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"Scientific/technical assistance for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes"

Feasibility study under Article 10 of Directive 2010/63/EU on sourcing non-human primates only from self-sustaining colonies

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Introduction

The use of animals for scientific purposes in the EU is governed by Directive 2010/63/EU on the protection of animals used for scientific purposes. This Directive includes controls on the origin, breeding, care and accommodation of animals. Recital 19 of the Directive states that "The capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport. In order to end the capturing of animals from the wild for breeding purposes, only animals that are the offspring of an animal which has been bred in captivity, or that are sourced from self-sustaining colonies, should be used in procedures after an appropriate transition period. A feasibility study should be carried out to that effect and the transition period adopted if necessary. The feasibility of moving towards sourcing non-human primates only from self-sustaining colonies as an ultimate goal should also be examined."

The respective Article 10 of the Directive requires that the Commission shall, in consultation with the Member States and stakeholders, conduct a feasibility study, which shall include an animal health and welfare assessment, of the obligation to ensure that non-human primates (NHP), listed in Annex II of the Directive may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity (F2 / F2+) or where they are sourced from self-sustaining colonies (SSC) - colonies in which animals are bred only within the colony, or sourced from other colonies, but not taken from the wild, and kept in a way that ensures that they are accustomed to humans).

Annex II states that marmosets (*Callithrix jacchus*) shall meet this requirement by 1 January 2013 and other non-human primates by five years after the publication of a feasibility study, provided the study does not recommend an extended period.

The required feasibility study was carried out, and published in November 2017. This concluded that no extension to the transition period was necessary, as it was considered that all non-human primates sourced for use in the EU would be either F2/F2+ or originating from self-sustaining colonies by November 2022.

Second Feasibility Study

Article 10 also requires that the Commission keeps under review the use of sourcing of non-human primates from self-sustaining colonies and, in consultation with the Member States and stakeholders, conducts a study to analyse the feasibility of sourcing animals only from self-sustaining colonies to be published by 10 November 2022. The 2017 report considered the appropriateness of the dates set out in Annex II to require that all non-human primates used in procedures are either offspring of non-human primates bred in captivity or have been sourced from a self-sustaining colony. The present study is solely to analyse the feasibility of sourcing animals only from self-sustaining colonies and will not result in any changes in the legal requirements.

Additional Background Information

The landscape of non-human primate research and supply has changed since the 2017 feasibility study report was published. It has been reported that there are problems with the supply of non-human primates since that report was published. Firstly, there has been the COVID-19 pandemic, as a result of which vaccine development was required, which has involved the use of non-human primates. Views were also expressed by respondents that the predicted demand in the EU for non-human primates has been increased by COVID-19, however, without providing supporting evidence. In addition, in January 2020, China announced the suspension of exports of wildlife including non-human primates http://www.xinhuanet.com/english/2020-01/26/c_138735496.htm . Furthermore, one EU Member State has decided to reduce the size of the colonies of non-human primates held and bred.

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Methodology

Term "self-sustaining colony"

The responses received during the 2017 Feasibility Study indicated that within the scientific community and organisations supplying non-human primates for scientific use, there were a number of different understandings of what constituted a self-sustaining colony (https://ec.europa.eu/environment/chemicals/lab_animals/pdf/related_topics/Article%2010%20Feasibility%20Study%20Final%20report%2031%20July%202017.pdf). As a result, much of the data from 2013 on self-sustaining colonies are open to differing interpretations depending on the definition used. In addition, at the time of the 2017 study there was no requirement to report on the generation of the supplied animals where they originated from a self-sustaining colony.

To resolve these issues, a recommendation from the Review of the Directive in 2017 (EUR-Lex - 52017DC0631 - EN - EUR-Lex (europa.eu)) proposed that the statistical reporting requirements under Article 54 would be adjusted to require information on the generation (F0; F1;F2/F2+)[1] of non-human primates used in research and testing, separately from the information on the type of colony animals were sourced from. These changes were adopted in Commission Implementing Decision 2020/569/EU, with the first revised data recorded in 2021. However, it is important to note in this context that these data are not available at EU level before 2023.

