- Competent Authority for ABS in the UK
- Technical and product-based Regulations

Department for Environment, Food & Rural Affairs
(DEFRA)

- Policy lead on the Nagoya Protocol
- National Focal Point (NFP)



ABS: Simply explained



www.abs-initiative.info/knowledge-center/multimedia/



The Convention on Biological Diversity

(third objective)

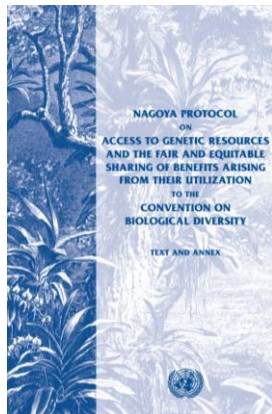
The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation

Adopted in 2010, entered into force in October 2014

**Regulation (EU) No. 511/2014
and Implementing Regulation
(EU) 2015/1866**

Compliance measures for users
in the EU

**UK Statutory
Instrument**



Prior Informed Consent (PIC)

- Permit from provider country (CNA)
- Sovereign rights over genetic resources



Mutually Agreed Terms (MAT)

- Contract between provider and user
- Terms of use, timeframes, transfer of material, benefit sharing
- Traditional knowledge

Internationally Recognised Certificate of Compliance (IRCC)

- Placed on ABS Clearing House
- Provisions for confidential information
- Evidence genetic resource was accessed in accordance with provider legislation
- Evidence of due diligence



ABS Clearing House



<https://absch.cbd.int/>



Assessing Scope

EU Regulation applies to genetic resources that meet all of the following conditions:

- I. from countries that **exercise sovereign rights**
- II. where countries have **established applicable access measures and ratified the Nagoya Protocol**
- III. if **accessed after 12 October 2014**
- IV. those that are not already **governed by specialised international instruments**

Activities **in** and **out** of scope of EU Regulation

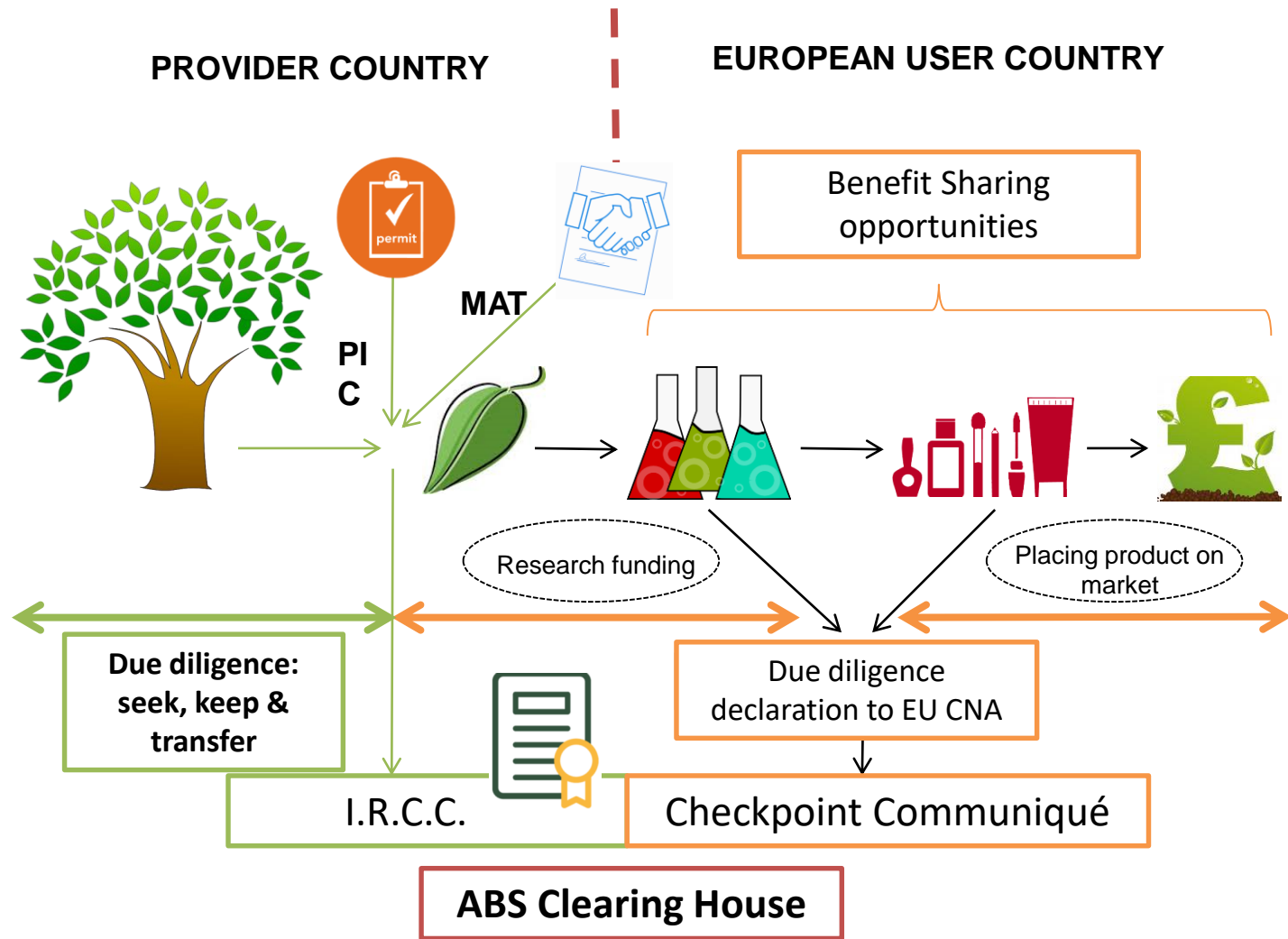


Due Diligence

Ascertain that the genetic resource utilised has been accessed legally.

