European Animal Research Association

Input for CITES[1] Working Group on Simplified Procedures for Biomedical Research

The European Animal Research Association (EARA) is a European organisation that communicates and advocates for biomedical research using animals by providing accurate and evidence-based information. We aim to educate the public on the benefits of animal research, co-operating with research stakeholders, and promoting the creation and development of national networks.

Our **vision** is to enhance the understanding and recognition of research involving animals across Europe, allowing for a more constructive dialogue with all stakeholders and a more efficient climate for research in Europe. Our **mission** is to uphold the interests of biomedical research and healthcare development across Europe. EARA was created by academic institutions, associations and the industry to provide a European platform for the public and other external stakeholders to be informed and learn about animal research, its benefits and limitations.

By providing accurate and evidence-based information of biomedical animal research, EARA informs and educates audiences in support of necessary research and facilitates a balanced debate on the role of animals in scientific research. Being a European-wide organisation, EARA encourages the creation and development of national networks and improves coordination between them.

I. Background and Regulatory Context (EU)

Animal research in the European Union (EU) is regulated under Directive 2010/63/EU on the protection of animals used for scientific purposes. The Directive aims to protect animals in scientific research, with the final aim of replacing all animal research with non-animal methods. The Directive harmonises animal research legislation throughout the EU, to ensure high standards of animal welfare and scientific research. It was implemented into national laws in each EU Member State in 2013.
Animals can only be used in research in EU when there is a convincing scientific justification, when the expected benefits of the research outweigh the potential risks in terms of animal suffering and when the scientific objectives cannot be achieved using non-animal alternative methods. Animals are used for a limited number of research purposes including basic research, applied research into human and animal diseases and cures, the protection of species and the environment, and education and training

The Directive sets out legal requirements to implement the 3Rs principles of replacement, reduction and refinement: replace animals with non-animal methods where possible; reduce the number of animals

[1] The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

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used to a minimum while still obtaining scientifically valid results; and refine practices to reduce any possible pain, suffering, distress or lasting harm to the animals.

In the EU, animals are used for a limited number of research purposes including basic research, applied research into human and animal diseases and cures, the protection of species and the environment, and education and training. The selection of species depends on the type, aim and method of the research. Scientists must use the species least able to experience pain and suffering, with which they can obtain relevant results. The origin of animals also matters: species including mice, rats, zebrafish, frogs, rabbits, cats, dogs and non-human primates need to be specifically bred for research purposes. Some animals can only be used if the research cannot be done in any other species or in exceptional circumstances: non-human primates may only be used for basic or specific medical research, or research aimed at conservation of the species.

II. Value of Simplified Procedures for Biomedical Research

Scientific research for biomedical purposes depends upon the timely movement of biological samples taken from research animals from one laboratory to another - often in different countries - to take advantage of complementary equipment, resources, and expertise. Cross-border cooperation also may be required because research protocols for a particular test may be validated in one country but not another. Timeliness in movements of the research samples is critical either because the samples themselves can quickly deteriorate or because of deadlines within approved studies. Greater use of simplified procedures for CITES permitting could significantly reduce delays in shipments of time-sensitive samples for important biomedical research. This in turn could significantly expedite the availability of new medicines and innovations for patients by cutting down the number of days required to bring them to the market.

Interestingly, Switzerland's response to Notification No. 2017/071 reflects that simplified procedures are not needed due to the rapid processing of CITES permits. Standard processing time by Swiss CITES authorities using an electronic permitting system is reported as "between 5 hours and 2 days" for routine requests. Non-routine requests are handled within five days. Rapid response is provided for emergency requests.

Like Switzerland, Germany, does not use simplified procedures for trade in biological samples. Nevertheless, in the experience of EARA, typically issues permits in four to five working days. German authorities also effectively respond to urgent requests to allow for issuance of permits even faster where necessary. In the UK, on the other hand, CITES permits routinely take up to fifteen working days to issue. Part of the reason for the delay is the use of regular post to deliver the permits. In the UK, as elsewhere, permits and certificates occasionally arrive with typographical or other errors. Reliance on

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regular post by the authorities can result in another eight to ten working days to replace faulty permits with corrected versions.

Information provided by Canada, France, and the United States in response to Notification No. 2017/071 also highlights the significant benefits of using simplified procedures for CITES Management Authorities. According to France, "Simplified procedures have always proven extremely satisfactory, both for applicants and for French Management Authorities." The reduction of time spent on processing and reporting on permits for the import/export of specimens that have negligible or no impact on the conservation of the species concerned directly translates into the possibility of re-purposing that saved time to focus on transactions with potentially serious conservation implications and/or enforcement to crack down on wildlife trafficking.