It was also important that the term self-sustaining colony was clearly understood by users, breeders and suppliers to ensure uniform, consistent reporting as the evidence base for this feasibility study. The clarification provided below has been drawn from the legal text and advice on the temporal objective provided in Article 10(1) and in Annex II of the Directive. Therefore, in reference to Directive 2010/63/EU:

*"Self-sustaining colony", in the **context** of **this feasibility study,** carried out by the European Commission, means*

- *established colonies in which **no wild-caught animals** have been **introduced after November 2017*** and*
- *colonies established after that date by using only F1 or higher generation **animals obtained from other self-sustaining colonies**, and having **never introduced wild-caught animals**.*

** Date of the publication of the first feasibility study. Please note, replacement / expansion of breeding stock must be obtained from other self-sustaining colonies.*

Collection of information from Member States

Information was requested from all Member States regarding

a) whether they used non-human primates;
b) whether they bred / supplied non-human primates for scientific use;
c) contact details of overseas breeders / suppliers of non-human primates supplied for scientific use in the EU.

Member States using non-human primates were requested to submit data on the numbers of these animals used, and some of the required information in advance of the usual submission to the EU Commission used to construct the annual statistics. This was to allow consideration of all five years of relevant non-human primate statistical data between 2017 and 2021.

Information was provided on the numbers, species, generation of non-human primates and whether they were sourced from self-sustaining colonies, using the above interpretation.

[1] F0 – a wild-caught animal; F1 – an animal born in captivity; F2 – an animal born from parents that were themselves born in captivity

> **Assumption:** This report assumes that information from the Member States on the use of non-human primates in 2021 includes **all first uses of non-human primates from all users** in that Member State.

Member States breeding non-human primates were requested to submit information on the colonies held using the form in Annex 3.

> **Assumption:** This report assumes that information from the Member States on non-human primate colony information includes **all colonies from all breeders** in that Member State.

Each breeder was also asked about the number of non-human primates supplied to the EU, the generation supplied and whether they were from a self-sustaining colony or not, using the form in Annex 3.

> **Assumption:** This report assumes that information from the Member States on the colony type and generation of non-human primates over the five-year cycle **includes each colony** as an individual breeding unit [without amalgamation] in that Member State.

The requested information from Member States on contact details for overseas breeders was collated and used to contact them.

This information was cross-checked against the details provided for the Feasibility Study of 2017 to try to ensure that there were no significant omissions. Information was sought from overseas suppliers. Where it was suspected that information might be missing, further information was sought, in a few cases on multiple occasions.

> **Limitation:** This report relies upon the expectation of a provision of complete lists of overseas suppliers, supplied by the Member States, and receiving information from all of them.

Collection of information from overseas breeders

A questionnaire similar to those sent to operators in the EU was sent to each of the known breeder/suppliers, with an offer of a meeting/videoconference to assist them in completion of the questionnaires / tables.
Meetings were held by videoconference with three of the main breeders/suppliers.
Data supplied were consolidated by species.
Statistics on sourcing, use and generation of non-human primates have been taken from the public ALURES Statistical EU database, apart from 2021 data that was submitted directly by the Member States for the purposes of this study.
Information concerning the supply and colony sizes was provided in confidence by both Member State and overseas breeders and suppliers. The provided data are presented only in a summarised form to safeguard anonymity and commercial information.
There is a lag between supply time and the time that animal use at the end of the study is reported. Therefore, comparison of numbers supplied with numbers used year by year should not be attempted.

Consultation on data collection and draft report with Member States and stakeholders

A presentation was given at the meeting of the National Contact Points responsible for the implementation of the Directive in November 2021 discussing the process for data collection.
A stakeholder consultation was held on draft study conclusions on 3 November 2022.

