

**ANIMALS IN SCIENCE COMMITTEE
ADVICE ON
NON-HUMAN PRIMATES
BRED FOR USE IN SCIENTIFIC PURPOSES**

12 September 2022

Introduction

Around 2,500 scientific procedures are undertaken using non-human primates in the UK each year. The majority of the NHPs currently used in the UK are cynomolgus macaques, supplied from overseas breeding establishments, in studies undertaken for regulatory purposes (e.g. to assess the safety and efficacy of new medicines and vaccines). A smaller number, predominantly common marmosets, rhesus macaques and cynomolgus macaques sourced from closed 'self-sustaining' breeding colonies in the UK, are used in basic research (e.g. neuroscience) and applied research (e.g. trying to address disease through prevention or treatment).¹

The capture of non-human primates (NHPs) from the wild gives rise to significant animal welfare, health and ethical issues. We are also aware that the conservation status of cynomolgus macaques has recently changed².

European Directive 2010/63/EU, which the UK was committed to prior to its exit from the European Union, establishes requirements relating to the supply and breeding status of the NHPs used in scientific procedures.

The rationale for these provisions appears in Recital 19 of the Directive, which states '*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.*'

From November 2022, the EU is set to require Member States to use only non-human primates that are the offspring of animals which have themselves been bred in captivity (so-called F2 or F2+ animals), or those that are sourced from 'self-sustaining' colonies, except where scientific justification can be made.³

A requirement for all NHPs used in scientific procedures in the UK to be the offspring of animals which have themselves been bred in captivity, or which are sourced from 'self-sustaining' colonies, is not currently in the UK legislation. The Home Office has stated that during the process - which took place in 2012 - of amending the Animals (Scientific

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085383/annual-statistics-scientific-procedures-living-animals-2021_v8.pdf

² Status upgraded by IUCN from 'vulnerable' to 'endangered' as of March 2022:

<https://www.iucnredlist.org/species/12551/199563077#assessment-information>

³ "In order to end the capturing of animals from the wild for breeding purposes Article 10 of the directive on the protection of animals used for scientific purposes requires Member States to ensure that non-human primates listed in Annex II of the directive may be used in procedures only when they are the offspring of non-human primates, which have been bred in captivity or when they are sourced from self-sustaining colonies. This requirement takes effect in November 2022."

Written Answer: Joint answer given by Mr Sinkevičius on behalf of the European Commission - 10.8.2021
https://www.europarl.europa.eu/doceo/document/E-9-2021-003039-ASW_EN.html

Procedures) Act 1986 to incorporate the provisions of Directive 2010/63/EU, there was still uncertainty around when⁴ the requirements would be applied to rhesus and cynomolgus macaques or other species of non-human primate. However, subject to ASPA Schedule 2C 25(3), the requirement for common marmosets used in research to be purpose bred was introduced into the UK, as required by the Directive, from 1 January 2013.

On 23 June 2022, the Animals in Science Committee (ASC)⁵ was commissioned⁶ to advise the UK Government on this matter. The ASC was asked to provide advice, including on four policy questions, after carefully considering relevant factors including regard to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

Noting that the animal welfare and ethical impacts of supplying non-human primates for research are already well-documented, the ASC focused its evidence gathering⁷ on clarifying the breeding status of the NHPs currently supplied and used in the UK (as of July 2022) and the factors that may or may not potentially impact on this in the short and longer term.

We surveyed organisations directly involved in the breeding, supply or use of non-human primates under the Animals (Scientific Procedures) Act 1986 (ASPA) within the UK (see Appendix 1). Other organisations relevant to the use of NHPs were also contacted and therefore the scope of our assessment includes all species of NHPs, and both commercial and academic establishments.

⁴ Annex II of Directive 2010/63/EU states that the requirements should be applied to rhesus macaques, cynomolgus macaques and other species of non-human primates *'5 years after the publication of the feasibility study referred to in Article 10(1), fourth paragraph, provided the study does not recommend an extended period'*. N.B. the feasibility study was published in 2017 and concluded there were no reasons to extend the dates applicable for introducing these requirements – so the date for introduction in the EU remains as November 2022.

⁵ The Animals in Science Committee is required by Article 20(1) of the Animals (Scientific Procedures) Act 1986 to *'provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State'*.

⁶ [Advice on non-human primates bred for use in scientific procedures - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/advice-on-non-human-primates-bred-for-use-in-scientific-procedures)

⁷ [ASC response to commission on non-human primates - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/asc-response-to-commission-on-non-human-primates)

Executive summary

The recommendations in this report have the ultimate aim of ensuring that all non-human primates used in scientific procedures in the UK come from breeding colonies that do not source any non-human primates from the wild.

We suggest a requirement for only allowing the use of animals whose parents have both been born in captivity, or those who come from colonies that are permanently closed and 'self-sustaining'. However, we recognise that for a number of practical reasons, this is not immediately possible and so we have provided advice for how a number of specific and time-limited exemptions could be implemented.