III. Volume of Shipments of Samples for Biomedical Research

CITES Resolution Conf. 12.3 (Rev. CoP17) "RECOMMENDS that Parties use simplified procedures to issue permits and certificates to facilitate and expedite trade that will have a negligible impact, or none, on the conservations of the species concerned, e.g., 1) where biological samples of the type and size specified in Annex 4 of the present Resolution are urgently required: … E. for diagnostic or identification purposes." Annex 4 shows the various types of samples and their use for biomedical research among other things.

Review of the CITES trade database focusing exclusively on trade in biological sample specimens (Term: "SPE") for "medical (including biomedical research)" purposes (Purpose Code: "M") for the ten-year period of 2006 through 2016 shows massive imports and exports. It should be noted from the outset that imports and exports of samples for biomedical research are limited to samples from primate species. Given the extensive, top quality biomedical research taking place in the UK, it is worth looking at the details of UK imports and exports of biological samples from primates for biomedical research.

First, as the following table demonstrates, biomedical research is a global endeavour. Imports of samples to the UK for biomedical research are limited to just thirteen countries over the ten-year period; however, within that same time the UK exported samples to 35 countries for biomedical research in those countries.

UK Exports		UK Imports
Bangladesh	Mongolia	Barbados
Brazil	Morocco	Canada
Bulgaria	Nepal	China
Canada	Pakistan	France
Chile	Paraguay	Israel
Croatia	Romania	Mauritius

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Egypt	Russian Federation	Peru
Ethiopia	Saudi Arabia	Singapore
Hong Kong	Senegal	South Africa
India	Singapore	Switzerland
Indonesia	South Africa	Taiwan
Iran	Sri Lanka	United States
Israel	Switzerland	Vietnam
Japan	Thailand	
Jordan	Tunisia	
Kazakhstan	Turkey	
Kuwait	United Arab Emirates	
Lao	United States	
Malaysia	Vietnam	
Mexico		

Secondly, the UK data demonstrates that hundreds of thousands of CITES permits are being issued to move samples for biomedical research. If we focus exclusively on reporting for samples by number of pieces (excluding data regarding samples that are traded and reported by units of measure e.g., g, mg, l, ml, etc.), the CITES database indicates that the UK alone imported **232,059** specimens and exported **372,941** specimens for medical purposes in ten years. The UK has repeatedly emphasised in recent months that it intends to focus heavily on maintaining and growing scientific research and innovation in both the public and private sectors in the post-Brexit period: increased demand for timely movement of research samples therefore is likely to swell in the coming years.

Finally, the UK trade data presented in the table below shows that biomedical research depends primarily on movement of samples from Appendix-II listed primate species. In the ten-year period described above, none of the 232,059 imports were from Appendix I-listed species. Of the **372,941** specimens that were exported, only **31** samples from Appendix I-listed primate species. This is highly relevant given that simplified procedures are applicable only for Appendix II-listed species.

2006-2016	**United Kingdom**	
	Imports	**Exports**
Appendix I species	0	31
Appendix II species	232,059	372,910
Total SPE for M	**232,059**	**372,941**

France, Germany and Switzerland also are important countries for biomedical research. Tables attached in Annexes 1-3 of this document and summarised in the table below show gross imports and exports of sample specimens from primate species for biomedical research to/from each country for the ten-year period. Again, focusing only on shipments of specimens (SPE) for medical purposes (M) recorded by the

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number of samples, the figures reflect a large volume of trade in samples (and very few samples of Appendix I-listed species).

2006-2016	France		Switzerland		Germany	
	Gross Exports	**Gross Imports**	**Gross Exports**	**Gross Imports**	**Gross Exports**	**Gross Imports**
App. I	0	0	48	48	6	6
App. II	45,917	46,111	100,213	100,213	304,833	304,833
Total SPE for M	**45,917**	**46,111**	**100,261**	**100,261**	**304,839**	**304,839**

Obviously, an applicant may apply to send multiple samples in a single shipment, thus expediting processing and permitting. It should be noted, however, that biomedical research is iterative by nature, requiring samples to be send over periods of time. This results in the repeated need to apply for and obtain CITES permits for individual shipments.

It also is necessary to recall that some countries, such as the UK, require that each type of sample is addressed in separate permits. Accordingly, whereas Germany would record various types of samples (e.g., plasma, serum, and fixed tissues samples) on a single permit, the UK would require three permits for the same samples.

Given the speed with which Switzerland issues permits and that it also is an important player in research and development for human and veterinary medicines, it also is interesting to consider the extent to which it is processing applications for the movement of samples for biomedical research. As shown in Annex 3, Switzerland has exported **87,195** specimens with the M purpose code (as reported by exporting country and excluding specimens recorded in g, ml, etc. as above).