Results

2020 data from ALURES statistical EU database

Table: Non-Human Primates used for the first time by species, source and generation

Numbers of non-human primates by species

Species	Number of animals
Prosimians	54
Marmoset and tamarins	196
Cynomolgus monkey	4220
Rhesus monkey	227
Vervets (Chlorocebus spp.)	34
Baboons	53
Total	**4784**

Numbers of non-human primates by source

NHP Source (origin)	Number of animals
Animals born at a registered breeder within EU	643
Animals born in rest of Europe	1
Animals born in Asia	1584
Animals born in America	36
Animals born in Africa	2291
Animals born elsewhere	229
Total	**4784**

Numbers of non-human primates by generation

NHP Generation	Number of animals
F1	865
F2 or greater	3622
Self-sustaining colony	297
Total	**4784**

These tables from 2020 are included to give a recent “snapshot” close to the time of this report, to provide some context. Of 8 626 247animals used in procedures for the first time in 2020, relatively few non-human primates were used. Most of these non-human primates are sourced from outside the EU, and the majority are F2/F2+.

Sources of different species of non-human primates by year 2017 to 2021

Blank cells indicate no sourcing in a given year from that region

Prosimians (*Prosimia*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	98					
2018	170					
2019	194					
2020	54					
2021	107					

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Squirrel Monkeys (eg. *Saimiri sciureus*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	5			2		1
2018	25					
2019						
2020						
2021	10					

Marmosets and Tamarins (eg. *Callithrix jacchus*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	377				42	46
2018	381					
2019	222					
2020	195	1				
2021	170					

Baboons (*Papio* spp.)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	25					
2018	30					
2019	33					
2020	53					
2021	42					

Vervets (*Chlorocebus* spp.)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017				33		
2018				12	4	
2019	7			18		
2020				34		
2021				3		

Rhesus Macaques (*Macaca mulatta*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	317		14	19	3	
2018	296		24			
2019	222		23			6
2020	186		11	2		28
2021	210		7	21		5

Cynomolgus Macaques (*Macaca fascicularis*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	218	5	2591		4290	123
2018	323		3229		4013	54
2019	226		3175		3071	276
2020	155		1573		2291	201
2021	138		2214		2499	224

Other species of Old World Monkeys (*Cercopithecoidea*)

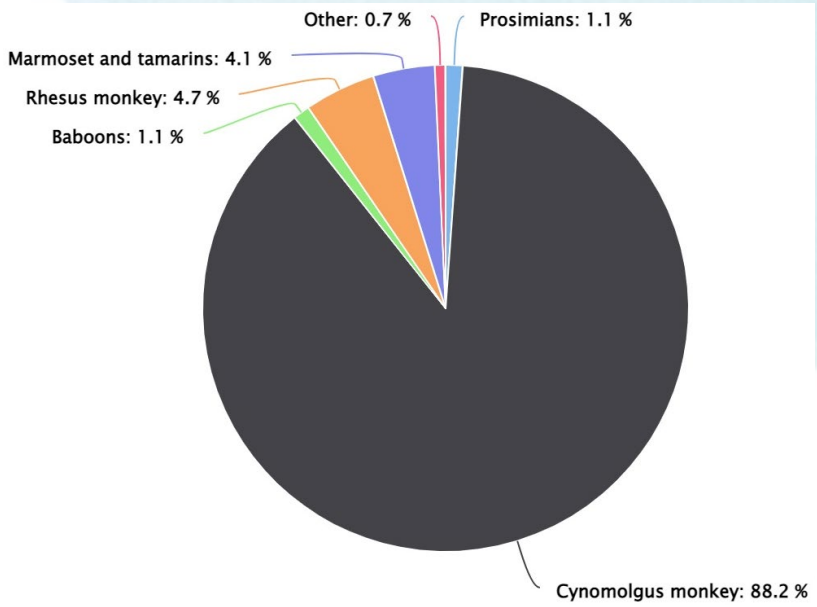
	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	14		9			
2018			22			
2019			2			
2020						
2021						

Other species of New World Monkeys (*Ceboidea*)

	EU	Rest of Europe	Asia	America	Africa	Elsewhere
2017	3					
2018						
2019						
2020						
2021						

Data from the EU and overseas have been considered separately. It is important to note that there are no binding requirements on the EU or overseas breeders/suppliers in regards to the provision of animals from self-sustaining colonies. There is a requirement for EU breeders to have a strategy in place to increase the proportion of animals that are the offspring of non-human primates that have been bred in captivity, but there is no such requirement in the rest of the world (of which we are aware). Directive obligations relate to the EU users of non-human primates as to what type of animals can be used in scientific procedures (Art 10(1) and Annex II).
Apart from a few uncommonly used species, seven main types of non-human primates have been used between 2017 and 2021. This study will not consider the occasional use of other species of Old and New World Monkeys.