We focus on the definitions used for 'Self-sustaining colony' and for F1 and F2 status, suggesting that universal definitions be used for all species, and across all guidance, reports, and communications.

In order to encourage more overseas breeders to move to being 'self-sustaining' according to our suggested definition, we also recommend that the UK establishes November 2022 as the starting point for establishing the classification of a self-sustaining colony. All UK-based breeding colonies should meet this criterion with immediate effect.

We distinguish between potential exemptions to our policy recommendations based on scientific grounds, and exemptions based on the grounds of supply issues. While we have not received any evidence demonstrating possible scientific reasons why an F1 animal might be required instead of an F2, we recommend that a process exists, as it does under European Directive 2010/63/EU, to allow justifications for such exemptions to be formally assessed. We do, however, recognise that there are currently issues relating to the global supply of non-human primates for use in scientific procedures. For this reason, we are recommending a two-year exemption period (until November 2024) to a UK requirement for all NHPs used to be either F2/F2+ or sourced only from self-sustaining colonies that may allow F1 cynomolgus macaques - but only from self-sustaining colonies - to be used for scientific research in the UK. Any requests to use F1 cynomolgus macaques that are not from a self-sustaining colony should require special justification on a case-by-case basis, and before animals are imported.

Finally, we make recommendations that work should continue aimed at reducing the demand for the use of NHPs in research and that the UK could consider expanding its own self-sustaining colonies of NHPs in order to expand the supply of non-human primates from self-sustaining colonies.

Definitions used

Before detailing our responses to the four specific questions commissioned by the Home Office, the Animals in Science Committee feel it is important to provide remarks and

observations around the definitions that have been, and are being, used in discussions on this issue.

During the course of our evidence gathering it has become apparent that over recent years the Animals in Science Regulation Unit (ASRU) has used a number of different definitions for the terms F0, F1, F2, and 'self-sustaining colony', relating to the breeding generation and supply status of NHPs. While multiple changes to the definitions raise the risk of confusion or misunderstanding among those breeding, supplying, or using NHPs, and among other interested stakeholders, it has also become clear and is of concern that different definitions have been used for the same data for different audiences. For example, the definitions supplied to NHP users to guide their completion of the annual Return of Procedures forms for 2020 (available via the National Archives) and 2021 (confirmed as part of evidence gathering from ASPEL instructions) have been different to those used to inform readers viewing that same data in the annual [Statistics of Scientific Procedures on Living Animals, Great Britain](#) which were published in 2021 or 2022 respectively (see Appendix 2). We believe that this means there is a risk that the information in the statistics is not accurate.

Definitions used, relating to the statistics produced for 2021, are provided below as an example:

Instructions for applicants filling in annual animal use returns for 2021 (published 2021)

- **Self-sustaining**

Marmosets, Tamarins, and other new-world primates

A self-sustaining colony is a colony that contains no wild caught animals, is kept in a way that ensures animals are used to humans and is sustained using animals from within or from other self-sustaining colonies.

Macaques and other old-world primates

A self-sustaining colony is a colony that no longer sources animals from the wild (it may contain some existing wild caught animals) and is sustained using only captive bred animals.

- **Breeding generation**

F0 - wild caught

F1 - progeny of wild caught females

F2 - progeny of captive bred females

Report of Annual Statistics of Scientific Procedures on Living Animals, Great Britain: 2021 (published 2022)

- **Self-sustaining**

Means a colony in which animals are bred only within the colony or sourced from other colonies, where they have been bred, but not taken from the wild, and where these animals are kept in a way that ensures they are accustomed to humans

- **Breeding generation**

F0: wild caught primates

F1: first generation of purpose bred primates

F2: second generation of purpose bred primates

This example from 2021 illustrates the significant differences in the definitions for those who are required to complete the annual returns of their animal use compared to those that were reported in the annual statistics of animal use.

Recommendation 1 - a universal definition of F0, F1, F2 and 'self-sustaining colony' should be used across all guidance, reports, and communications.

It is the view of the Animals in Science Committee that this situation is being further compounded by the fact that the actual definitions now being used by the ASRU may not represent what a member of the public might expect them to and therefore could give an inaccurate impression of the breeding status of NHPs currently used in the UK. Based on the evidence that we have gathered it appears that the experiences of male NHPs, newly taken from the wild for use in breeding centres, are being obscured by the definitions now being used for the generation of NHP. For example, a change in the 2020 instructions for licence holders completing annual returns for 2020 to the definition used by ASRU to determine whether an animal is F1 or F2 only requires consideration of the maternal line, meaning animals can still be categorised as F2, even where their father has been recently captured from the wild and taken into a breeding centre (see Appendix 2i)⁸.

Furthermore, the evidence we received also highlighted an inconsistency around the interpretation and use of the term 'self-sustaining', meaning that two establishments felt unable to describe their NHPs as coming from such a colony when completing our questionnaire, but had described their NHPs as coming from a self-sustaining colony for the purposes of completing the Return of Procedures form for the annual statistics.