IV. Positive Experience with Simplified Procedures

The submissions of Canada and the United States show significant current use of simplified procedures to move biological samples from *Primates spp.* for medical purposes. Australia indicates that its legislation also would permit use of simplified procedures for shipments of biological samples of Appendix II-listed species.

The CITES Parties that use simplified procedures have highlighted various mechanisms to avoid abuse and ensure effective control and enforcement concerning the activities eligible for the procedures. The

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"multi-shipment permitting" system in Canada relies on an initial verification of the legal origin and source of material and revocation of the "privilege" in the case of any contravention. To qualify for a "master file" in the U.S., applicants must provide information about their entire inventory which is evaluated by U.S. CITES authorities. U.S. authorities also may impose reporting requirements as part of establishing a master file. As permits are only valid for six months, those benefiting from simplified procedures must repeatedly return to the CITES authorities for additional permits, thus providing an extra measure of control. Australia's system (which is not currently used for biomedical research samples) goes a step further and requires entities given "multiple consignment authorities" to inform the CITES authorities of each shipment. This data can then be cross-checked with customs data collected at the borders. Such mechanisms provide sufficiently robust controls to avoid misuse.

V. Additional Benefits could be realised with E-Permitting

Switzerland credits its lack of need to implement simplified procedures to its use of an electronic permitting system. According to the submission, 98% of the applications Switzerland receives are handled electronically and impressive processing times result.

The EU submission also reflects the positive experience of France with e-permitting and its value for enforcement and control purposes. According to the information provided by France, "The CITES e-permitting system makes possible to easily conduct checks and extract data. In addition, endorsement through the Customs system is restricted to permits/certificates whose electronic files have been duly completed only."

The power of e-permitting to facilitate but also to control and report on legal trade should not be underestimated. Its use in combination with simplified procedures could bring achieve substantial improvements in the interest of biomedical research.

VI. Experiences of Applicants

EARA experience with the movement of samples sheds light on how processing times can enable or inhibit biomedical research. Attached in Annex 4 are unedited comments provided by several EARA members in response for information on their positive or negative experiences with CITES permitting for the movement of biological samples for biomedical research. Comments are broken down by type of company and geographical focus. While they underline the benefits of simplified procedures (and e-permitting), the comments also reflect the need for further improvements even where simplified procedures are used. The U.S. master file approach and the French electronic permitting system appear to be appreciated.

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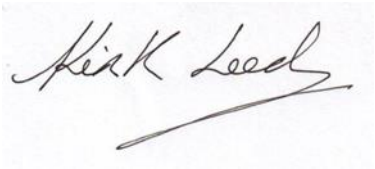
VII. Conclusion

What is obvious from the foregoing review is that there is a tremendous volume of imports and exports of biological samples (predominately from Appendix II-listed specimens) that pose negligible or no threat to conservation of the species but which create significant costs for both applicants and CITES authorities in terms of manpower and delays related to CITES permitting.

Efficient electronic systems such as those used by the Swiss can eliminate the need for a simplified system, but Swiss results will not be achieved everywhere and certainly not overnight. Therefore, the positive experience of Canada and the U.S. among others with the use of simplified procedures should be considered by more Parties to effectively expedite permitting for movement of samples for biomedical research while providing sufficient controls to enable oversight and enforcement.

To date, only the UK has indicated that it has experienced problems with utilising simplified procedures. However, these problems related to attempts to use simplified procedures for retail goods bought by consumers, not biomedical samples taken from the same animals that are repeatedly shipped by known research institutions and companies.

EARA and its members urge all CITES Parties in which substantial biomedical research takes place to make a small investment now to implement Simplified Procedures and to further explore the use of e-permitting to expedite sample shipment in the interest of human and animal health and to conserve resources for more critical CITES work.



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ANNEX 1 - FRANCE

Gross Exports from France of SPE for M (2006-2016)						
Appendix II-listed species						**TOTAL**
Chlorocebus	*Macaca*		*Papio*		*Primate spp*	
46	10251	90	2	2	14	
	1211		6	3		
	8193		25	3		
	112		6	3		
	7196					
	3145					
	9562					
	506					
	5541					
46	**45717**	**90**	**39**	**11**	**14**	**45,917**