The Cynomolgus monkey is the species used most frequently (88% in 2020, see below) with the majority bred and supplied from overseas. Other species of non-human primates were generally used in relatively low numbers and many of these animals were sourced from within EU.



Summary of the information collected from EU breeders

Reports were provided from five Member States on 15 colonies of non-human primates bred in the EU.

Squirrel Monkeys

Small numbers of squirrel monkeys were used in 2021 which were sourced only from the EU. The EU colony is reported to be self-sustaining. The last F1 breeding animal is expected to be retired in 2025.

Prosimians

Small numbers of prosimians were used and sourced only from the EU. All were supplied from a colony reported to be self-sustaining.

Marmosets

All colonies of marmosets in the EU breeders were reported to be self-sustaining. When there is a need to replenish breeding stock with new breeding animals, all colonies reported that they would be taken from other self-sustaining colonies.

Baboons

Baboons were sourced either in the EU or born in the rest of Europe but not at an authorised breeder. There are three colonies of baboon in the EU. Two of the three are reported as self-sustaining colonies. Where self-sustaining colony, the last F1 is expected to be retired from breeding in 2030. For the colony which was reported as not self-sustaining, the intention is to establish a self-sustaining colony by 2033. It is possible that this colony is already self-sustaining, but that there has been a misinterpretation. This colony still holds F0 animals as might be expected for animals with such longevity: baboons often breed until age 15-20 and can live until 30 in captivity. The colony also has F1 animals.

Rhesus Macaques

The majority of rhesus macaques (*Macaca mulatta*) used in 2021 were sourced from the EU. There are three breeding colonies in the EU of rhesus macaques. All three colonies are self-sustaining colonies. There are no F0 animals in any colony in 2021, although in the previous five years there have been F0s reported. This indicates that over this five-year period there have been reducing numbers of wild caught animals remaining in the EU colonies. It was reported that the last F0 may be retired from breeding in 2035. There are F1s in two of the three colonies.

The future supply of rhesus macaques from the EU is uncertain due to changes in national policies concerning the breeding of non-human primates, such that demand may well not be able to be met. The Dutch Minister for education, culture and science announced in 2019 that they aim to reduce the size of their breeding colony by about 1/3 by 2025.[2]

Cynomolgus Macaques

Only 3% of cynomolgus macaques (*Macaca fascicularis*) used in 2021 were sourced from the three EU colonies. Two of these are self-sustaining colonies. One is not but there is an intention to make it self-sustaining by 2028. This colony contains F0 and F1 animals, the last of which are expected to be retired from breeding in 2028 and 2030 respectively. Replenishing of breeding stock in all three colonies is expected to be from animals taken from other self-sustaining colonies only.

[2] Communication from the Dutch National Contact Point for the implementation of Directive 2010/63/EU

Summary of the information collected from overseas breeders/suppliers

Vervets

Between 2017 and 2021, most vervets used in the EU were sourced from overseas colonies. The information from the major overseas breeder confirms that this is a self-sustaining colony and has been for many years. It is reported to contain no F0 or F1 animals.

Squirrel Monkeys

There were no reports from overseas breeders of squirrel monkeys. In 2021 no animals were supplied from overseas breeders for use in the EU. Overseas sources have not been used since 2017.

Marmosets and Tamarins

There were no reports from overseas breeders of marmosets nor tamarins. In 2021 no animals were supplied from overseas breeders for use in the EU. Overseas sources have not been used since 2017. 1 animal was supplied from the rest of Europe in 2020. No breeder was identified via NCPs which was within Europe but not in the EU.