If an overseas breeding centre is able to label itself as 'self-sustaining', and the animals it supplies are presented as such in the annual statistics publication, even though those

⁸ The annual animal use statistics using these definitions for 2020 would have been published in 2021

centres may only recently have brought in new wild-caught males to replenish stocks, then this would clearly be undermining the concept of not taking NHPs from the wild for the purpose of breeding individuals for use in scientific procedures. The underlying intention should be to avoid the health and welfare issues associated with stimulating or allowing the capture and taking of animals from the wild. As well as the obvious need to avoid this outcome, this example further re-emphasises the importance of having very clear definitions that all breeders, suppliers and users of NHPs, and the regulator, understand and use consistently and that are transparent for the general public.

Recommendation 2 - the definitions of NHP generation, and self-sustaining colony used, for NHPs in the annual animal use statistics for 2020 and 2021 should be clarified. The data in published reports should be amended where needed to ensure that the data is accurate for readers, and so that any future benchmarking comparisons made on this issue are accurate, informative and can take account of the differing definitions that have been used over time.

When the UK transposed the requirements of Directive 2010/63/EU, Article 10(1) described a 'self-sustaining' colony as '*a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans*'. This is the definition that the UK still uses when describing 'self-sustaining' colonies for marmosets and tamarins. However, the Home Office (in contrast to the European Union) uses a slightly different definition of 'self-sustaining' colonies for macaques in at least one of its communications (see Appendix 2)

Provided here as an example of another jurisdiction considering this issue and attempting to clarify any doubts or misunderstandings around what the definition should actually mean in practice, in November 2021 the European Union updated its own definitions of a self-sustaining colony for any species of NHP to mean that they are:

- established colonies in which no wild caught animals have been introduced after November 2017
- 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

Both options preclude the introduction of any individuals newly captured from the wild. This should be the key feature and imperative of what a 'self-sustaining colony' should be.

It is our advice that these definitions should be used as the broad basis for the UK's own future definition – although the date used as the starting point (which is November 2017 in the current EU definition) should be reviewed and set at one that both takes account of recent changes in the landscape of NHP supply and also maximally encourages and stimulates overseas breeding colonies to strive to achieve this goal. We state this,

because under the current EU definitions, any breeding colony which has taken animals in from the wild since November 2017 could never in the future describe itself as ‘self-sustaining’ regardless of how many years may subsequently elapse without them having taken in wild caught animals. We believe this potentially limits incentives for breeding centres to now move to being a newly, permanently closed colony – an action to be encouraged as it would ultimately be beneficial for animal welfare for as long as NHPs continue to be used in research and testing. The ASC suggests a date of November 2022 for the introduction of the UK’s own definition.

Recommendation 3 - there should be a single definition for ‘self-sustaining colony’ across all NHP species.

Recommendation 4 - the definition of ‘self-sustaining colony’ must incorporate the concept of the colony being ‘permanently closed’ to further introductions of male or female animals (unless they originate from other existing ‘closed’ colonies) and should also preclude the addition of any individuals newly captured from the wild after a fixed date.

Recommendation 5 - all UK-based establishments breeding NHPs for use in the UK should meet the UK definition of a ‘self-sustaining’ colony from November 2022 onwards.

Recommendation 6 - the date used as the starting point for classifying overseas breeders as self-sustaining should be established to act as the greatest encouragement for breeders, who have not already done so, to move to being ‘self-sustaining’ in policy and practice. For the animals supplied to the UK we suggest this permanently fixed date could be set at November 2022.

Commissioned Question 1

Should new requirements be applied to the use of NHPs in scientific procedures in the UK, such that they must be the offspring of NHPs bred in captivity (F2) or from a self-sustaining colony?

As the UK helped to formulate, and since 2013 was working towards⁹, the principle of only using F2/F2+ NHPs as the transition was made towards the ambition of fully ‘self-sustaining’ colonies, codifying and implementing such requirements now into UK regulations would not represent a ‘new’ policy direction. Furthermore, in not doing so if the EU does implement this requirement, post-November 2022, UK animal welfare protections in this area will be objectively lower than those in place within the EU, and lower than they would have been had the UK remained within the EU.

In support of the original vision and aims of such provisions, we believe that the UK should continue to maintain the ambition and policy goal for all NHPs used in scientific

⁹ In addition to meeting the requirements of Article 10 of Directive 2010/63/EU, between January 2013 and January 2020 the UK was also required under Article 28 to ‘ensure that breeders of non-human primates have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity’.

procedures in the UK to come from self-sustaining colonies. The goal should be to achieve this for all NHP species within a reasonable timeframe. We understand that the UK has been making good progress towards this and is already self-sufficient in marmosets, tamarins and in rhesus macaques, and has a self-sustaining colony for cynomolgus macaques but that this only meets a small proportion of the current demand for that species. Moreover, current global supply issues (described in more detail in answer to Commissioned Question 4) mean that some limited exceptions for the use of F1 NHPs not from a self-sustaining colony may be required.