Gross Imports to France of SPE for M (2006-2016)											
Appendix II-listed species											**TOTAL**
Chlorocebus	*Macaca*						*Papio*			*Primate spp*	
46	13	394	84	5	27	10251	2	2	2	14	
	52	10	170	2	16	1198	6	3	16		
	34	6968			3	7720	25	3	3		
	23	1703			9	52	6	3	3		
	38	7556			34	202					
	63	250			19	1404					
	81	3691				1850					
	1646	70				141					
	16					10					
						172					
46	**1966**	**20642**	**254**	**7**	**108**	**23000**	**39**	**11**	**24**	**14**	**46,111**

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ANNEX 2 - GERMANY

Gross Exports from Germany of SPE for M (2006-2016)

Appendix I-listed species			Appendix II-listed species						TOTAL
Gorilla	*Microcebus*	*Pongo*	*Callithrix*	*Chlorocebus*	*Macaca*				
1	4	1	2435	3	1513	70	5193	12	
			3875	23	11991		2693	12	
			8239	28	9776		6	10	
			3366	49	21844		443		
			3150	50	17609		699		
			324	78	41709		4401		
			2689		25190		6		
			102		23050		1543		
			621		27172		15		
			3		41761				
					43080				
1	4	1	24804	231	264695	70	14999	34	304,839

Gross Imports to Germany of SPE for M (2006-2016)

Appendix I-listed species			Appendix II-listed species																				TOTAL
Gorilla	*Microcebus*	*Pongo*	*Callithrix*				*Chlorocebus*			*Macaca*													
1	4	1	3348	125	333	2435	23	5	3	52	928	11252	96	1120	2512	160	35	1513	57	70	443	5193	12	
			3310		823	3875	23		29		2027	15031			1501	945		11991			695	2693	12	
			3150		44	4558	20		50		1321	19029			2152			8848			4401	6	10	
			621			56			78		4221	13478			929			8080			6	4		
			3			324					1422	14435			1557			1042			15	1543		
						1741						7828			1836			20528						
						58						13292			8930			10783						
												7632			2996			4974						
																		16187						
																		14038						
																		29937						
1	4	1	10432	125	1200	13047	66	5	160	52	9919	101977	96	1120	22413	1105	35	127921	57	70	5560	9439	34	304,839

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ANNEX 3 - SWITZERLAND

Year	App.	Taxon	Importer	Exporter	Origin	Importer reported quantity	Exporter reported quantity	Term	Purpose
2006	II	Macaca fascicularis	US	CH	MU	176		specimens	M
2007	II	Chlorocebus aethiops	US	CH		72		specimens	M
2007	II	Macaca fascicularis	GB	CH	MU	30		specimens	M
2007	II	Macaca fascicularis	GB	CH	MU	471		specimens	M
2007	II	Macaca fascicularis	US	CH	MU	168		specimens	M
2009	II	Callithrix jacchus	DE	CH	DE	150	150	specimens	M
2009	II	Macaca fascicularis	CA	CH	PH	53	53	specimens	M
2009	II	Macaca fascicularis	DE	CH	MQ		45	specimens	M
2009	II	Macaca fascicularis	DE	CH	MU	5206	4771	specimens	M
2009	II	Macaca fascicularis	FR	CH	DE		3	specimens	M
2009	II	Macaca fascicularis	FR	CH	MU		13	specimens	M
2009	II	Macaca fascicularis	GB	CH	CN		228	specimens	M
2009	II	Macaca fascicularis	GB	CH	MU	464	1000	specimens	M
2009	II	Macaca fascicularis	GB	CH	VN		30	specimens	M
2009	II	Macaca fascicularis	IN	CH	PH		132	specimens	M
2009	II	Macaca fascicularis	US	CH	PH	1	56	specimens	M
2009	II	Macaca	US	CH	VN		36	specimens	M

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		fascicularis							
2009	II	Macaca mulatta	US	CH	FR		18	specimens	M
2009	II	Macaca mulatta	US	CH	FR		40	specimens	M
2009	II	Macaca mulatta	US	CH			1	specimens	M
2010	I	Gorilla gorilla	DK	CH		2	2	specimens	M
2010	II	Macaca fascicularis	DE	CH	CN	4	4	specimens	M
2010	II	Macaca fascicularis	DE	CH	DE	4	4	specimens	M
2010	II	Macaca fascicularis	DE	CH	KH	4	4	specimens	M
2010	II	Macaca fascicularis	DE	CH	MU		512	specimens	M
2010	II	Macaca fascicularis	DE	CH	MU	7343	5058	specimens	M
2010	II	Macaca fascicularis	FR	CH	MU		40	specimens	M
2010	II	Macaca fascicularis	GB	CH	CN		60	specimens	M
2010	II	Macaca fascicularis	GB	CH	PH		30	specimens	M
2010	II	Macaca fascicularis	JP	CH	MU		342	specimens	M
2010	II	Macaca fascicularis	US	CH	MU		1221	specimens	M
2010	II	Macaca fascicularis	US	CH	PH	4	4	specimens	M
2010	II	Macaca mulatta	GB	CH	CN		6	specimens	M
2010	II	Macaca mulatta	GB	CH	FR		19	specimens	M
2010	II	Macaca mulatta	GB	CH	FR		10	specimens	M
2010	II	Macaca mulatta	US	CH	CN		42	specimens	M