Rhesus Macaques

In 2021, rhesus macaques were sourced from overseas/ elsewhere (14%) as well as EU (86%) colonies. Overseas sources include Asia, America, and elsewhere. However, no data were obtained from any overseas breeders for this species.

Cynomolgus Macaques

Cynomolgus macaques were mainly sourced from overseas (97% in 2021). These were sourced from 21 colonies. Of these, nine were reported to be self-sustaining. However, some of the colonies which were currently self-sustaining, reported difficulties in maintaining the self-sustaining colony status as no F1+ animals are available to replace existing breeders. It was reported that six of these nine colonies are reducing in size, as the breeders are not being replaced, suggesting that fewer cynomolgus macaques from these self-sustaining colonies will be available in the future.

Of the 12 colonies which were not self-sustaining, it was reported that there was a plan to establish self-sustaining colony in one of them, and that this may be achieved in 2032.

Only four of the colonies did not contain F0 animals. Dates for retiring the F0 animals were given for six of the colonies ranging from 2026 to 2032. One comment was made that F0 males are needed for breeding; F1 males are not good breeders as there is a high level of infanticide (this is discussed in the previous feasibility study report section 9.1.5 Article 10 Feasibility Study Final report 31 July 2017.pdf).

Only six of the colonies reported having no F1 animals. Only one of these had no F0 and no F1.

Of those with F1 animals, five are reported to be open colonies which will restock with new breeding animals from sources other than self-sustaining colonies (i.e. from open colonies or from the wild). Dates for retiring F1 animals ranged from 2026 to 2038.

It appears that one breeder has colonies which include only F0 animals for breeding to supply F1s to North America.

Information on overseas cynomolgus macaque colonies (supply) versus demand

Limitation: We are aware of some breeders who we were unable to be contacted directly. Despite attempts to fill data gaps or acquire qualitative information in other ways, we are aware that the data on Asian, in particular from China, sourced animals is incomplete.

Limitation: Any comment on the availability of cynomolgus macaques from self-sustaining colonies in comparison to the expected demand in the future is based on incomplete data, and therefore difficult to draw any definitive conclusions.

Limitation: Interpretation of what constitutes a self-sustaining colony for the purposes of this Directive and the feasibility study was only established in 2021. This is likely to mean that

prior to 2021, there was incorrect reporting of self-sustaining colonies, and consequently misreporting in the EU statistical database.

From 2017 to 2021, between 36% and 47% of the cynomolgus macaques used in the EU have originated from Asia.

From the information supplied from overseas breeders, and comparing with statistics on sourcing from use data, it could be concluded that data from ~75% of cynomolgus macaques sourced in Asia was available for this report. This assumes that all animals sourced were used, and so this is likely to result in a slight over-estimate.

Information available for this study on colony status of cynomolgus macaques sourced from Africa is considered complete.

Discrepancies in reporting animals as from self-sustaining colonies

In the EU, until 2020, when an animal was sourced from a self-sustaining colony it had to be reported under "generation" as obtained from self-sustaining colonies (irrespective of its generation). From 2021, the indication of whether the colony was self-sustained is reported separately. Consequently, animals that were sourced from self-sustaining colonies versus total number of cynomolgus macaques used for the first time can be drawn from the EU statistics for the entire period (2017-2021) for this feasibility study.

Nevertheless, as stated in the limitations, EU users rely on the information provided to them by their overseas suppliers whether or not the animal was sourced from a self-sustaining colony. If the term self-sustaining colony was not correctly understood by overseas suppliers at the time of purchase, this would consequently result in inaccurate reporting in the EU statistics.

Overall, on the basis of the overseas/supplier data, between 2017 and 2021, it appears to have been possible to supply in excess of 80% of cynomolgus macaques from self-sustaining colonies.

However, there are significant discrepancies between the numbers provided by overseas breeders on whether cynomolgus macaques were supplied to the EU from self-sustaining colonies, and the data reported by EU users in the annual EU statistics.