- Seek, keep and transfer information along the value chain
- ABS Clearing House and contacting NFP
- IRCC or equivalent
- Best practices and Registered Collections
- Submission of due diligence declarations





Approach to Enforcement



Approach to Enforcement

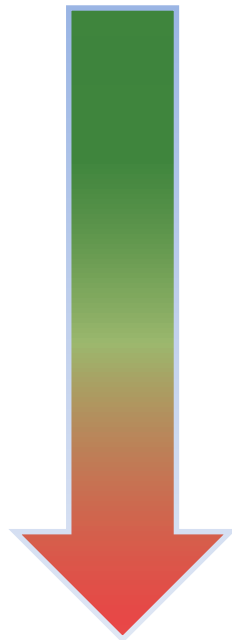
Regulators' Code

- support compliance & growth
- engage with those we regulate
- base our activity on risk
- share information
- offer clear guidance
- be transparent

We do not take enforcement action because an organisation asks a question or highlights a problem



Approach to Enforcement



- Education
- Informal Warning
- Enforcement undertaking
- Compliance / Enforcement / Stop Notice
- Formal Caution
- Fines
- Product withdrawal / Seizure
- Court Action
- Publicity

Thank you

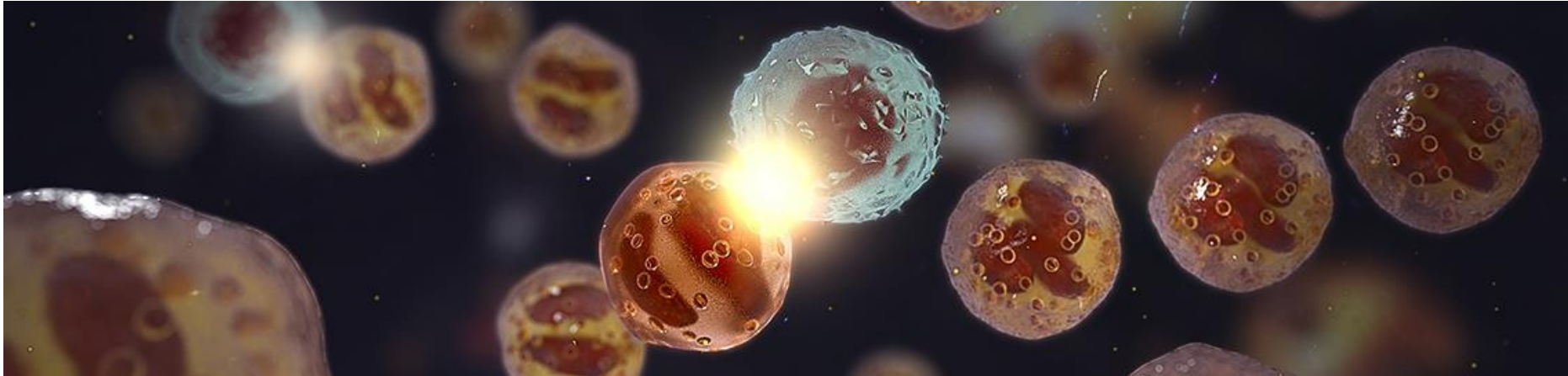


Simplifying Nagoya

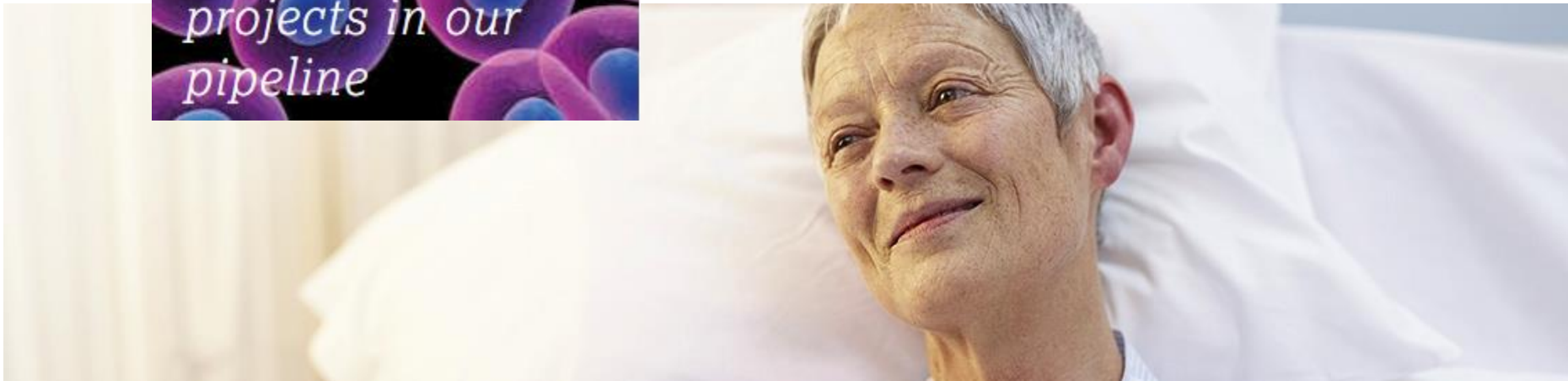
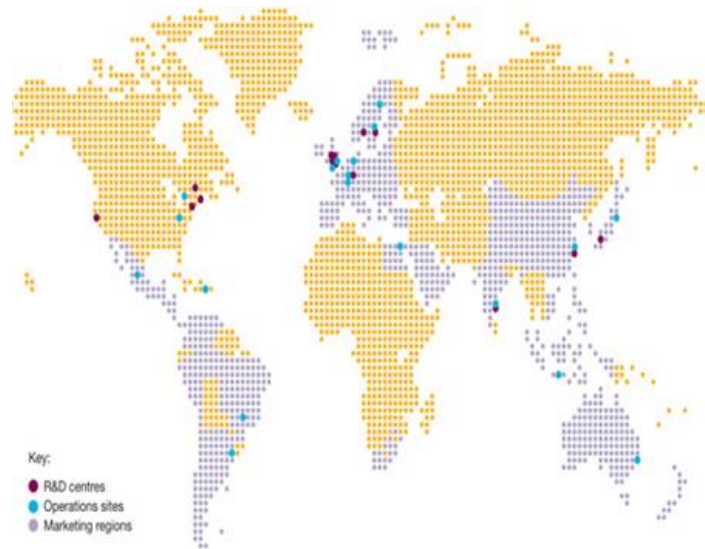
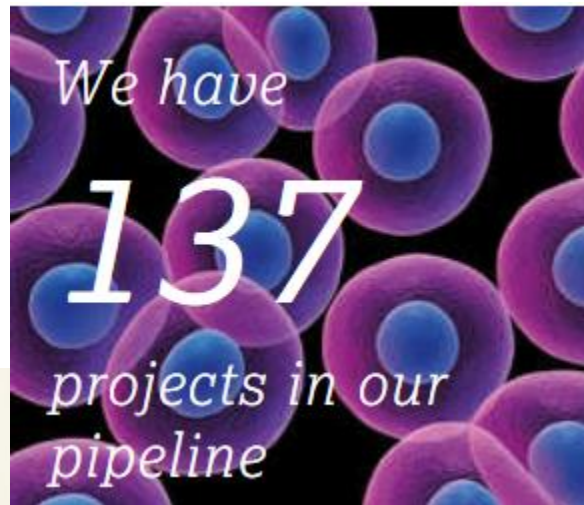
Nigel Budgen