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2010	II	Macaca mulatta	US	CH	FR		140	specimens	M
2010	II	Macaca mulatta	US	CH	FR		70	specimens	M
2011	II	Macaca fascicularis	CA	CH	MU		820	specimens	M
2011	II	Macaca fascicularis	CN	CH	MU		3	specimens	M
2011	II	Macaca fascicularis	DE	CH	MU	1756	2343	specimens	M
2011	II	Macaca fascicularis	DE	CH	VN	325		specimens	M
2011	II	Macaca fascicularis	DE	CH	VN		325	specimens	M
2011	II	Macaca fascicularis	FR	CH	CN		6	specimens	M
2011	II	Macaca fascicularis	FR	CH	MU	40		specimens	M
2011	II	Macaca fascicularis	FR	CH	PH		4	specimens	M
2011	II	Macaca fascicularis	FR	CH	VN	17		specimens	M
2011	II	Macaca fascicularis	GB	CH	CN	30	99	specimens	M
2011	II	Macaca fascicularis	GB	CH	MU	101	2762	specimens	M
2011	II	Macaca fascicularis	GB	CH	VN		2538	specimens	M
2011	II	Macaca fascicularis	JP	CH	MU	342		specimens	M
2011	II	Macaca fascicularis	US	CH	ID		875	specimens	M
2011	II	Macaca fascicularis	US	CH	KH	250	250	specimens	M
2011	II	Macaca fascicularis	US	CH	MU	256	256	specimens	M
2011	II	Macaca fascicularis	US	CH	PH	164		specimens	M
2011	II	Macaca	US	CH	CN	42		specimens	M

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		mulatta							
2011	II	Macaca mulatta	US	CH	FR	140	10	specimens	M
2011	II	Macaca mulatta	US	CH	FR	70	60	specimens	M
2012	II	Chlorocebus aethiops	AU	CH	XX		1	specimens	M
2012	II	Macaca fascicularis	CA	CH	CN		891	specimens	M
2012	II	Macaca fascicularis	CA	CH	MU		44	specimens	M
2012	II	Macaca fascicularis	DE	CH	CN	50	55	specimens	M
2012	II	Macaca fascicularis	DE	CH	DE	10	10	specimens	M
2012	II	Macaca fascicularis	DE	CH	KH	35	35	specimens	M
2012	II	Macaca fascicularis	DE	CH	MU	1415	1399	specimens	M
2012	II	Macaca fascicularis	DE	CH	PH	9		specimens	M
2012	II	Macaca fascicularis	DE	CH	VN	6	12	speci mens	M
2012	II	Macaca fascicularis	ES	CH	CN		1802	specimens	M
2012	II	Macaca fascicularis	ES	CH	MU		788	specimens	M
2012	II	Macaca fascicularis	FR	CH	CN	131	125	specimens	M
2012	II	Macaca fascicularis	FR	CH	VN	183	12	specimens	M
2012	II	Macaca fascicularis	GB	CH	MU	792	939	specimens	M
2012	II	Macaca fascicularis	GB	CH	MU	4790	3697	specimens	M
2012	II	Macaca fascicularis	IT	CH	MU	72	72	specimens	M
2012	II	Macaca fascicularis	US	CH	CN	32	32	specimens	M

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2012	II	Macaca fascicularis	US	CH	KH	8	8	specimens	M
2012	II	Macaca fascicularis	US	CH	MU		732	specimens	M
2012	II	Macaca fascicularis	US	CH	MU	1662	2101	specimens	M
2012	II	Macaca fascicularis	US	CH	PH		1	specimens	M
2012	II	Macaca mulatta	DE	CH	CN	2596	2596	specimens	M
2012	II	Macaca mulatta	DE	CH	VN	6		specimens	M
2012	II	Macaca mulatta	FR	CH	FR	13	9	specimens	M
2012	II	Macaca mulatta	FR	CH	FR	9		specimens	M
2013	I	Elephas maximus	NL	CH	LK	2		specimens	M
2013	I	Elephas maximus	NL	CH	MM	2		specimens	M
2013	I	Elephas maximus	NL	CH	XX	4		specimens	M
2013	I	Elephas maximus	NL	CH		2		specimens	M
2013	I	Pongo abelii	DE	CH	DE		3	specimens	M
2013	I	Pongo abelii	DE	CH	DE		3	specimens	M
2013	I	Pongo abelii	DE	CH	XX		3	specimens	M
2013	I	Pongo abelii	DE	CH			12	specimens	M
2013	I	Pongo abelii	ES	CH	ID	5	8	specimens	M
2013	I	Pongo pygmaeus	ES	CH	ID	7	7	specimens	M
2013	I	Pongo pygmaeus	ES	CH	MY	3	4	specimens	M
2013	II	Cebus xanthosternos	NL	CH			6	specimens	M
2013	II	Macaca fascicularis	DE	CH	CN	4	14	specimens	M