The table below on the left summarises the information provided by overseas breeders about the numbers of cynomolgus macaques supplied to the EU in respect of whether the colony was self-sustained – in line with the clarification provided for this study.

The table below on the right presents the data as reported in the EU statistics on cynomolgus macaques having completed the first use in that year and whether the animal was sourced from a self-sustained colony – in line with the information provided by the supplier at the time of purchase.

Year	Colony type	Overseas breeder/supplier data (excluding China)	Total supplied to EU		Colony type as reported EU statistics *)	Total used in EU (including from China) *)
2017	Non-self-sustaining colonies	640 (11%)			5291 (73%)	
	Self-sustaining colonies	**5382 (89%)**			**1936 (27%)**	
		Total	6022			7227
2018	Non-self-sustaining colonies	551 (9%)			5744 (75%)	

	Self-sustaining colonies	**5324 (91%)**			**1875 (25%)**	
		Total	5875			7619
2019	Non-self-sustaining colonies	441 (8%)			4377 (65%)	
	Self-sustaining colonies	**5253 (92%)**			**2371 (35%)**	
		Total	5694			6748
2020	Non-self-sustaining colonies	502 (9%)			4183 (99%)	
	Self-sustaining colonies	**5379 (91%)**			**37 (1%)**	
		Total	5881			4220
2021	Non-self-sustaining colonies	1081 (18%)			1810 (36%)	
	Self-sustaining colonies	**4875 (82%)**			**3265 (64%)**	
		Total	5956			5075

* See earlier information regarding limitations to comparing supply and use data

Based on data provided by EU users for 2021, the availability of self-sustaining colonies (64%) may be much less than the other data predicts. Data prior to 2021 on self-sustaining colonies is too unreliable because of the varying interpretations of what constitutes a self-sustaining colony.

Reasons for discrepancies in numbers include

No data was received from China, and therefore is not included in data supplied from overseas breeders. It is known that some cynomolgus macaques have been supplied from China in the period 2017-2019. The Chinese export ban was introduced in 2020.

Cynomologus macaques could have also been sourced at other breeder(s) not known/contacted for the purposes of this study.

Overseas breeders were asked to use the 2021 clarification of interpretation of “self-sustaining colony” for each of the years 2017-2021: numbers in EU statistics reported using the clarified interpretation only for 2021 data.

UK data is not included after 2019. Much larger proportions of cynomolgus macaques used for the first time were reported by UK to be from self-sustaining colonies (between 71% and 79% between 2017-2019). The absence of this UK data after 2019 will affect proportions reported as from self-sustaining colonies, as well as numbers.

Some cynomolgus macaques will have been supplied but not used / finished procedures and therefore not yet reported in annual statistics during the year when supplied. Some animals may have been purchased for breeding purposes within EU colonies.

Other issues affecting supply and demand

In the context of supply and demand, it is important to note that cynomolgus macaques are an introduced, invasive species in Mauritius. Trapping wild cynomolgus macaques there is permissible and encouraged by authorities for those with a monkey breeding and export licence. Breeders stopped trapping in the late 2000's since the existing farms were of a size allowing matching of supply and demand, thereby maintaining closed colony status at that time. The market dynamics altered in the late 2010's with increasing NHP demand required for the testing of large molecules/biologicals, which was not a prominent use up until then.

During discussions on supply for the future we were told that breeders have been driven to reconsider their strategy of maintenance of self-sustainable colonies. This was reported to be due to market pressures: the rise in demand is currently using all the purpose-bred animals produced by the breeders, leaving no non-human primates for replacement of breeding animals which are coming to the end of their effective reproductive life. In order to maintain self-sustaining colonies, the breeders would need to decrease the supply for use, thus exacerbating the shortage of animals, which was made worse following the export ban introduced by China.

Outcome of Member Stake and stakeholder consultation

There was a consultation with Member States and stakeholder groups on 3rd November 2022 at which the draft results of the feasibility study were presented. No substantive comments were made, requiring changes to the final report.

Attendees were reminded that the legislation does not contain a requirement to source NHP only from self-sustaining colonies. The conclusions of this feasibility study will, therefore, not have an impact on the legal requirements in force, and therefore this report will not impact on the availability of NHPs for science in EU.