BBS NP Seminar 2018

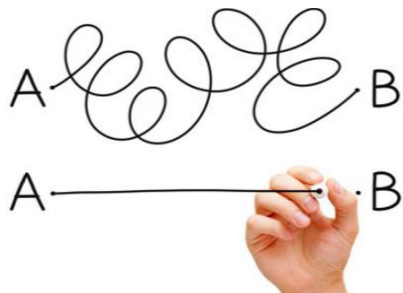
22nd February 2018



AstraZeneca: New Human Medicines



New e-tool helps our scientists navigate complexity of bio-piracy prevention



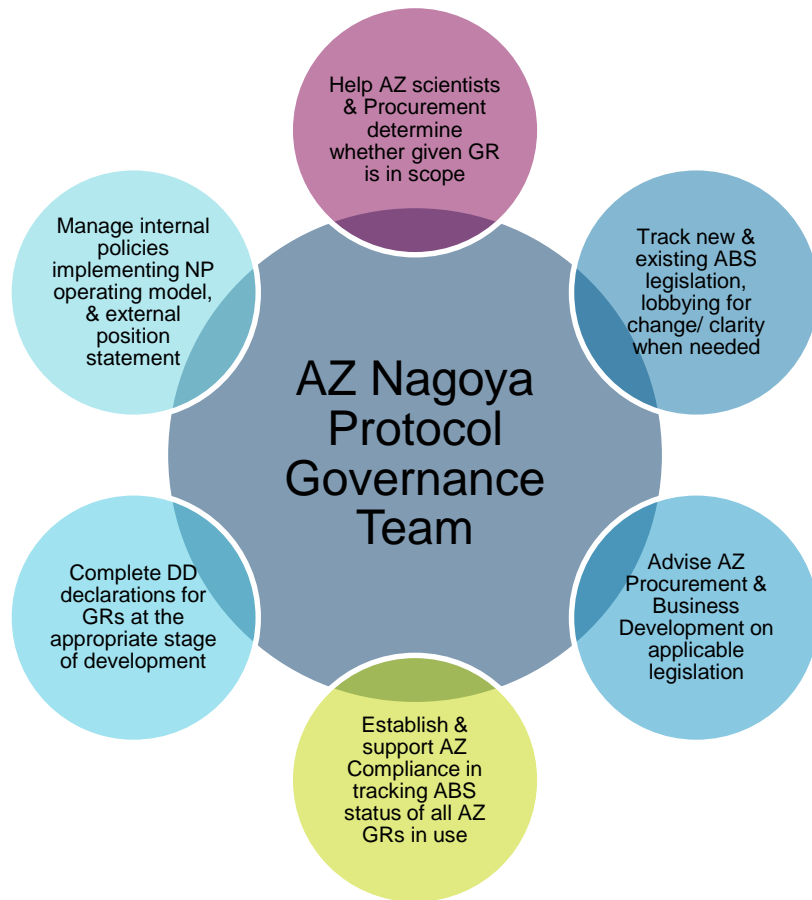
#thinksimple

AstraZeneca Approach

1. Established a Nagoya Governance Team: to execute responsibilities
2. Define the Company's public policy position
3. Modified the Bioethics Policy
4. Developed a Global Standard defining individual responsibilities
5. Developed a Nagoya Sourcing e-tool to determine if GRs are in or out of scope
6. Created a 3 minute training video that provides an overview of the Nagoya Protocol and our responsibilities: https://youtu.be/1Hv_tBm_hg8
7. Communicate through R&D LTs and cascade to scientist



AZ operating model



Governance Team representatives from:

IMED/Chair – R&D

Regulatory – R&D

Medl –Ops

Procurement – Ops

Global Sustainability – Corp

Corp. Affairs*

Legal/IP *

Business Development*

Compliance *

*support as required



AstraZeneca Approach

1. Established a Nagoya Governance Team to execute responsibilities
2. Define the Company's public policy position
3. Modified the Bioethics Policy to include NP
4. Developed a Global Standard defining individual responsibilities
5. Developed a Nagoya Sourcing e-tool to determine if GRs are in or out of scope
6. Created a 3 minute training video that provides an overview of the Nagoya Protocol and our responsibilities: https://youtu.be/1Hv_tBm_hg8
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Responsible research

Society depends on us to conduct effective, ethical and thorough research in the development of our medicines and treatments. We set high standards of ethical practice across all aspects of our research activity worldwide, from clinical trials to research with animals.

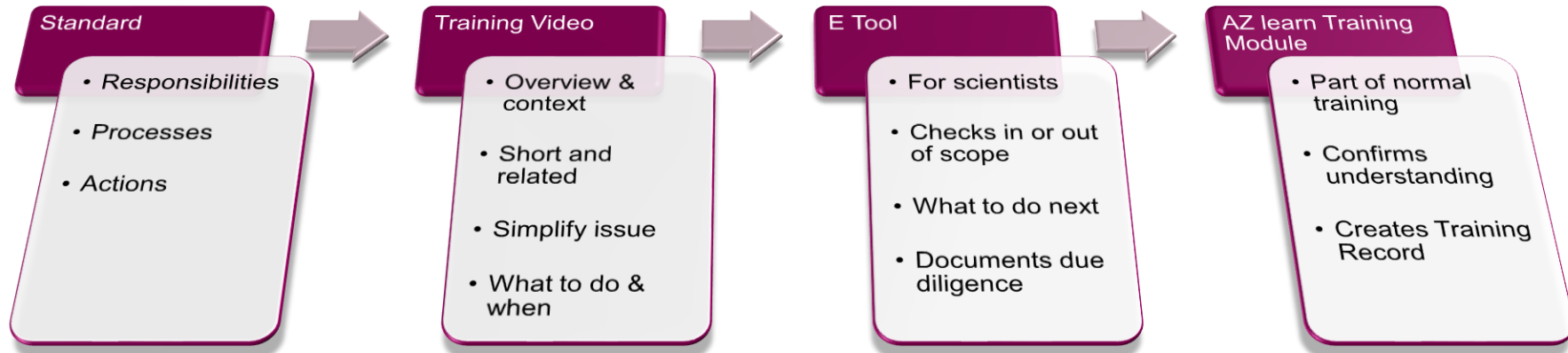
We take every safety precaution and responsible decision required of us by regulators around the world. Our [Code of Conduct](#) requires that our research be conducted in accordance with all relevant external laws and regulations. It also requires compliance with our [Bioethics Policy](#), which describes our commitment beyond legal compliance and defines the ethical standards, principles and behaviours governing all our research and development (R&D) activity worldwide. [Our Global Standard Expectations of Third Parties](#) document outlines our ethical standards for external partners.

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The NP Tool Kit



Questions include:

e-Tool

The material, its use, exceptions, & where R&D will take place

Utilisation

Description of the Biological Material: Genetic Resource or Derivative:

Please describe the biological material or resource and its intended research use by AstraZeneca: **do not include commercially sensitive information.**

Please include species name:

GMO of H1N1/Duban/2015 virus by reverse genetics

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Cancel

Commodities used as Commodities.

Will the genetic resource or derivative to be used as a commodity* in the research?

(*a commodity is defined as a biological material for which R&D has been completed prior to this planned research use. Nothing new is planned to be revealed about the commodity by its use in this research. A commodity is usually commercially available for a specific use. (eg reagent or test kit)

If the same commodity is subjected to further R&D to identify new uses, it is no longer being used as a commodity.)