As described previously, in this context, self-sustaining should mean a 'closed' colony with no animals - either male or female - being newly taken from the wild and introduced to replenish stock. However, for enabling maintenance of desired genetic diversity, individuals may be exchanged with or brought in from other 'self-sustaining' colonies. Wild caught individuals already housed in breeding centres may also continue to be used for breeding.

Recommendation 7 - until the goal of sourcing NHPs only from self-sustaining colonies can be achieved for all species of NHPs, we recommend that UK policy should be that, as from November 2022, all NHPs used must be either:

- F2/F2+ (i.e. offspring where both parents have been bred in captivity)
- from a self-sustaining colony

Under this policy, the use of F1 NHPs would be acceptable only if coming from a (closed) self-sustaining colony.

Recommendation 8 - any requests to use F1 NHPs not from a self-sustaining colony (i.e. where individuals are still taken from the wild to replenish breeding stock) should require special justification on a case-by-case basis, and before animals are imported. In any case, this should only be allowed until November 2024 (for more on this, see later section answering Commissioned Question 4). As this measure would likely require co-ordination and input from different UK Government departments, the ASC is happy to work with the Home Office to develop a system for how this could work in practice.

Recommendation 9 - subject to ASPA Schedule 2C 25(3), the use of F0 NHPs in scientific procedures within the UK should continue to be prohibited.

Commissioned Question 2

Which NHPs should any new requirements apply to – all species, or only some?

The original requirements within European Directive 2010/63/EU setting out ambitions around the breeding status of NHPs used, in order to end the capture and use of wild caught animals in breeding centres, cover *all* NHPs. The UK helped to formulate these policy goals and we think that they should continue to be applied for all species of NHP used in the UK.

We understand that the UK currently (as of July 2022) uses four species of NHPs in scientific procedures - common marmosets, red bellied tamarins, rhesus macaques and cynomolgus macaques. No other species have been used in the UK for many years and we have not received or seen any evidence that this is likely to change.

The [ASPA](#) already requires [Schedule 2C 25(1)(d)] that all marmosets must be at least F2, or from a self-sustaining colony, subject to [Schedule 2C 25 (3)]. This is written into UK legislation, and we have not been presented with any evidence that this has caused any issues for the scientific community.

For rhesus macaques and red bellied tamarins, while ASPA does not currently require all individuals to be F2/F2+ or from a self-sustaining colony, it has been the case that only individuals fulfilling these criteria have been used in scientific procedures in the UK over the past 8 years, since data has been available¹⁰. The Animals in Science Committee is satisfied that the future demand for these individuals will be able to be met using the criteria of only allowing individuals that are F2/F2+ or from a self-sustaining colony, assuming that the existing UK colonies (such as the Centre for Macaques) are maintained.

N.B. for common marmosets and rhesus macaques, some limited import of individuals - from other self-sustaining colonies outside of the UK - has occurred e.g., to allow for the introduction of genetic diversity into UK breeding colonies but maintaining sufficient animals to meet UK demand has not posed any problems.

For cynomolgus macaques, the situation is more complex. While the self-sustaining colony of cynomolgus macaques already present in the UK supplies a sufficient number of animals to satisfy the requirements of government agencies, the small number of establishments in industry who use the majority of cynomolgus macaques in the UK, are still dependent on a supply of NHPs from overseas breeding centres because their demand far exceeds what could currently be provided from within the UK.

Recommendation 10 - requirements for NHPs only to be used in research and testing in the UK where they are the offspring of NHPs bred in captivity, or where they come from a 'self-sustaining colony' should apply to all species of NHPs.

Commissioned Question 3

When should any new requirements come into force?

Recommendation 11 - the requirement for all NHPs used in scientific procedures in the UK to be F2/F2+, or to come from self-sustaining colonies, should take effect from November 2022.

¹⁰ Based on the evidence received by the ASC, which was reviewed in addition to Tables 2.3 and 2.3h of the Statistics of scientific procedures on living animals, Great Britain:
www.gov.uk/government/statistics/statistics-of-scientific-procedures-on-living-animals-great-britain-2021

These are the timelines that the UK was, and would still, have been working to, had the UK remained within the EU. Such a policy position will also going forward likely put the UK in line with the European Union - which will effect a ban on the use of F1s from November 2022 (and is currently considering the feasibility of implementing a requirement that will necessitate that only the use of NHPs from self-sustaining colonies be permitted).

Commissioned Question 4

Where new requirements are applied for NHPs, what exemptions should be permissible, with what justification, and should certain exemptions be limited for a certain time period?

The Animals in Science Committee is aware that in recent years a number of events have impacted on the global supply of, and demand for, NHPs. Partly due to their use in Covid-19 related studies, there has been an increase in global demand for NHPs. At the same time, there has been a reduction in global supply - principally due to the decision of China, the world's largest supplier country, to largely place a ban on exporting NHPs to the rest of the world.