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2013	II	Macaca fascicularis	DE	CH	CN	4		specimens	M
2013	II	Macaca fascicularis	DE	CH	MU	2895	3048	specimens	M
2013	II	Macaca fascicularis	DE	CH	PH	6	8	specimens	M
2013	II	Macaca fascicularis	DK	CH	MU		24	specimens	M
2013	II	Macaca fascicularis	FR	CH	MU		72	specimens	M
2013	II	Macaca fascicularis	GB	CH	MU	945	1190	specimens	M
2013	II	Macaca fascicularis	GB	CH	MU	5739	7010	specimens	M
2013	II	Macaca fascicularis	US	CH	KH		98	specimens	M
2013	II	Macaca fascicularis	US	CH	MU	2973	5132	specimens	M
2013	II	Macaca fascicularis	US	CH	MU		3087	specimens	M
2013	II	Macaca fascicularis	US	CH	MU	1091		specimens	M
2013	II	Macaca fascicularis	US	CH	PH	82		specimens	M
2013	II	Macaca fascicularis	US	CH	VN		6	specimens	M
2014	II	Callithrix jacchus	FR	CH	DE		10	specimens	M
2014	II	Cebus xanthosternos	NL	CH			2	specimens	M
2014	II	Macaca fascicularis	DE	CH	CN	8		specimens	M
2014	II	Macaca fascicularis	DE	CH	MU	2826	3254	specimens	M
2014	II	Macaca fascicularis	DE	CH	PH	2		specimens	M
2014	II	Macaca fascicularis	ES	CH	CN	320	320	specimens	M
2014	II	Macaca	FR	CH	MU	13		specimens	M

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		fascicularis							
2014	II	Macaca fascicularis	FR	CH	PH	9	9	specimens	M
2014	II	Macaca fascicularis	GB	CH	GB		405	specimens	M
2014	II	Macaca fascicularis	GB	CH	MU	1288		specimens	M
2014	II	Macaca fascicularis	GB	CH	MU	1238	1254	specimens	M
2014	II	Macaca fascicularis	GB	CH	VN	982		specimens	M
2014	II	Macaca fascicularis	US	CH	CN	35	233	specimens	M
2014	II	Macaca fascicularis	US	CH	ID		24	specimens	M
2014	II	Macaca fascicularis	US	CH	KH	50		specimens	M
2014	II	Macaca fascicularis	US	CH	MU	374	376	specimens	M
2014	II	Macaca fascicularis	US	CH	MU	1143	2392	specimens	M
2014	II	Macaca mulatta	GB	CH	AT		3	specimens	M
2015	I	Pan troglodytes	DK	CH		3		specimens	M
2015	I	Pan troglodytes	DK	CH		3		specimens	M
2015	II	Callithrix jacchus	DE	CH	DE	81	81	specimens	M
2015	II	Callithrix jacchus	FR	CH	DE		5	specimens	M
2015	II	Callithrix jacchus	FR	CH	ZA		1	specimens	M
2015	II	Macaca fascicularis	CA	CH	CN		1550	specimens	M
2015	II	Macaca fascicularis	DE	CH	CN	24	386	specimens	M
2015	II	Macaca fascicularis	DE	CH	MU	6410	9517	specimens	M