☐ Yes

☒ No

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Cancel

The ABS Clearing-House

ABSCH

Where is the material to be utilised or used?

Please select which country the research will be carried out.

European Union Member State

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In or Out ?

Scopes out activities....



Animal models/tools used for preclinical & clinical testing



Commodities used as commodities



New product is developed through research on a GR



Chemical leads identified from a GR collection



GR which constitutes the basis of a product e.g. Vaccine



GMO research that using genes derived from a GR



e-Tool

Outcomes:

Use in or out of scope/more info needed/PIC or MAT required

The described use of genetic resource or derivative **does not fall** under the scope of the Nagoya Protocol. The information will be retained and no further action is required.

Please add your name and date to confirm answers given.

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Submit

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The conclusion is that this biological material is **likely to fall in** scope of the Nagoya Protocol.

This material needs to be assessed using Due Diligence Form 2. It will be sent to you by the Nagoya Governance Team. Further consultation with the supplier and how the material is sourced may be needed before the use of this material can start.

Please add your name and date to confirm answers given.

Back

Submit

Cancel

Sovereign Rights Apply

In conclusion it is **highly likely that this biological genetic resource is in scope** of the Nagoya Protocol and may require a PIC and MAT before research can start on the material from the supplier or country of origin.

An e mail will be sent to the Nagoya Governance Team when the form is submitted to assist with the next steps.

Please enter your name and date to confirm the answers given in the form.

Nigel Budgen 9/2/2016

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Submit

Cancel

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Case Study: Venom Extracts and Fractions

**UK High Through Put (HTP)
Screening for Chemical Leads**



**UK Compound Library :
Specialising in venoms**



**Tracked To Source: 5 African
(incl.Togo) 4 Asian Countries and
US**

Pre & Post October 2014



AstraZeneca Approach

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Key Learning

- Define Accountability
- Integrate with policies
- Create a NP Tool kit
- Use case studies
- Assume suppliers know less than you and will need help
- Revisit DD as required, things change eg Brazil Genetic Heritage (SisGen)

Confidentiality Notice

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Prokarium's perspective as an SME on the Nagoya Protocol

Dr Rocky Cranenburgh
Chief Scientific Officer

Thursday 22nd February 2018

BIA/BEIS briefing seminar: The Nagoya Protocol - will it impact your R&D and business development?

Simmons & Simmons, CityPoint, London





Use a culture collection

- Culture collections (e.g. NCTC, ATCC) have a wide range of microbes deposited before October 2014 and therefore not subject to the NP.

E.g. *Salmonella* Typhi from PHE's

NCTC No.	Current Name	Other Collection No	Type Strain	Price
NCTC 9432	Bacillus circulans	STOSB	No	Price
NCTC 786	Salmonella enterica subsp. enterica serotype Typhi	CN 6236; LISTER	No	Price
NCTC 5764	Salmonella enterica subsp. enterica serotype Typhi	R 2 ROUGH (K63)	No	Price
NCTC 10787	Salmonella enterica subsp. enterica serotype Typhi	ATCC 6539; HOPKINS 26; PCI 413	No	Price
NCTC 5760	Salmonella enterica subsp. enterica serotype Typhi	2 V (K 59)	No	Price
NCTC 8001	Salmonella enterica subsp. enterica serotype Typhi	KASALI TH; VI-NEGATIVE VARIANT	No	Price
NCTC 8395	Salmonella enterica subsp. enterica serotype Typhi	TY 2 ROUGH	No	Price
NCTC 779	Salmonella enterica subsp. enterica serotype Typhi	JOHN HOPKINS; 779	No	Price
NCTC 3390	Salmonella enterica subsp. enterica serotype Typhi	S	No	Price
NCTC 5761	Salmonella enterica subsp. enterica serotype Typhi	WATSON VI(K60)	No	Price
NCTC 6029	Salmonella enterica subsp. enterica serotype Typhi	T2 AS (K115)	No	Price
NCTC 6964	Salmonella enterica subsp. enterica serotype Typhi	OSTEOMYELITIS	No	Price
NCTC 8383	Salmonella enterica subsp. enterica serotype Typhi	TY 6 S	No	Price
NCTC 8393	Salmonella enterica subsp. enterica serotype Typhi	ATCC 10749; ATCC 14901; 0 901	No	Price
NCTC 8394	Salmonella enterica subsp. enterica serotype Typhi	H 901	No	Price
NCTC 8396	Salmonella enterica subsp. enterica serotype Typhi	MRS S (R2.B.MU)	No	Price
NCTC 160	Salmonella enterica subsp. enterica serotype Typhi	RAWLINGS; 160	No	Price
NCTC 8382	Salmonella enterica subsp. enterica serotype Typhi	BHATNAGER; CN 5595; VI 1 (1940)	No	Price
NCTC 8384	Salmonella enterica subsp. enterica serotype Typhi	WATSON	No	Price
NCTC 8385	Salmonella enterica subsp. enterica serotype Typhi	ATCC 19430; TY 2	Yes	Price