This has meant greater pressure (to meet the demand) on the NHP breeders based elsewhere, particularly in Mauritius - who had previously been making very good progress towards primarily supplying F2 individuals and operating as 'self-sustaining' colonies. For many years, Mauritius has been significantly the largest supplier of cynomolgus macaques to the UK and EU. As supply to the global market from China has diminished since 2020, so other countries, such as the USA, have instead increasingly been looking to these same Mauritian suppliers, which has meant increased competition among institutions to secure animals for use in scientific procedures. We do note however that the latest official statistics highlight that the UK continues to successfully source the majority of its imported cynomolgus macaques from breeding facilities in Mauritius (Africa), and we also note from our own evidence gathering, that as of July 2022, the majority of cynomolgus macaques used in the UK continue to be F2/F2+ individuals. (Note: these animals have the potential to have a wild caught father using the current definition supplied to those completing annual returns).

We also understand that the Government of Mauritius has in the past two years adopted a policy of allowing the breeding facilities there to newly capture wild, free-living individuals (where they are a non-native species) and use them in breeding centres¹¹. As well as this action stimulating a new increase in the capture of macaques from the wild, with all the associated animal welfare, health and ethical concerns that this brings, this decision obviously also has a knock-on effect on the ability of those breeders to continue to call their whole operation 'self-sustaining'.

We recognise that as well as the new capture of wild animals for breeding purposes providing an economic benefit to the companies involved (as they can increase the

¹¹ e.g <https://www.traveldailynews.com/post/animal-protection-groups-outraged-as-mauritius-government-gives-permission-for-capture-of-wild-monkeys>

numbers of NHPs they can ultimately supply, which increases their revenues) and to the Mauritian economy (as breeding companies pay the government a fee for each macaque exported¹²), further permissions from the Mauritian Government for them to do so could also end up affecting the decisions those breeding centres may make around the future composition of the breeding status of individuals within their colonies. For example, those breeding centres might choose to export the F1 offspring of these newly captured animals to the USA market, rather than keeping them to help breed an increased number of F2 individuals for the relatively smaller UK and EU markets.

That said, there are other breeders elsewhere in the world (e.g, Vietnam, Cambodia) who also continue to supply cynomolgus macaques of F2 status to the global market - though the health status of these individuals may be different (e.g. they may not be free of Herpes B virus). The animal welfare provisions and standards in place at any breeding centre - including how they compare to each other, and what would be expected of such a centre were it to be sited in the UK - also need to be given significant consideration when users are making such justifications regarding where they will source their animals.

Importers and UK users of cynomolgus macaques in industry stated in their evidence that an immediate implementation of a complete ban on the use of any F1 animals, given the global supply problems described above, could mean they would be unable to source sufficient animals for programmes of work in the UK. It was suggested that this might lead to delays in the timelines of, for example, regulatory studies required to deliver new therapeutics, or to the relocation of such studies to other countries, which may potentially have weaker animal welfare standards than the UK.

Recommendation 12 - given the impact the current decision by China to stop exporting macaques has had on the global supply of NHPs, in combination with other factors, we recognise that in the case of cynomolgus macaques only, there is an argument for implementing a time-limited exemption period to the UK requirement for all NHPs used to be either F2/F2+ or sourced only from self-sustaining colonies. We suggest an appropriate period would be for two years - until November 2024. This will enable users of imported cynomolgus macaques in the UK to stabilise alternative supplies (as well as providing additional time for China to lift its export ban as the world continues to come out of the worst aspects of the pandemic). N.B. as per our Recommendation 7, the use of F1 NHPs would still be permitted where these animals come from genuinely 'self-sustaining' colonies.

Recommendation 13 - during this time, we recommend that the UK government, as well as organisations supplying, and establishments using, imported cynomolgus macaques in scientific procedures should directly liaise with overseas breeding centres (e.g. in Mauritius and elsewhere) to strongly encourage them (or at least in the first instance the part of their operation which supplies NHPs to the UK) to put in place the policies and

¹² <https://theconversation.com/the-macaque-monkeys-of-mauritius-an-invasive-alien-species-and-a-major-export-for-research-176569>
<https://www.apf.gov.au/DocumentStore.ashx?id=fa4e56d8-3755-40cc-8f69-4a2a19a39972&subId=408086> (see page 8)

measures that would enable them to be truly and permanently 'self-sustaining' going forwards.

Further observations and comments from the Animals in Science Committee

The Directive includes a general provision to allow an exemption to the requirement to only use F2/F2+, or individuals from self-sustaining colonies, where there is legitimate and compelling 'scientific justification'. We recognise and expect that such cases should be exceedingly rare as there appear to be no obvious or specific scientific reasons which require the use of F1 animals instead of F2/F2+ generations, and, from the evidence gathered, we received no examples of when this might feasibly and legitimately be the case. However, we recommend that this potential exemption be included in UK policy.

Recommendation 14 - as is also contained within the Directive, there should be a general provision to allow an exemption to the requirement to only use F2/F2+, or individuals from self-sustaining colonies, where there is legitimate and compelling 'scientific justification'. Should any application be received by the Government regulator (e.g. the Animals in Science Regulation Unit) which seeks to invoke this exemption, then these should be passed to the Animals in Science Committee to review and provide advice on, on a case-by-case basis.