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2015	II	Macaca fascicularis	DE	CH	PH	29	2	specimens	M
2015	II	Macaca fascicularis	FR	CH	MU	2528	2660	specimens	M
2015	II	Macaca fascicularis	FR	CH	PH	2	4	specimens	M
2015	II	Macaca fascicularis	GB	CH	GB	1595	1595	specimens	M
2015	II	Macaca fascicularis	GB	CH	MU	1420	1620	specimens	M
2015	II	Macaca fascicularis	GB	CH	VN		357	specimens	M
2015	II	Macaca fascicularis	SE	CH	MU	8	8	specimens	M
2015	II	Macaca fascicularis	US	CH	CN	85	741	specimens	M
2015	II	Macaca fascicularis	US	CH	MU	349	352	specimens	M
2015	II	Macaca fascicularis	US	CH	MU		153	specimens	M
2015	II	Macaca fascicularis	US	CH	MU	284		specimens	M
2016	II	Callithrix jacchus	DE	CH	DE	249		specimens	M
2016	II	Macaca fascicularis	DE	CH	CN	84		specimens	M
2016	II	Macaca fascicularis	DE	CH	MU	4826		specimens	M
2016	II	Macaca fascicularis	DE	CH	PH	18		specimens	M
2016	II	Macaca fascicularis	DE	CH	VN	320		specimens	M
2016	II	Macaca fascicularis	FR	CH	MU	408		specimens	M
2016	II	Macaca fascicularis	GB	CH	MU	438		specimens	M
2016	II	Macaca fascicularis	US	CH	MU	144		specimens	M
TOTAL						**71,006**	**87,195**		

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ANNEX 4 – COMPANY COMMENTS

Company No. 1: Global Pharmaceutical Company with CA/US focus

1. The transport of tissues and research samples from Contracted Research Organizations in Canada to the USA is unduly complex and is required for *each* tissue and sample from *each* covered species (e.g. typically *M. fascicularis*, a common research species).
2. The ability to obtain a permit for a research sample can significantly delay preclinical research studies and in some instances impacts the ability to obtain critical information that will support drug development (e.g. shipping of fragile and perishable samples for advanced scientific assays or analysis in the US, peer review of histologic samples)
3. It is not always possible to anticipate the need to ship samples internationally in advance for optimal analysis. This is a science driven, time-sensitive decision and process. The current process does not easily allow timely permit approval to facilitate this need.
4. The permit process can inhibit the ability to ship samples time-critical or fragile samples internationally for additional analysis. This impacts the ability to maximize the value of these tissues and data and could compromise sample integrity.
5. The CITES permit process can drive where studies are performed, domestically vs. internationally. This complicates and can delay studies based on CRO availability and capability or impact the ability to use international expertise.
6. The process must be repeated for each shipment in each direction (e.g. tissues sent from Canada to the US and then again to be returned)
7. Tracking of all samples can lead to significant administrative burdens.
8. E-permits and/or SP's would be a great improvement
9. CITES covered tissues or samples can directly support Clinical studies and FDA filings and delays may impact the time required to bring innovative medicines to the market.

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Company No 2: Global CRO with USA/EU focus

Country	Process	Website	Time to receive permits	Cost - Fees	Comments
United States	Application form CITES required document copies Courier Cheque processing	Website for forms	90 days	$75 -$100	Multi-use available (Master File) Time to get permits long.
France	Download documents required (Import CITES Export Cites, Sanitary Certificate…) for the application and fill in all the information needed on form.	Dedicated website. Registration required	2-3 weeks	$0.00	The website is easy to use and efficient.
Canada	Fill out application form and CITES Summary form provided by Environment Canada (EC) Copies of all CITES required documentation Application and CITES docs are scanned and emailed to EC	Website available for general application forms	4-6 weeks typically	$0.00	Easy communication and resolution of any issues Multi-use permits possible EC uses our FedEx account to send permits to us Application form we use is ‘prototype’ for us

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United Kingdom	Application form Copies of all CITES documents Cross match with all the import and export licenses prior to application, quantify the materials, use correct descriptions and keep it consistent with inventory documents. If there are samples from animals imported under multiple original import applications, we must split them onto separate applications. One per import (from the originating country, e.g. China).	Courier and Post	3 (90%)-6 (100%)weeks	£37	Multiple payment options There is a discount for additional forms under the same import, so it doesn't add much expense, just more forms!

Company No. 3: Global Pharmaceutical Company with US/UK focus

1. From the viewpoint of the United States, importing CITES material is relatively smooth as a CITES import permit are only required for Appendix-I species (which aren't typically used in the pharma industry).
2. The process for getting an Export or Re-Export CITES permit can very lengthy, it can take several months to gather the information that United States Fish Wildlife Service (USFWS) require to be submitted with the application. Then the USFWS can often say to allow 60 days for review.
3. When a customer asks about a shipment of CITES material we typically tell them to expect the process to take 3-6 months!
4. USFWS did streamline things a few years ago for repeat shipments, so you can set up a master permit and then it is much quicker to obtain individual export permits against that master. But this will only cover shipments from the original animals documented in the master file.

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Company No. 4: Global Pharmaceutical Company/CRO with US/DE focus

There is no way to know how long it will take. It is not unheard of to take 2-3 months, and at least once, nearly 6 months. No reason/explanation is ever given.