Bacteria Collection: <i>Salmonella enterica</i> subsp. enterica serotype Typhi	
NCTC Number:	NCTC 8385
Current Name:	<i>Salmonella enterica</i> subsp. enterica serotype Typhi
Original Strain Reference:	Ty 2
Other Collection No:	ATCC 19430; TY 2
Previous Catalogue Name:	<i>Salmonella enterica</i> subsp. enterica
Type Strain:	Yes
Family:	Enterobacteriaceae
Hazard Group (ACDP):	3
Release Restrictions:	Terms & Conditions of Supply of Microbial Pathogens: Safety
Antigenic Properties:	serotype Typhi, serovar 9,12,v:d
Conditions for growth on solid media:	nutrient agar, 37, facultative anaerobe
Conditions for growth on liquid media:	nutrient broth, 37, facultative anaerobe
16S rRNA Gene Sequence:	>gb Z47544 TY2 ATCC 19430 TYPE STRAIN S typhi gene for 16S ribosomal RNA agagtttgatcctgg... >gb Z47544 TY2 ATCC 19430 TYPE STRAIN S typhi gene for 16S ribosomal RNA agagtttgatcctgg...
Miscellaneous Sequence Data:	>gb AY370864 ATCC 19430 Salmonella typhi strain ATCC 19430 gyrase B (gyrB) gene, partial cds agagtttcgggtgggt...
Bibliography:	FELIX A 1941 BRIT MED J 1 391; WEIL E & FELIX A 1920 Z IMMUN FORSCH 29 24
Extended Bibliography:	► Show bibliography
Data:	(ATCC 19430) Type strain / A. Felix, PHLS Colindale in 1953 / Isolated in 1918 / Vaccine production / Weil, E. & Felix, A. (1920) Z. Immunforsch. exp. Ther. 29, 24 / Felix, A. (1941) Br. med. J. i. 391 / Enterobacteriaceae Subcommittee (1963) Int. J. Syst. Bacteriol. 12 149
Accession Date:	01/01/1953
History:	ISOLATED BY CHERSON 1918
Authority:	(LE MINOR et al. 1982) LE MINOR and POPOFF 1987
Depositor:	FELIX A
Taxonomy:	TaxLink: S9096 (<i>Salmonella enterica</i> subspecies enterica (ex kauffmann and edwards 1952) le minor and popoff 1987) - Date of change: 16/06/2007 by NCTCUp to 16/06/2007: S2673 (<i>Salmonella typhi</i> (Schroeter 1896) Warren and Scott 1930) - Date of change: 5/02/2003
Other:	Serotype Typhi9, 12, Vi:dSalmonella SUBSPECIES I
Biosafety Responsibility:	It is the responsibility of the customer to ensure that their facilities comply with biosafety regulations for their own country

Accession Date: 01/01/1953

History: ISOLATED BY CHERSON 1918

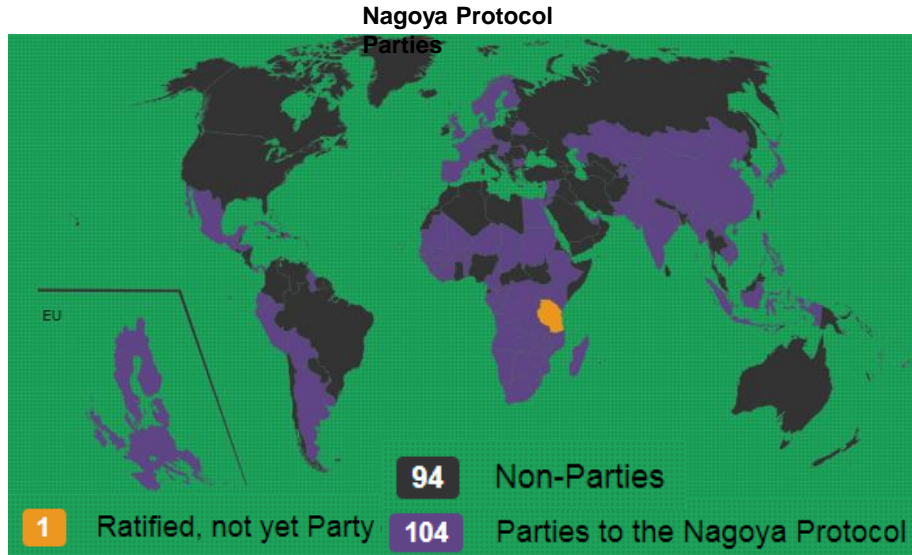
Authority: (LE MINOR et al. 1982) LE MINOR and POPOFF 1987