It was noted from the evidence received that expanding the cynomolgus macaque breeding colonies already within the UK could not be practically done to the degree needed to enable the UK to become 'self-sufficient' in meeting the needs of all current UK-based users within the next 3-5 years. However, over a longer term, for animal welfare reasons and to ensure a reliable supply for as long as NHPs continue to be used in research and testing, the feasibility and implications of developing more 'self-sustaining' colonies for this species within the UK could be assessed. It is expected that this would need to be a long-term strategy decision as it would require a timeframe of 10 years or more, and sizeable facilities (that do not currently exist) to be able to breed the numbers required.

Recommendation 15 - the UK Government could consider taking steps that would enable the UK to be more self-sufficient in the supply of cynomolgus macaques, in a similar way as has been established for the use of rhesus macaques and for common marmosets in academia, and for cynomolgus macaque use by government agencies.

Clearly, the supply of non-human primates is just one side of the equation. Factors leading to the 'demand' for using NHPs also need to be critically reflected upon, as reducing demand will also act to relieve pressure on supply. While a full critique of the scientific and wider benefits provided through the use of NHPs in scientific procedures is outside the remit of this commission, we do note that the majority of current NHP (principally cynomolgus macaque) use in the UK is in regulatory testing undertaken by Contract Research Organisations. To this end, the Animals in Science Committee strongly encourages the UK Government to help lead on efforts to increase, where

possible, opportunities that would enable the use of NHPs to be avoided, reduced and replaced.

Recommendation 16 - the UK Government should continue to engage in, and accelerate and expand where possible, efforts to reduce the demand for the use of cynomolgus macaques - primarily in regulatory testing - via working collaboratively with key stakeholders.

Appendix 1



6 July 2022

Request for information from establishments involved in the breeding, supply or use of non-human primates in scientific procedures.

On 23 June 2022, the Animals in Science Committee was commissioned by the Animals in Science Policy and Co-ordination Unit to provide advice on questions relating to the breeding of non-human primates for use in scientific procedures. This advice must be delivered by 12 September 2022.

A subgroup of the Animals in Science Committee has been established to take this work forward.

As part of our evidence gathering, we are engaging with a variety of organisations involved in the breeding, supply and/or use of non-human primates (NHPs) under the Animals (Scientific Procedures) Act 1986.

We are inviting your organisation to provide responses to the following questions, as appropriate.

Please submit the completed questionnaire to asc.secretariat@homeoffice.gov.uk at the latest by 18 July 2022.

Confidentiality

The Home Office shall keep confidential and not disclose to any third party any part, or the whole, of any confidential information disclosed to it under this questionnaire and to treat the confidential information with the same degree of care and with sufficient protection from unauthorised disclosure as the Home Office uses to maintain its own confidential or proprietary information. Confidential information is planned to be held only until the ASC has provided the advice and any policy based on this advice has been published and then it will be deleted. Any data in the final report will be combined and anonymised so that contributors cannot be identified.

Animals in Science Committee

Glossary

NHP - non-human primate

F0 - a wild-caught animal

F1 - offspring bred in captivity from wild caught parent(s)

F2 - first generation of animals whose parents themselves were bred in captivity

F2+ - subsequent generations of animals whose parents themselves were bred in captivity

Self-sustaining colony - a colony in which animals are bred only within the colony or sourced from other colonies, where they have been bred, but not taken from wild, and where these animals are kept in a way that ensures that they are accustomed to humans.

Animal comes from a closed self-sustaining colony

Breeder - an establishment which is authorised by a licence granted under ASPA section 2C to breed Schedule 2 animals for use in regulated procedures, or for their tissues, or to breed any other protected animals primarily for those purposes

Supplier - an establishment which is authorised by a licence granted under ASPA section 2C to hold Schedule 2 animals bred elsewhere for supply to another establishment

User - an establishment which is authorised by a licence granted under ASPA section 2C to use animals in regulated procedures

1. Name of organisation

--

2. Please enter your full name and email address if you agree to further contact, if necessary

--

3. Is your establishment a licensed breeder, supplier or user of non-human primates under the UK Animals (Scientific Procedures) Act 1986? Tick all that apply.

	Marmosets	Rhesus macaques (Macaca mulatta)	Cynomolgus macaques (Macaca fascicularis)	Other species of NHP (please list)
Breeder				
Supplier				
User				

If none of the above apply, please describe the nature of your organisation

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Section to be completed by establishments breeding or supplying NHPs for use in scientific procedures under ASPA 1986

4.

In **2019**, how many non-human primates of each status did you breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments?

Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				

Supplied				
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Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

In **2020**, how many non-human primates of each status did you breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments?

Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

In **2021**, how many non-human primates of each status did you breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments?

Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				

Supplied				
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In the first six months of 2022, how many non-human primates of each status did you breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Bred				
Supplied				

Estimating for 2022 as a whole, how many non-human primates of each status do you expect to breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

Estimating for 2023, how many non-human primates of each status do you expect to breed (bred and supplied by you) for, or supply (bred elsewhere but supplied by you) to, UK user establishments? Please complete a new table for each species.

Species:				
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	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Breed				
Supply				

- 5. What capacity do you have to increase the current number of F2/F2+ NHPs you breed or supply each year? Please describe limiting factors, and timescales for increasing supply.**

Section to be completed by establishments licensed to use animals under ASPA 1986

- 6. Please describe the sector your organisation is part of, and also areas of research or testing using NHPs that your organisation is involved in (e.g. academia/pharmaceutical/CRO; regulatory testing; cancer research, neuroscience etc)**

- 7. Do you have requirements for specific characteristics of NHPs e.g. age, sex, health status?**

- 8. Do you have any difficulties at present in sourcing suitable NHPs for your studies? If yes, please give reasons, with supporting evidence.**

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9.

In **2019**, how many non-human primates of each status did you use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

In **2020**, how many non-human primates of each status did you use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

In **2021**, how many non-human primates of each status did you use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N

Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

In the first six months of 2022, how many non-human primates of each status did you use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Estimating for 2022 as a whole, how many non-human primates of each status do you expect to use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				

Re-used				
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Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Estimating for 2023, how many non-human primates of each status do you expect to use in regulated scientific procedures? Please complete a new table for each species.

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Species:				
	FO	F1	F2/F2+	From a self-sustaining colony? Y/N
Used for first time				
Re-used				

Section to be completed by all responding organisations

10. What would be the impacts on your organisation of the UK regulations requiring that only NHPs sourced from self-sustaining colonies be used in scientific procedures from November 2022 onward?

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11. What would be the impacts on your organisation of the UK regulations requiring that only F2 or F2+ NHPs be used in scientific procedures from November 2022 onward?

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12. Recent reports by others¹³ have concluded that *'there were currently no specific scientific reasons which required the use of F1 animals instead of F2/F2+' and that there is 'little, or no, price differential reported between F1 and F2/F2+ generations'.* Do you have observations on these statements or evidence to support or challenge their relevance to the situation as it is in July 2022?

13. Do you have any other comments that you would like to put forward to the Animals in Science Committee on this issue? NB. where potential issues, ideas or problems are highlighted, the Committee requires evidence to support these to be provided.

¹³ e.g. The *'Feasibility study required in Article 10 of Directive 2010/63/EU on the protection of animals used for scientific purposes'* commissioned by the European Commission and published in July 2017: https://ec.europa.eu/environment/chemicals/lab_animals/pdf/related_topics/Article%2010%20Feasibility%20Study%20Final%20report%2031%20July%202017.pdf

Appendix 2 - Definitions used for NHP generation (table 2.1) and self-sustaining colony (table 2.2) in the UK for the years 2019-2021

Each table contains the definition from a) Return of Procedures form¹⁴ b) the electronic system for capturing return of procedures information and c) the annual 'Statistics of Scientific Procedures on Living Animals, Great Britain'

Table Appendix 2.1 NHP generation

	2019	2020	2021
Instructions to users for completing annual return of procedures form Available on gov.uk website	Column K-Non-human primate generation • If sourced from a colony that is not self-sustaining then 'F0', 'F1' or 'F2 or greater' should be used. • If the colony has become self-sustaining then you should enter every animal from this colony as 'Self-sustaining colony' regardless of generation of the individual animal, and not as 'F0', 'F1' or 'F2 or greater'.	Column L-Non-human primate generation <i>Give the generation (maternal line) of each animal:</i> • F0 - Wild caught • F1 - Progeny of wild caught females • F2 or greater - Progeny of captive bred females	No section is included on NHP in the instructions (instructions included within the e-system – see next row)
Instructions to users within the e-system set up to accept return of procedures information N.B. not publicly available	Not applicable	Not applicable	• F0 - wild caught • F1 - progeny of wild caught females • F2 - progeny of captive bred females
Information provided to readers of the annual 'Statistics on	Not defined in main report. Generations are listed (without further definition) in Table 2.3 as:	Not defined in main report.	• F0 - Wild caught primates • F1 - first generation of purpose bred primates

¹⁴ <https://www.gov.uk/guidance/animal-testing-and-research-annual-returns>

scientific procedures on living animals, Great Britain' publication Available gov.uk website	• <i>wild caught</i> • <i>first generation</i> • <i>second generation or greater</i> <i>Self-sustaining colony</i>	Generations are listed (without further definition) in Table 2.3 as: • <i>wild caught</i> • <i>first generation</i> • <i>second generation or greater</i>	• <i>F2 - second generation of purpose bred primates</i>
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Table Appendix 2.2 Self-sustaining colony