Conclusions

This report details the information provided in 2022 on the sourcing of non-human primates from self-sustaining and other types of colonies. The following table summarises sourcing from self-sustaining colonies by species:

	All self-sustaining colonies	Potential that sourcing from self-sustaining colonies is achievable within 10 years
Squirrel Monkeys	Yes	
Prosimians	Yes	
Marmosets	Yes	
Baboons	2/3	1/3 expected by 2033
Vervets	Yes	
Rhesus Macaques • 86% sourced from EU • 14% sourced from overseas	EU: yes Overseas: unknown	Unknown
Cynomolgus Macaques • 3% sourced from EU • 97% sourced from overseas	EU: Yes Overseas: No	No

The COVID-19 pandemic has demonstrated that demand for non-human primates can fluctuate significantly. Supplies of non-human primates are necessarily economically driven unless there is subsidy from scientific users / sponsors (e.g., funding bodies, pharmaceutical companies performing

or contracting work, Member States) to support the establishment and maintenance of self-sustaining colonies. Aspirations which were held to supply the EU with non-human primates only from self-sustaining colonies have been altered by changes in demand, the ability to supply it and business decisions relating to these. As a consequence of the significant increase in demand worldwide, and the closure of access to Chinese suppliers, the remaining breeders are struggling to meet demand, and as a consequence, progress towards self-sustaining colonies has stalled as wild-caught replacement breeders have been (re-)introduced, and F1 animals earmarked as replacement breeders are being sold for use in procedures.

There are other demands on breeders, for example in Mauritius, where cynomolgus macaques are an invasive species, for which there is a government support for removing animals from the wild (Monkey (govmu.org)). In this case, the introduction of wild-caught animals to increase breeding stock in times of high demand is a logical consequence. Introductions of such F0 animals to self-sustaining colonies will stop them from being classified as self-sustaining colonies (within the interpretation for the purposes of the Directive) at any time.

The IUCN Red List of Threatened Species 2022 now includes *Macaca fascicularis* (cynomolgus macaques (March 2022: Hansen, M.F. et al. 2022. e.T12551A199563077. https://dx.doi.org/10.2305/IUCN.UK.2022-1.RLTS.T12551A199563077.en). Following this, drivers to use self-sustaining colonies may return in the future, should this species be included in Appendix I of Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). This pressure would be international.

The evidence presented strongly suggests that for cynomolgus macaques, there is no realistic possibility of sourcing only from self-sustaining colonies in the short or medium term. It is possible that supplies of squirrel monkeys, prosimians, marmosets, and vervets may continue to be supplied entirely from self-sustaining colonies, but it is impossible to try to foresee all eventualities which could influence this. As macaques (both rhesus and cynomolgus) and vervets are all sourced significantly from overseas sources, and there are no EU drivers / requirements to these breeders to supply from self-sustaining colonies other than customer request and preference, EU users may be unable to obtain animals from self-sustaining colonies.

We are not aware of any requirement in other parts of the world to use higher generation and/or animals sourced from self-sustaining colonies. In a global context, the EU is a very small user of non-human primates (for example, 68K in 2019 in USA (USDA. A*nnual Report Animal Usage by Fiscal Year.* U.S. Department of Agriculture, Animal and Plant Health Inspection Service; Washington, DC, USA: 2019). Large breeders seem reluctant to adjust breeding practices to meet EU aspirations. There is little incentive for breeders to progress towards closed self-sustaining colonies which are expensive to establish and maintain.

At this time, it is not possible to determine if or whether the aspiration of sourcing from self-sustaining colonies will be achieved in the future, but with the recent changes in usage, availability, demand and breeding practices in some centres, it is unlikely to be achieved for all commonly used non-human primate species in the foreseeable future.