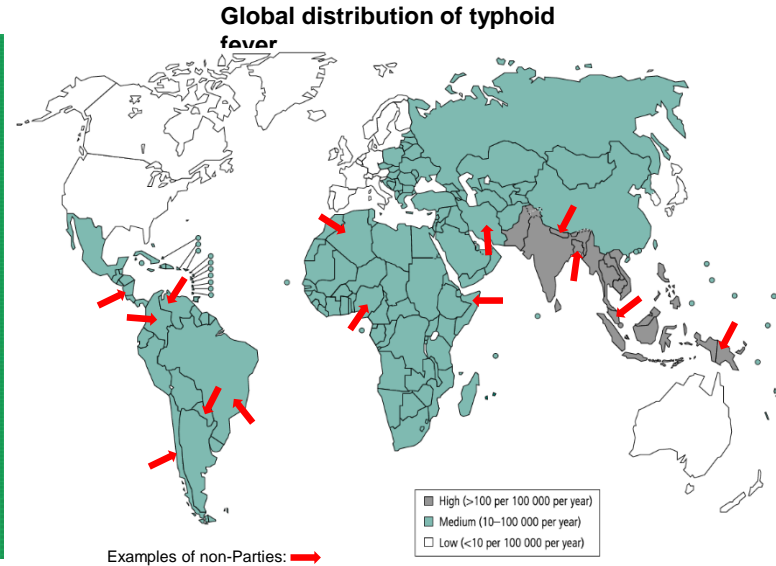


Select a non-NP party country

- Micro-organisms know no borders: chose a non-NP country for new source material.
- E.g. selecting a strain of *Salmonella* Typhi for inclusion in a vaccine:



<https://absch.cbd.int/>



Adapted from Crump *et al.* 2004, Bulletin of the WHO

- In this example, around 85 countries would be suitable.





Potential inclusion of DSI

- ⌘ The proposed inclusion of Digital Sequence Information under the NP would present problems for biotech companies.
- ⌘ The country of origin of DSI is not always recorded.
- ⌘ DSI is often edited, codon-optimised or compiled from alignments of other sequences.
- ⌘ If an 'NP sequence' forms part of an alignment, is the resulting consensus sequence subject to the NP?
- ⌘ Synthetic genes can include multiple components from different organisms – how would these be treated?





DSI example: finding LT-B (1/3)

- ⌘ The labile toxin LT from enterotoxigenic *Escherichia coli* (ETEC) causes diarrhoea; subunit B (encoded by *eltB*) is a target for vaccine development, but ETEC has a global distribution.
- ⌘ First, search Genbank for type strain H10407...

Escherichia coli ETEC H10407, complete genome

GenBank: FN649414.1

[FASTA](#) [Graphics](#)

[Go to:](#) ☒

LOCUS	FN649414	5153435 bp	DNA	circular	BCT 27-FEB-2015
DEFINITION	Escherichia coli ETEC H10407, complete genome.				
ACCESSION	FN649414				
VERSION	FN649414.1				
DBLINK	BioProject: PRJEA42749 BioSample: SAMEA272237				
KEYWORDS	complete genome.				
SOURCE	Escherichia coli ETEC H10407				
ORGANISM	Escherichia coli ETEC H10407 Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacterales; Enterobacteriaceae; Escherichia.				
REFERENCE	1				
AUTHORS	Crossman,L.C., Chaudhuri,R.R., Beatson,S.A., Wells,T.J., Desvaux,M., Cunningham,A.F., Petty,N.K., Mahon,V., Brinkley,C., Hobman,J.L., Savarino,S.J., Turner,S.M., Pallen,M.J., Penn,C.W., Parkhill,J., Turner,A.K., Johnson,T.J., Thomson,N.R., Smith,S.G. and Henderson,I.R.				
TITLE	A commensal gone bad: complete genome sequence of the prototypical enterotoxigenic Escherichia coli strain H10407				
JOURNAL	J. Bacteriol. 192 (21), 5822-5831 (2010)				
PUBMED	20802035				
REFERENCE	2 (bases 1 to 5153435)				
AUTHORS	Aslett,M.A.				
TITLE	Direct Submission				
JOURNAL	Submitted (22-DEC-2009) Aslett M.A., Pathogen Sequencing Unit, Wellcome Trust Sanger Institute, Wellcome Trust Genome Campus, Hinxton, Cambridge, Cambridgeshire. CB10 1SA, UNITED KINGDOM				

no location origin in Genbank, so read journal article...

Bacterial strains and sequencing. The ETEC O78:H11:K80 strain H10407 was isolated from an adult with cholera-like symptoms in the course of an epidemiologic study in Dacca, **Bangladesh** prior to 1973 (19) and was shown to cause diarrhea in adult volunteers (6, 17). The *E. coli* H10407 isolate that was sequenced was from the Walter Reed Army Institute of Research (WRAIR) cGMP stock manufactured in February 1998 as lot 0519. The whole genome was

... isolated sufficiently long ago, and from a non-NP country - good. Now we need to check that this is in fact representative of LT-B diversity, and perhaps generate a consensus sequence for vaccine development.





DSI example: finding LT-B (2/3)

BLAST alignment to ensure a globally representative sequence...