	2019	2020	2021
Instructions to users for completing annual return of procedures form Available on gov.uk website	Column K-Non-human primate generation • If sourced from a colony that is not self-sustaining then 'F0', 'F1' or 'F2 or greater' should be used. • If the colony has become self-sustaining then you should enter every animal from this colony as 'Self-sustaining colony' regardless of generation of the individual animal, and not as 'F0', 'F1' or 'F2 or greater'.	<i>For new world primates (marmosets and tamarins) a self-sustaining colony is a colony that does not contain any wild caught animals, is kept in a way that ensures animals are accustomed to humans and is sustained only using animals sourced from either within or from other self-sustaining colonies</i> (Guidance notes last updated March 2020) <i>For Macaques (and other old-world primates) a self-sustaining colony is a colony that no longer sources animals from the wild and is sustained only using captive bred animals. In the case of old-world primates however the colony may still contain some wild caught animals provided it is no longer sourcing animals from the wild</i>	No section is included on NHP in the instructions (instructions included in e-system – see next row)

Instructions to users within the e-system set up to accept return of procedures information N.B. not publicly available	Not applicable	Not applicable	<i>Marmosets, Tamarins, and other new-world primates</i> <i>A self-sustaining colony is a colony that contains no wild caught animals. Is kept in a way that ensures animals are used to humans and is sustained using animals from within or from other self-sustaining colonies.</i> <i>Macaques and other old-world primates</i> <i>A self-sustaining colony is a colony that no longer sources animals from the wild (it may contain some existing wild caught animals) and is sustained using only captive bred animals.</i>
Information provided to readers of the annual ‘Statistics on scientific procedures on living animals, Great Britain’ publication Available gov.uk website	Not defined in main report. without further definition in Table 2.3 as: • <i>wild caught</i> • <i>first generation</i> • <i>second generation or greater</i> • <i>Self-sustaining colony</i>	Not defined in the text of the main published report. NHP generation information is recorded in Table 2.3. The ‘Notes’ to Table 2.3 includes the commentary that: • <i>No establishments had recorded the use of non-self-sustaining colonies in procedures in 2020.</i> • <i>In 2020, the recording of generation of non-human primates was changed to record both the colony status, and the generation of the colony (self-</i>	<i>‘self-sustaining colony means a colony in which animals are bred only within the colony or sourced from other colonies, where they have been bred, but not taken from the wild and where these animals are kept in a way that ensures they are accustomed to humans’</i>

		<i>sustaining or non-self-sustaining). This data is not comparable to data recorded pre-2020, which has been included in table 2.3h.</i>	
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Appendix 2.3 Additional definitions

1. Guidance on the Operation of the Animals (Scientific Procedures) Act 1986

Section 5.18.6

‘Use of purpose bred primates’

Available on gov.uk website

A ‘self-sustaining colony’ is one kept in a way that ensures the animals are accustomed to humans and which consists only of animals that have been bred in captivity, either within the colony or in another self-sustaining colony.

[in place since March 2014]

2. Animals (Scientific Procedures) Act 1986 - Schedule 2C (Part 3: Conditions for Project Licences)

Clause 25(1d) ‘a condition to the effect that a marmoset must not be subjected to a regulated procedure as part of the specified programme of work unless it is the offspring of marmosets bred in captivity or it has been obtained from a self-sustaining colony of marmosets’

Clause 25 (3) ‘A project licence is not required to include a condition mentioned in sub-paragraph (1)(c), (d) or (e) if the Secretary of State is satisfied that there is scientific justification to the effect that compliance with the condition would prevent the purposes of the programme of work specified in the licence from being achieved.’

Clause 25(6) ‘For the purposes of sub-paragraph (1)(d) a colony of animals is a “self-sustaining colony” if— (a) the colony is kept in captivity in a way that ensures the animals are accustomed to humans; (b) the colony consists only of animals that have been bred in captivity; and (c) the colony is sustained only by animals being bred within the colony or animals being sourced from other colonies that meet paragraphs (a) and (b)’

[in place since 1 January 2013]

3. Questions for project licence applicants (contained within the electronic licence system): Not publicly available

Non-human primates

Why do you need to use non-human primates, rather than any other type of animal, to achieve your objectives?

Are any of these non-human primates endangered?

Endangered animals are any of the species listed on Annex A of Council Regulation 338/97 and are not bred in captivity.

Why can't you achieve your objectives by using non-human primates that are not endangered?

Also explain how you will comply with other regulations including CITES.

Explain how the project is for one of the permitted purposes.

*The permitted purposes for the use of endangered non-human primates are: * translational or applied research for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * the development, manufacture or testing of the quality, effectiveness and safety of drugs for the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions or their effects in man * research aimed at preserving the species of animal subjected to regulated procedures.*

Might any of these non-human primates be wild-caught?

Why can't you achieve your objectives without using wild-caught non-human primates?

Purpose bred animals

Will all animals used in your project be purpose bred?

This means animals that have been bred primarily to be used in regulated procedures or for the use of their tissues or organs for scientific purposes.

Where will you obtain non-purpose bred animals from?

Consider the source of all animals you plan to use, as this information will help to assess the impact on the scientific output and the quality of the animal.

Why can't you achieve your objectives by only using purpose bred animals?