Kathy McCall (née Ryder), David Anderson
10th November 2022

Annex 1: Conclusions of Art 10 (1) feasibility study (2017)

Section 4 – Results of the feasibility study on the progress to using second and/or higher generation purpose-bred non-human primates

With the aim of ending capture of non-human primates from the wild for both scientific and breeding purposes, the Directive allows, after an appropriate transition period, the use only of non-human primates that are the offspring of animals which have been bred in captivity (F2/F2+), or that are sourced from self-sustaining colonies (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017DC0631&from=en). The understanding of self-sustaining colony is that once closed, the colony no longer can be reopened. It is also implicit from the intentions of the legislators that "other colonies" from which animals can be sourced, must be considered to be also self-sustaining captive-bred colonies, and from which no wild-caught animals can be obtained as breeders.

The current deadline in the Directive Annex II is set at November 2022, apart from Marmosets which have been required to be F2/F2+ since January 2013. Article 10 requires a feasibility study to assess the appropriateness of Annex II deadlines, and to propose amendments, where appropriate. The key findings and conclusions of the feasibility study are presented below.

The majority of the species used within EU are already available as F2/F2+.

The main species of concern is the Cynomolgus macaque whose global supply of F2/F2+ animals already now comfortably exceeds the current and projected EU demand. However, the additional five years (2017-2022) are needed to complete the transition, including Herpes B-virus-free animals from suppliers in Mauritius who are not yet able to fulfil the scientific demand with F2/F2+ animals.

Considering the current and projected EU demand of the relevant species and their supply from EU and non-EU countries, the impacts of the transition on science, animal welfare and health, the feasibility study does not support altering the dates set out in Annex II of the Directive.

However, to facilitate accurate reporting that allows measuring the progress towards the Directive goals, Commission Implementing Decision 2012/707/EU should be adjusted to obtain annual information on the generation of non-human primates supplied also from self-sustaining colonies.

Annex 2: Glossary

Breeder	Establishment which breeds and supplies animals for scientific procedures.
F0	'F0' refers to animals that are captured from the wild.
F1	'F1' refers to animals that are born in captivity to one, or two parents, that were captured from the wild.
F2	'F2' refers to animals that are born in captivity to parents **both** of which were themselves born in captivity.
F2+	'F2 or greater' refers to animals that are born in captivity to parents **both** of which were themselves born in captivity.
Herpes B virus	Herpes B virus (*Cercopithecine herpesvirus 1*[CHV-1]), is an infectious agent that is found in populations of macaque monkeys. Monkeys infected with this virus usually have no symptoms or only mild symptoms, but if the virus infects humans, it is life threatening.
NHP	Non-human primate
Self-sustaining colonies (SSC)	• *established colonies in which **no wild-caught animals** have been **introduced after November 2017*** and* • *colonies established after that date by using only F1 or higher generation **animals obtained from other self-sustaining colonies**, and having **never introduced wild-caught animals**.* ** Date of the publication of the first feasibility study. Please note, replacement / expansion of breeding stock must be obtained from other self-sustaining colonies.*
Supplier	Establishment which sources animals from breeders and supplies on to user establishment.
User	Establishment/organisation in which animals are used in scientific procedures.

Annex 3: Questionnaire to EU Breeders and O/S Breeders

Part 1

Are you suppling animals to EU only from self-sustaining colonies as interpreted below? **[yes/no]**
If no, do you intend to establish a self-sustaining colony? **[yes/no]**
By when do you expect to be able to do this? **[year]**
Does the colony contain any F0 (wild-caught) animals? **[number]**
If so, when do you think the last one will be retired from breeding? **[year]**
Does the colony contain any F1 animals? **[yes/no]**
If so, when do you think the last one will be retired from breeding? **[year]**
When you need to replenish breeding stock, will new breeders be taken only from other self-sustaining colonies as defined below? **[yes/no]**
If not, why not? **[free text]**

Part 2

Species:				
Total colony size	**Breeding females:**		**Males in breeding:**	

Number of animals:	**Non-Self-Sustaining Colony***			**Self-Sustaining Colony***		
Supplied to EU users	**F0**	**F1**	**F2/F2+**	**F1**	**F2/F2+**	**Total**
2017						
2018						
2019						
2020						
2021						
Projected demand EU						
2022						
2023						
2024						