Escherichia coli O182:H21 strain D181 plasmid unnamed1, complete sequence

Escherichia coli plasmid E873p3, strain E873

Escherichia coli ETEC H10407 p666 plasmid

Escherichia coli ETEC H10407 plasmid pEntH10407 DNA, complete genome

Escherichia coli strain PE0615 elt operon, complete sequence

Escherichia coli strain 4321-1 elt operon, complete sequence

Escherichia coli strain 214-III elt operon, complete sequence

heat-labile enterotoxin A subunit, heat-labile enterotoxin B subunit (Escherichia coli, 21d, Genomic, 1275 nt)

E.coli heat labile enterotoxin a 3' end and enterotoxin b (toxB) gene, complete cds

Escherichia coli Q114:H49 strain 90-9280 plasmid unnamed1

Escherichia coli strain 90-9276 plasmid unnamed2

Escherichia coli Q15:H11 strain 90-9272 plasmid unnamed

Escherichia coli strain ETEC-2264 plasmid unnamed1, complete sequence

Escherichia coli B7A plasmid pEB3, complete sequence

Escherichia coli strain 4702-1 elt operon, complete sequence

Escherichia coli strain 121-1 elt operon, complete sequence

Escherichia coli genes for heat-labile enterotoxin A subunit and B subunit, complete cds

Escherichia coli O6:H16 strain M9682-C1 plasmid unnamed2, complete sequence

Escherichia coli O6:H16 strain F6699 plasmid unnamed2

Escherichia coli strain F5658C1 plasmid unnamed2, complete sequence

Escherichia coli O6:H16 strain 2014EL-1346-6 plasmid unnamed5, complete sequence

Escherichia coli O6:H16 strain 2011EL-1370-2 plasmid unnamed2, complete sequence

Escherichia coli strain FMU073332 plasmid pEcoFMU07332d sequence

Escherichia coli strain FORC_031 plasmid pFORC31.1, complete sequence

Escherichia coli eltB and double eltA flanked by IS600 and IS1294, strain ETEC ESE1, 164

Escherichia coli strain ETEC_118-5 elt operon, complete sequence

Escherichia coli ETEC_1382/75 plasmid p1018 complete sequence

Escherichia coli E24377A plasmid pETEC_80, complete sequence

Escherichia coli strain 4692-1 elt operon, complete sequence

Escherichia coli Q25:H16 strain F5505-C1 plasmid unnamed2, complete sequence

Escherichia coli strain ATCC 43886 plasmid unnamed2, complete sequence

Escherichia coli O182:H21 strain D181 plasmid unnamed1, complete sequence

GenBank: CP024249.1

[FASTA](#) [Graphics](#)

[Go to:](#) ☐

LOCUS CP024249 167230 bp DNA circular BCT 02-NOV-2017
DEFINITION Escherichia coli O182:H21 strain D181 plasmid unnamed1, complete sequence.
ACCESSION CP024249
VERSION CP024249.1
DBLINK BioProject: [PRJNA218110](#)
BioSample: [SAMN07656207](#)
KEYWORDS .
SOURCE Escherichia coli O182:H21
ORGANISM [Escherichia coli O182:H21](#)
Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacteriales; Enterobacteriaceae; Escherichia.
REFERENCE 1 (bases 1 to 167230)
AUTHORS Smith,P., Lindsey,R.L., Rowe,L.A., Batra,D., Stripling,D., Garcia-Toledo,L., Drapeau,D., Knipe,K. and Strockbine,N.
TITLE High-Quality Whole Genome Sequences for 21 Enterotoxigenic Escherichia coli Strains Generated with PacBio Sequencing
JOURNAL Unpublished
REFERENCE 2 (bases 1 to 167230)
AUTHORS Smith,P., Lindsey,R.L., Rowe,L.A., Batra,D., Stripling,D., Garcia-Toledo,L., Drapeau,D., Knipe,K. and Strockbine,N.
TITLE Direct Submission
JOURNAL Submitted (23-OCT-2017) EDLB, CDC, 1600 Clifton Road, Atlanta, GA 30333, USA
COMMENT This genome has a [base modification file](#) available.

```
##Genome-Assembly-Data-START##  
Assembly Method      :: HGAP v. 3  
Genome Representation :: Full  
Expected Final Version :: Yes  
Genome Coverage       :: 101.0x  
Sequencing Technology  :: PacBio  
##Genome-Assembly-Data-END##
```

Journal not published yet – where is it from?

What about the rest of these sequences?

What would be the status of a consensus sequence?





DSI example: finding LT-B (3/3)

🔗 Pubmed search for journal article:

High-Quality Whole-Genome Sequences for 21 Enterotoxigenic *Escherichia coli* Strains Generated with PacBio Sequencing

Peyton Smith,^{a,b} Rebecca L. Lindsey,^a Lori A. Rowe,^a Dhvani Batra,^a Devon Stripling,^a Lisle Garcia-Toledo,^{a,b} Daniel Drapeau,^{a,b} Kristen Knipe,^a Nancy Strockbine^a

^aCenters for Disease Control and Prevention, Atlanta, Georgia, USA

^bOak Ridge Institute for Science and Education, Oak Ridge, Tennessee, USA

ABSTRACT Enterotoxigenic *Escherichia coli* (ETEC) is an important diarrheagenic pathogen. We report here the high-quality whole-genome sequences of 21 ETEC strains isolated from patients in the United States, international diarrheal surveillance studies, and cruise ship outbreaks.





Nagoya Protocol summary

- Prokarium has not been adversely affected by the NP yet.
- The primary decision that the NP has necessitated is to trace the origins of any biological material that may end up in a future commercial product.
- Prokarium recommends that other biotech SMEs use material deposited in culture collections prior to October 2014, or sources from non-NP party countries thereafter.
- The biggest challenge to biotech SMEs from the NP would result from the proposed extension to Digital Sequence Information.



Questions?