1. Communications regarding problems with the application can be very frustrating. At least once, I had an application expire, causing us to start again because we didn't know there was an outstanding question from the reviewer. The reviewer claimed to have left a phone message but no one received anything on our end, and no further attempt was made to contact us. With no response from us for two weeks, they declared it an abandoned application and dismissed it.
2. You cannot routinely call to check up on the status of an application, as that might anger them, so it is a risky road to pursue. Applications can also expire if they have been in the system for a certain period of time without action. Likewise, a permit expires in 6 months if not used, so this company couldn't apply for an entire study all at once, they had to be phased in. Each shipment required a separate permit, even though it was samples from all the same animals.
3. As a CRO, our studies depend on us being able to send samples or slides to labs in Europe and it was a minefield to try and get the permits in time for the various samples (these could be blood, plasma, tissue, or glass slides), and then have them in hand before the permit expired.
4. The Pharmaceutical Industry seemed to get better treatment compared to CROs. For instance, a couple of my clients in pharma would tell me that they were issued permits fairly quickly because they maintained an NHP master file, with identifications of animals that were pre-cleared. When we tried to do the same I was told that system was a bit cumbersome, and they were "not allowing new master files to be created".
5. At the time we had to pay by cheque, not sure if this is still the case, but they would not take a credit card as they didn't have the capacity to do that. We learned to mail separate applications in separate envelopes with separate cheques. It happened on a couple of occasions that we got one check to cover two applications sent together. They cashed the check, processed one application, and told me that the other had been rejected because there was no payment attached.
6. In the US, this process is managed by the FWS who have at times (verbally) admitted that research permits for the bio-medical research are sometimes given lower priority than zoos and sanctuaries depending on who is assigned that particular application, and also evidence of allowing permit applications to languish for weeks due to their process time and staffing. A lot of people are strong proponents of an e-permit system.

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Company No. 5: Global Pharmaceutical Company with FR/US focus

1. The French system is viewed as being quite an efficient system in general. One suggestion for improvement is to get an annual permit for redundant shipments as exists in the US.
2. We have been using e-permitting for 2 years now to import samples from the US. I have obtained a total of 6 import permits. Once the initial application is in, I do get approval the same day and receive the original document within 2 days by mail e-permitting makes things easy.

Company No 6: Primate Importer: MU/US/IL focus

1. One area which is very important is samples. If you have a worker bitten by monkey and you want to send the serum sample sometimes it takes 2 weeks then another week to ship it and another week to do the test. By that time if the animal has B virus the worker is already dead.
2. In research CITES is relevant only when wild animals are involved. When you transfer a wild animal or part of a wild animal it makes sense to be under CITES rules, but it makes much less sense when we want to ship a sample for medical testing.
3. When we have a case of a worker or a person bitten by a macaque the scientific procedure in all hospitals in most of the countries is to test immediately the monkey for herpes B and to start some kind of treatment to the affected person. In those cases, time is important and many times from my experience of working with thousands of macaques there is understandably a level of hysterical reaction by the bitten person and his family.
4. The need of CITES permit for exporting 0.5 ml of serum for medical testing for person or animal who need to be treated is not logical. The permit in some countries is issued on specific days and the whole process is between 5-20 days. Then you need to ship the sample usually to the USA and then lab has to do its work. This is too long and patient might be already treated if not dead when this is done.
5. We suggest to have an option to send serum/blood samples without CITES permit as it has nothing to do with trade or to have the online option for that.
6. We would also suggest that the CITES professional committee should have scientific representative from the research community, as this will help to better communicate with the unique needs of this community.

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Company No. 7: Global Pharmaceutical Company with DE/IT focus

1. For Italy there are no simplified procedures in place for CITES applications. We believe this causes us severe problems.
2. In Germany we have the possibility to make an application, the "collective application/notification" (§37 TierSchVerV). With this you can apply in one document for equal procedures. It is the same template as for the "normal" German applications and notifications.
3. A collective notification might be a toxicology procedure, with the same procedures/methods but different indications of the compounds (e.g. oncology and immunology, neurology etc.). If the collective application/notification is approved, we have the requirement to inform the competent authority at least 10 working days prior to start a study about the specifics of this test: e.g. specific animal number, name of the test compound, methods used in this test, start of the testing. Then we have to wait for the approval of this study.
4. At the moment this system seems to work ok, do not have any problems with it. Our regional government (competent authority) is very fast in the approval of the specific studies. It is a little bit more work for the scientists to write for any new study under a permission a short document and send it to the competent authorities. But until now we had no delay in a study because of that.

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